

SUMMARY MONTHLY SAFETY REPORT 3
for
ACTIVE SUBSTANCE: PF-07302048 (BNT162b2)

ATC CODE: J07BX03¹

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01 FEBRUARY 2021 through 28 FEBRUARY 2021

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Report Prepared by: Worldwide Medical & Safety

Pfizer - BioNTech

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¹ Temporary ATC code.

² It corresponds to the earliest conditional approval date.

EXECUTIVE SUMMARY

This is the 3rd Summary Monthly Safety Report (SMSR) for PF-07302048 [Coronavirus disease 2019 (COVID-19) mRNA Vaccine, hereafter referred to as BNT162b2)], covering the reporting interval 01 February 2021 through 28 February 2021.

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

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

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

It is estimated that approximately 126,212,580 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021 and that approximately 59,939,685 doses of BNT162b2 were shipped worldwide during the current reporting interval from 01 February 2021 through 28 February 2021.

BNT162b2 has received temporary authorisation for emergency supply in 28 countries and conditional marketing authorisation approval in 39 countries globally.

The RSI for this SMSR is the BNT162b2 CDS Version 1.0, dated 12 February 2021, in effect at the end of the reporting period. After the data-lock point of this SMSR, on 02 March 2021, the CDS was updated with the following safety-related changes: Diarrhoea, Pain in extremity (arm) and Vomiting were added as adverse reactions in Section 4.8 Undesirable effects.

During the reporting period, the following safety topics and signals were addressed:

1. Diarrhoea was evaluated and was added to the RSI as an adverse reaction;*
2. Vomiting was evaluated and was added to the RSI as an adverse reaction;*
3. Delayed syncope was evaluated and determined not to be a risk;
4. Eye pain and Eye swelling were evaluated and determined not to be risks;
5. Hearing loss and Tinnitus were evaluated and determined not to be risks;
6. Dizziness was evaluated and subsequently subsumed in an evaluation of vaccine stress--related responses that is ongoing;
7. Immune thrombocytopenia was evaluated and determined not to be a risk;
8. Facial paralysis was evaluated and determined not to be a risk at this time; but will be re-evaluated once final safety data from the Study C4591001 is available in mid-April 2021;
9. Herpes Zoster evaluation is ongoing;
10. Paraesthesia and Dysaesthesia were evaluated subsequently subsumed in an evaluation of vaccine stress-related responses that is ongoing;
11. Tachycardia was subsumed in an evaluation of vaccine stress-related responses that is ongoing;
12. Guillain-Barre syndrome was a safety topic determined not to be a validated signal;
13. Myocarditis and pericarditis were safety topics determined not to be a validated signal;
14. Severe cutaneous adverse reactions were safety topics determined not to be a validated signal.

* Diarrhoea and Vomiting were determined as identified risks (not important for the purpose of inclusion in the Risk Management Plans and Pharmacovigilance Plans); the related events were added as adverse reactions to the RSI after the data-lock point of this SMSR, on 02 March 2021.

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

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LIST OF ABBREVIATIONS

| Acronym | Term |
|----------------|---|
| AE | adverse event |
| AESI | adverse event of special interest |
| BC | Brighton Collaboration |
| BMI | body mass index |
| CDC | Centers for Disease Control and Prevention |
| CDS | core data sheet |
| CI | confidence interval |
| COPD | chronic obstructive pulmonary disease |
| COVAX | COVID-19 Vaccines Global Access |
| COVID-19 | coronavirus disease 2019 |
| DLP | data lock point |
| DME | designed medically event |
| DNA | deoxyribonucleic acid |
| DSPC | Distearoyl-sn-glycero-3-phosphocholine |
| EEA | European Economic Area |
| EMA | European Medicines Agency |
| EU | European Union |
| EUA | emergency use authorisation |
| EURD | European Union Reference Date |
| HC | Health Canada |
| HCP | healthcare professional |
| HLGT | (MedDRA) High Group Level Term |
| HLT | (MedDRA) High Level Term |
| HPRC | Health Product Risk Communication |
| IBD | international birth date |
| ICH | International Conference on Harmonisation |
| LNP | lipid nanoparticle |
| MAH | marketing authorisation holder |
| MedDRA | medical dictionary for regulatory activities |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| mRNA | messenger ribonucleic acid |
| NAAT | nucleic acid amplification tests |
| PCR | Polymerase Chain Reaction |
| PI | prescribing information |
| PRAC | Pharmacovigilance Risk Assessment Committee |
| PT | (MedDRA) Preferred Term |
| PVP | pharmacovigilance plan |
| RMP | risk management plan |
| RNA | ribonucleic acid |
| ROW | rest of world |
| RT-PCR | Reverse Transcription-Polymerase Chain Reaction |
| RSI | reference safety information |

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| Acronym | Term |
|----------------|---|
| TME | targeted medically event |
| SAE | serious adverse event |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| SmPC | Summary of Product Characteristics |
| SMQ | standardised MedDRA query |
| SMSR | summary monthly safety report |
| SOC | (MedDRA) System Organ Class |
| UK | United Kingdom |
| US | United States |
| VAED | vaccine-associated enhanced disease |
| VAERD | vaccine-associated enhanced respiratory disease |
| VAERS | vaccine adverse event reporting system |

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1. INTRODUCTION

This is the 3rd SMSR for PF-07302048 (COVID-19 mRNA Vaccine, hereafter referred to as BNT162b2), covering the reporting interval 01 February 2021 through 28 February 2021. The format and content of this SMSR is in accordance with the EMA coreRMP19 Guidance (EMA/544966/2020) and, as applicable, with ICH Guideline E2C (R2) Periodic Benefit-Risk Evaluation Report [Step 5, January 2013] considering the information for the evidence from post-EUA/conditional marketing authorisation approval data sources.

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

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

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

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

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

Table 1. List of SMSRs

| SMSR Number | Reporting Period |
|-------------|---|
| 1 | 01 December 2020 Through 31 December 2020 |
| 2 | 01 January 2021 Through 31 January 2021 |

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2. WORLDWIDE APPROVAL OR AUTHORISATION STATUS

BNT162b2 received first temporary authorisation for emergency supply under regulation 174 in the UK on 01 December 2020 and is currently authorised for emergency use in 28 countries.

BNT162b2 received first regulatory conditional marketing authorisation approval in Switzerland on 19 December 2020 and is currently conditionally approved in 39 countries.

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

3. ACTIONS TAKEN IN THE REPORTING INTERVAL FOR SAFETY REASONS

On 05 February 2021 Health Canada requested to issue a joint Pfizer-Health Canada Health Product Risk Communication to communicate revisions to Product Monograph (addition of 6-dose vial information and text on anaphylaxis). Final HPRC was approved on 08 February 2021.

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

4. CHANGES TO REFERENCE SAFETY INFORMATION

The RSI for this SMSR is the BNT162b2 CDS Version 1.0, dated 12 February 2021, in effect at the end of the reporting period which is located in [Appendix 1](#).

After the data-lock point of this SMSR, on 02 March 2021, the CDS was updated with the following safety-related changes made: Diarrhoea, Pain in extremity (arm) and Vomiting were added as adverse reactions from post-authorisation experience in Section 4.8 Undesirable effects.

5. ESTIMATED EXPOSURE AND USE PATTERNS

5.1. Cumulative and Interval Exposure Data

It is not possible to determine with certainty the number of individuals who received BNT162b2 during the period of this review. Estimated worldwide shipped doses may serve as a reasonable indicator of subject exposure.

With these caveats in mind, it is estimated that:

- approximately 126,212,580 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021;
- approximately 59,939,685 doses of BNT162b2 were shipped worldwide during the current reporting interval from 01 February 2021 through 28 February 2021.

The estimated cumulative number of shipped doses of BNT162b2 by region³ based on data provided in the shipment tracker (b) (4)⁴ from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021, are summarized in Table 2.

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

| Region/Country/Other | % of Doses | Total Number of Shipped Doses |
|---|---------------|-------------------------------|
| Europe | (b) (4) | (4) |
| European Union ^a (27) | | |
| European Free Trade Association ^a (3) | | |
| Switzerland ^a | | |
| UK ^b | | |
| Other Countries | | |
| Commonwealth of Independent States^c | | |
| North America^b | | |
| US | | |
| Canada | | |
| Central and South America^d | | |
| Asia | | |
| Japan ^a | | |
| Other Countries ^e | | |
| Oceania | | |
| Australia/New Zealand ^a | | |
| Other Countries | | |
| Africa | | |
| Total | 100.0% | 126212580 |

- a. In this Region BNT162b2 was conditionally approved;
- b. In this Region BNT162b2 received authorisation for emergency supply;
- c. Includes: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan;
- d. In this Region BNT162 received authorisation for emergency supply; in Colombia BNT162b2 is also shipped for COVAX;
- e. In this Region BNT162b2 received authorization for emergency supply, except for South Korea where BN6162b2 is shipped for COVAX.

³ Currently there are no available data that allow to estimate exposure by gender and age group.

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

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The estimated interval number of shipped doses of BNT162b2 by region⁵ based on data provided in the shipment tracker (b) (4)⁶ from 01 February 2021 through 28 February 2021, are summarized in Table 3.

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

| Region/Country/Other | % of Doses | Total Number of Shipped Doses |
|---|---------------|-------------------------------|
| Europe | (b) | (4) |
| European Union ^a (27) | | |
| European Free Trade Association ^a (3) | | |
| Switzerland ^a | | |
| UK ^b | | |
| Other Countries | | |
| Commonwealth of Independent States^c | | |
| North America^b | | |
| US | | |
| Canada | | |
| Central and South America^d | | |
| Asia | | |
| Japan ^a | | |
| Other Countries ^e | | |
| Oceania | | |
| Australia/New Zealand ^a | | |
| Other Countries | | |
| Africa | | |
| Total | 100.0% | 59939685 |

- a. In this Region BNT162b2 was conditionally approved;
- b. In this Region BNT162b2 received authorisation for emergency supply;
- c. Includes: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan;
- d. In this Region BNT162 received authorisation for emergency supply; in Colombia BNT162b2 is also shipped for COVAX;
- e. In this Region BNT162b2 received authorization for emergency supply, except for South Korea where BN6162b2 is shipped for COVAX.

Table 4 provides the estimated interval/cumulative number of shipped doses of BNT162b2 from the receipt of the first conditional marketing authorisation approval through 28 February 2021 for the 27 European Countries and for the 3 of the European Free Trade Association.

⁵ Currently there were no available data that allow to estimate exposure by gender and age group.

⁶ The (b) (4) is the most accurate tracker of shipment used as data source for all the Regions and Countries; US shipment data not available in the (b) (4) were taken from the (b) (4) (b) (4).

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

| EU Country | Total Number of Interval Shipped Doses | Total Number of Cumulative Shipped Doses |
|--|--|--|
| European Union (27) | (b) | (4) |
| Austria | | |
| Belgium | | |
| Bulgaria | | |
| Croatia | | |
| Cyprus | | |
| Czech Republic | | |
| Denmark | | |
| Estonia | | |
| Finland | | |
| France | | |
| Germany | | |
| Greece | | |
| Hungary | | |
| Ireland | | |
| Italy | | |
| Latvia | | |
| Lithuania | | |
| Luxembourg | | |
| Malta | | |
| Netherlands | | |
| Poland | | |
| Portugal | | |
| Romania | | |
| Slovakia | | |
| Slovenia | | |
| Spain | | |
| Sweden | | |
| European Free Trade Association | | |
| Iceland | | |
| Liechtenstein | | |
| Norway | | |
| Total | | |

6. DATA IN SUMMARY TABULATIONS

6.1. Reference Information

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

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6.2. Cumulative and Interval Summary Tabulations from Post-Marketing Data Sources⁷

As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1) received on the second SMSR (01 Jan 2021 to 31 Jan 2021), the MAH should specify the last date that EudraVigilance data were accessed for the purposes of preparing future SMSR.

Cases from EudraVigilance are downloaded with a 3-day delay, therefore for example cases with a Eudravigilance availability date of 28 February 2021 were accessed and downloaded on 03 March 2021. However, among cases received or downloaded during the reporting period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in that month's SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final data. Each month, Pfizer applies a Late condition process that retrieves cases received in the previous reporting period/s but not included in that month's SMSR due to lack of completeness, in order to include them in the current SMSR, therefore ensuring that no cases are excluded from inclusion in the SMSRs.

- [Appendix 2](#) and [Appendix 2.1](#) respectively provide interval and cumulative numbers of case reports (serious and non-serious, medically confirmed and non-medically confirmed) received from post-marketing authorisation data sources,⁷ overall, by sex, country, age groups and in special populations, and summary tabulations of events by PT and SOC respectively for the interval and cumulative periods.
- The cumulative data include all data up to 28 February 2021 while the interval data are for the period from 01 February 2021 to 28 February 2021.
- [Appendix 2.2](#) provides an interval summary tabulation of case reports with DMEs from post-marketing data sources.⁷
- [Appendices 2.3](#) and [2.4](#) provide data stratified by country. In these appendices, spontaneous cases (including regulatory authority and literature cases) are presented separately from non-interventional cases:
 - [Appendix 2.3](#) provides a cumulative and interval summary tabulation of cases by medically confirmed and non-medically confirmed status (fatal, serious and non-serious).
 - [Appendix 2.4](#) provides a cumulative and interval summary tabulation of fatal cases.
- [Appendix 2.5](#)⁸ and [Appendix 2.6](#) provide a cumulative and interval summary tabulation of adverse reactions from post-marketing authorisation data sources⁷ respectively by PT

⁷ This refers to post-EUA/conditional marketing authorisation approval data sources.

⁸ Due to a technical formatting issue, 1 blank page (92) appears in this Appendix; the total data are however correctly displayed.

and by HLT organized according to SOC. Please refer to [Appendix 2.5.1](#)⁹ and [Appendix 2.6.1](#) for data per country.

Adverse events totals presented in [Appendix 2](#), [Appendix 2.1](#) and for safety topic evaluations in [Section 9.5](#) may differ from those presented in [Appendix 2.5](#) and [Appendix 2.6](#), due to the fact that [Appendix 2.5](#) and [Appendix 2.6](#) only display the number of serious and non-serious reactions from spontaneous sources, serious reactions from non-interventional studies and from solicited sources as described above, whereas [Appendix 2](#), [Appendix 2.1](#) and the safety topic evaluations includes all reported events.

[Appendix 2.5.2](#),¹⁰ [Appendix 2.5.3](#)¹¹ and [Appendix 2.5.4](#) were added to include a cumulative and interval summary tabulation of adverse events from post-authorisation data sources⁷ by PT per country, stratified respectively for age, gender and relevant co-morbidities.

Available relevant information with regard to the differences in vaccination prioritization in EU countries,¹² US¹³, UK and ROW¹⁴ was taken into account in the evaluation of adverse events trends, clusters or signals.

⁹ Due to a technical formatting issue, 8 blank pages (154, 164, 200, 277, 531, 656, 672 and 686) appear in this Appendix; the total data are however correctly displayed.

¹⁰ Due to a technical formatting issue, 5 blank pages (142, 316, 785, 801 and 931) appear in this Appendix; the total data are however correctly displayed.

¹¹ Due to a technical formatting issue, 2 blank pages (68 and 177) appear in this Appendix; the total data are however correctly displayed.

¹² Overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA. ECDC, February 2021.

¹³ <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table-phase-1b-1c.html>.

¹⁴ WHO Roadmap for Prioritizing Population Groups for Vaccines against COVID-19; ACIP COVID-19 Vaccines Working Group, Phased Allocation of COVID-19 Vaccines (Dec 01, 2020); JCVI updated interim advice on priority groups for COVID-19 vaccination (Sept 25, 2020)

7. MEDICATION ERRORS

Cases potentially indicative of medication errors¹⁵ that occurred in the reporting period are summarized below.

- Number of cases: 858 (3.6% of 23,558 cases, the total PM⁷ dataset) of which 644 (75.1%) are medically confirmed, compared to 872 (6%) in the second monthly report of which 74.5% were medically confirmed). Out of the 858 cases, 13 cases describing medication errors occurring in an unspecified number of individuals, and 3 additional cases, describing medication errors occurring with co-suspects were determined to be non-contributory and are not included in the discussion.
- Number of relevant medication error cases: 842
Number of relevant events: 1189.
- Number of medication errors by country:
 - There were 393 cases describing medication errors, which occurred in the EU/EEA countries [France (139), Czech Republic (87), Germany (50), Italy (25), Finland (21), Portugal (18), Sweden (10), Austria (8), Greece, Spain and Poland (5 each), Norway and Denmark (4 each), Romania (3), Belgium, Croatia and Slovakia (2 each), Lithuania, Slovenia and Ireland (1 each)].
 - There were 449 cases with medication errors from other countries [US (332), UK (67), Canada (16), Puerto Rico (12), Chile (7), Mexico (4), Israel (3), Switzerland and Northern Mariana islands (2 each), Angola, Costa Rica, Oman, Saudi Arabia (1 each)].

¹⁵ MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

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

- In the EU/EEA region there were 11 clusters, the largest in France (96 cases), Czech Republic (83 cases), Germany (25 cases) and in Finland (12 cases);
- In other countries there were 19 clusters, the largest in US (14 cases), Puerto Rico (10 cases), Chile (7 cases) and in Canada (2 cases).
- Medication error PTs in the EU and ex-EU¹⁶
 - In the EU/EEA countries, a total of 652 PTs indicative of medication errors were reported; those events reported at least thrice included: Poor quality product administered (243), Product temperature excursion issue (141), Product preparation error (96), Incorrect route of product administration (69), Inappropriate schedule of product administration (25), Underdose (22), Product preparation issue (21), Product administered at inappropriate site (9), Wrong technique in product usage process (7), Incorrect dose administered (5) and Circumstance or information capable of leading to medication error (3).¹⁷
 - In other countries, a total of 537 medication errors were reported; those events reported at least thrice included: Inappropriate schedule of product administration (173), Underdose (53), Poor quality product administered (51), Product administered to patient of inappropriate age (37), Incorrect route of product administration (31), Product temperature excursion issue (24), Circumstance or information capable of leading to medication error (22), Product preparation error (18), Product administered at inappropriate site, Product preparation issue, and Wrong technique in product usage process (14 each), Accidental exposure to product (13), Exposure via skin contact (12), Incomplete course of vaccination (11), Accidental overdose and Wrong product administered (8 each), Incorrect dose administered (7), Incorrect dosage administered (5), Product dose omission issue and Product administration error (4 each), Product storage error (3).

¹⁶ As per EMA assessment received on the first SMSR, the MAH was requested to should keep medication errors under close scrutiny especially within the EU context and discuss whether the current product information is sufficiently clear or whether there is room for improvement. The Rapporteurs should be notified immediately in case of unexpected findings or trends.

¹⁷ The PTs reported less than 3 times included: Accidental overdose and Medication error (2 each) and Accidental exposure to product, Exposure via skin contact, Intercepted product preparation error, Lack of vaccination site rotation, Product administered to patient of inappropriate age, Product administration error and Transcription medication error (1 each).

- Medication errors by seriousness:
 - Serious (24); out of these, 12 serious medication errors¹⁸ were reported in EU/EEA countries [Croatia, France, Germany, Lithuania and Romania (2 each), and Denmark and Italy (1 each)].
Seriousness criteria were hospitalization and disability or permanent damage (1 event each) and important medical events (10 events); all but 1 event were medically confirmed.
 - Non-serious (1165).
- Medication error case outcomes:
 - Fatal (5)¹⁹ (cross-ref with [Section 9.5.3, Death](#)),
 - Resolved/resolving (167, of which 85 are serious),
 - Resolved with sequelae (3, of which 2 are serious)
 - Not resolved (90, of which 58 are serious),
 - Unknown (577, of which 21 are serious).

Medication Errors Harm Analysis

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

- Medication errors associated with harm [i.e., resulting in adverse reaction(s)] were reported in 17²⁰ cases (15 in the second SMSR);

¹⁸ PTs: Incorrect route of product administration (3), Accidental overdose, Inappropriate schedule of product administration, Incorrect dose administered, Incorrect route of product administration, Lack of vaccination site rotation, Poor quality product administered, Product administration error, Product preparation issue, Product temperature excursion issue, Underdose (1 each).

¹⁹ As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1), MAH should provide details regarding the fatal cases of medication errors and more clearly indicate whether or not the medication error caused or contributed to serious adverse event or outcome. All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak.

²⁰ Two cases reported both medication errors with harm and without harm.

- Medication errors without harm [i.e. not resulting in adverse reaction(s)]²¹ were reported in 774 cases (in 321 of them there were co-reported AEs) compared to 713 cases of which 288 included co-reported AEs in the second SMSR;
- Intercepted medication errors were reported in 2 cases, compared to 2 cases in the second SMSR;
- Potential medication errors were reported in 51 cases, compared to 106 cases in the second SMSR.

Medication errors associated with harm (21 medication errors in 17 cases)

There were 8 cases from the EU/EEA area [Sweden (4), France (2), Germany and Italy (1 each)] and 9 from non-EU/EEA countries [US (7), UK (2)].

Serious medication errors

In 4 cases (involving 5 medication error events), serious medication errors potentially contributed to the occurrence of serious adverse events.

- Seizure, Circulatory collapse, Tachycardia, Loss of consciousness, Presyncope, Somatic symptom disorder, Facial paralysis, Hypotension, Vertigo, and Paraesthesia occurred in a 30-year-old woman 15 minutes after she received a dose of vaccine exposed to temperature excursion (PTs Product temperature excursion issue, Poor quality product administered). No antiepileptics treatment were administered since “seizure self-limited once the woman was in flat position with legs lifted”. The events seizure, paraesthesia, facial paralysis, circulatory collapse, tachycardia, and unconsciousness resolved after treatment including fluid and electrolyte replacement solution and paracetamol; the outcome was unknown for the remaining events (cross-reference with [Section 9.5.2](#)).
- Myositis, Vaccination site pain, Neuralgic amyotrophy and Back pain were reported in a 52-year-old man after receiving the vaccine (PT Lack of vaccination site rotation). The events were considered complications from vaccine absorption by the allergy and toxicology specialists. The events (except vaccination site pain) were resolving after treatment at the time of the report.
- Pain/arthralgia accompanied by nausea and paraesthesia occurred to a 51-year-old woman after she received the vaccine intramuscularly towards the humeral head and not in the deltoid muscle (PT Product administration error); the events were resolving after treatment.
- The vaccine was administered 2 cm below the deltoid muscle (PT Product administered at inappropriate site) in an adult woman who experienced “constantly itching scabbing

²¹ AEs may be co-reported in a case, but they are not considered to be a result of the medication error.

over granulating and oozing 6 weeks post injection”. The outcome of the events was unknown.

Non-serious medication errors

In 13 cases (involving 16 medication error events), non-serious medication errors potentially contributed to the occurrence of non-serious adverse events.

Administration of undiluted vaccine (2 events, 1 case)

- A 41-year-old woman experienced anal incontinence the night after she received a dose of undiluted vaccine. The subject recovered the following day; it was unknown if treatment was given.

Errors in the route of administration (11 events, 10 cases)

- This error occurred in 5 cases in the EU/EEA area (4 from Sweden and 1 from France) and in 5 US cases. The vaccine was administered subcutaneously (6 events); “not intramuscularly” (3 events), and through other routes (IV, oral, 2 events). Local vaccination site reactions mainly included erythema, swelling, pruritus, and warmth and pain.

Errors of vaccination at the wrong anatomical site (3 events, 3 cases)

- This error occurred in 3 cases (from the US). The vaccination was not administered in the deltoid (PT Product administered at inappropriate site). Vaccination site erythema and Pain in extremity (2 each), Skeletal injury and Contusion (1 each) were reported.

Medication errors without harm²⁰ (1113 medication errors in 774 cases)

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

Overall, there were

- 381 cases from the EU/EEA area [France (137), Czech Republic (86), Germany (49), Italy (24), Finland (21), Portugal (18), Austria (8), Sweden (6), Greece and Poland (5 each), Denmark and Spain (4 each), Norway and Romania (3 each), Belgium, Croatia and Slovakia (2 each), Lithuania and Slovenia (1 each)] and
- 393 from non-EU/EEA countries [those with more than 1 medication error included the US (285), the UK (64), Canada (14), Puerto Rico (12), Chile (7), Mexico (3) Northern Mariana Islands, Israel and Switzerland (2 each)].

Vaccine preparation errors (320 events, 2 of which were serious): events mainly described errors in storage conditions or during dilution (before use).

- *Temperature excursion (167 events):* in the majority of the events, the vaccine was left at room temperature or in the refrigerator for a longer time than specified in the RSI; no adverse events were reported upon vaccine administration.
- *Incorrect dilution (138 events):* Dilution was performed either with a smaller volume of normal saline (8 events), or with a larger volume of normal saline (6 events) than instructed; dilution with improper volume was reported with a variable total number of available doses after dilution from a single vial (15 events). There were 97 events of dilution performed with a different solvent (water for injection for 96 events) rather than normal saline. In another 12 events the vaccine was administered without performing the dilution; no adverse events were reported upon vaccine administration.
- *Other preparation errors (15 events).*

Vaccine administration errors (793 events, 17 of which were serious): events mainly described errors in administration of vaccine dose not adequately prepared (see Preparation subset), errors in the volume or dosage of the vaccine administered, errors in administering the second dose in less than 21 days or after more than 21 days, and errors in route of administration.

- *Administration after inadequate preparation (294 events, all non-serious):* these events referred to vaccine administered after inadequate preparation: dilution performed with water for injection instead of normal saline (95 events); vaccine administered incorrect thawing procedure (left at room temperature for a longer time than the one specified in the RSI), or thawed and inadvertently refrozen (166 events); and other 33 errors including presence of particulates [single black particles (4), small white floating particles (2), piece of latex (1) and another not further detailed particle (1)] after vaccine administration.
- *Incorrect interval between doses (148 events, 2 of which serious²²):* the second dose of the vaccine was administered at less than 21 days of interval (98 events); interval between the first and the second dose ranged between 0 day (3 events) and 18 days, with the majority of the second doses administered between the 15th and the 18th day after the first dose (51 events); the second dose was administered after more than 21 days (50 events).

²² PTs Inappropriate schedule of product administration (2), Asthenia, Chills, COVID-19, Diarrhoea, Drug ineffective, Fatigue, Headache, Lymphadenopathy, Nausea, Off label use, Pain, Pyrexia, Vomiting (1 each).

- *Errors in the route of administration (93 events, of which 4 serious²³):* the vaccine was administered subcutaneously (55 events)²⁴; intravenously (14 events), parenterally without any further detail (9 events); and through other routes (15 events).
- *Errors in the volume administered (78 events, of which 3 serious²⁵):* partial doses were administered due to leakage, syringe or needle malfunction (74 events); higher volume of right dose of vaccine was administered (4 events).
- *Paediatric Individuals <16 Years of Age (38 events, of which 3 serious²⁶):* the vaccine was inadvertently administered to paediatric individuals below 16 years (see [Section 9.5.4 Use in Paediatric Individuals <16 Years of Age](#)).²⁷
- *Dose of vaccine not administered (33 events, of which 1 serious²⁸):* the second dose was not administered at the scheduled date. In 15 instances, the dose was not administered either because the vaccinees were recovering from AEs occurred after first dose or they became COVID-19 positive or due to the impossibility to attend at the scheduled date; only saline was injected or the syringe was empty (2 each); in the remaining instances the second dose was not administered for not further detailed causes (14 events).
- *Accidental exposure to vaccine (27 events, all non-serious):* all involved skin exposure.
- *Errors in vaccine dosage (25 events, of which 2 serious):* these errors include administration of vaccine at higher concentrations (10 events) and at lower concentrations (6 events) than recommended and 7 events in which the vaccine was administered undiluted or a third dose was administered (2 events, 1 case).
- *Vaccination site other than deltoid muscle (20 events, of which 1 serious²⁹):* the vaccine was administered in the vaccinee's arm but not in the deltoid muscle (14 events); the

²³ PTs Chills, Deep vein thrombosis, Drug ineffective, Erythema, Fatigue, Feeling abnormal, Feeling hot, Feeling of body temperature change, Gait disturbance, Headache, Hyperaemia, Lymphadenopathy, Malaise, Myalgia, Pain in extremity, Rash pruritic, Suspected COVID-19, Vaccination site discolouration, Vaccination site pain, Vaccination site thrombosis.

²⁴ In 1 case route was reported as partly subcutaneous and partly intramuscular.

²⁵ PTs Accidental overdose and Product administration error (2 each), Cough, Fatigue, Headache, Incorrect dose administered, Malaise, Pain in extremity, Pyrexia, Underdose, Vaccination site pain (1 each).

²⁶ PTs Headache (3), Product administered to patient of inappropriate age (3), Pyrexia and Pain in extremity (2 each), Arthralgia, Back pain, Chills, Mastitis, Myalgia, Peripheral swelling, Swelling, Vertigo and Wheezing (1 each).

²⁷ Out of these 38 cases, 18 were not further detailed in [Section 9.5.4](#) as reporting information was not consistent for paediatric subjects (e.g. age category of adult or medical history and medications clearly for adults).

²⁸ PTs Product dose omission issue, Drug ineffective, COVID-19.

²⁹ PTs Neurological symptom, Neuralgic amyotrophy, Pain in extremity, Paraesthesia, Joint dislocation, Chest discomfort, Pain, Wrong technique in product usage process.

administration site was in the leg, thigh or in the gluteus (4 events), in the hand and in the abdomen (1 event each).

- *Wrong vaccine administered (10 events, all non-serious)*: the vaccinees received one dose of Moderna vaccine and 1 dose of BioNTech-Pfizer vaccine (8 events); in 2 instances the vaccinees were told to receive one dose of Moderna vaccine, but the vaccination card reported the BioNTech-Pfizer vaccine was administered.
- *Other vaccine administration errors (28 events, of which 1 serious³⁰)*: the majority of the events were indicative of issues with syringes and needles or related to the use of concomitant drugs³¹ (7 events each); expired vaccine (3 events³²) and not further detailed in the 11 remaining ones.

Intercepted medication errors (2 medication errors in 2 cases)

There were 2 cases of which 1 was from the EU/EEA area (Norway) and 1 from non-EU/EEA countries (US).

In the first case a woman of unknown age who had received her first dose in the morning, was called in the afternoon of the same day for the second dose because her last name was misspelt; her second dose was rescheduled. In the second case, a physician prepared a syringe with a double amount of vaccine; the dose was not administered.

Potential medication errors (53 medication errors in 51 cases)

There were 3 cases from the EU/EEA area [Czech Republic, Ireland and Spain (1 each)] and 50 from non-EU/EEA countries [US (43), Canada (2) and 1 case each from Israel, Mexico, Oman, Saudi Arabia and the UK].

- Potential dosing interval error (53 events, all non-serious): events mainly described potential errors in the scheduling for the second dose not according to the 21 days interval. In some instances, the scheduled date for the second dose is planned at 4 weeks interval; in other instances, the planned date was scheduled at a different interval for vaccine unavailability or for individual unavailability.

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

³⁰ PTs Headache, Pyrexia, Fatigue, Vaccination site pain, Cough, Malaise, Pain in extremity, Incorrect dose administered, Underdose (1 each).

³¹ Co-suspect in 1 instance.

³² Three events (in 2 cases) described administration of the vaccine after its expiry date; in the first case, the vaccine was administered 5 days after the expiry date; no information was available for the second case.

8. GENERAL OVERVIEW

A total of 23,558 case reports (13,389 medically confirmed and 10,169 non-medically confirmed) containing 91,934 events fulfilled criteria for inclusion in this SMSR. Refer to [Appendix 2](#) for the summary tabulations of all cases received during the current reporting period.

PRESENTATION OF CASE CHARACTERISTICS

Table 5. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

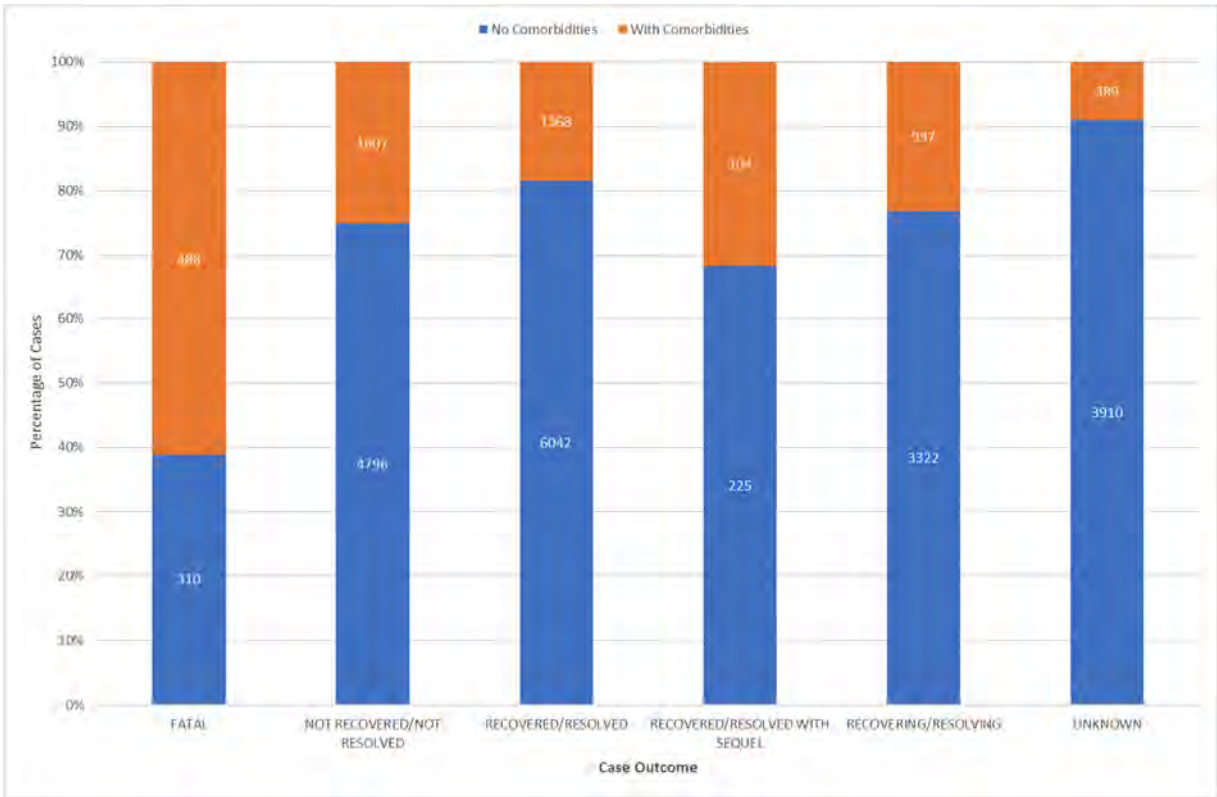
| | Characteristics | Relevant cases (N=23558) |
|---|------------------------------------|--------------------------|
| Gender: | Female | 17040 |
| | Male | 5317 |
| | No Data | 1201 |
| Age range (years): 0.06 -107 years Mean = 52.6 years n = 20433 | ≤ 17 | 91 ^a |
| | 18-30 | 2654 |
| | 31-50 | 7579 |
| | 51-64 | 4526 |
| | 65-74 | 2234 |
| | ³ 75 | 3544 |
| | Unknown | 2927 ^b |
| Case outcome: | Resolved/Resolving | 11729 |
| | Resolved with sequelae | 329 |
| | Not resolved at the time of report | 6403 |
| | Fatal | 798 |
| | Unknown | 4299 |
| Presence of relevant comorbidities | Yes | 4953 ^c |
| | No | 18605 |

- Including 27 cases for which a paediatric age was initially reported but that they re-evaluated as not consistent with this age upon review (see [Table 12](#), Use in Paediatric Individuals <16 Years of Age) and 17 breastfed babies for which paediatric age was reported;
- Including 14 breastfed babies for which age was not reported;
- Cases retrieved applying the criteria in place to identify the reports involving the special populations of Immunocompromised patients, Patients with autoimmune or inflammatory disorders, Frail patients with comorbidities (e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders) described as Missing Information in [Table 12](#). One of these cases was made invalid hence excluded from the discussion in [Table 12](#) below.

Case outcome by age group, gender and presence of relevant comorbidities is presented in [Figure 1](#), [Figure 2](#) and [Figure 3](#). Across all age groups, there were more females than males reporting adverse events. The fatal cases reported more comorbidities, but this is expected considering that the majority of fatal outcomes occurred in patients 75 years and older as shown in [Figure 2-B](#) (please also see *Death* in [Table 11](#) and *Frail patients with co-morbidities e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders*, described as Missing Information in [Table 12](#)).

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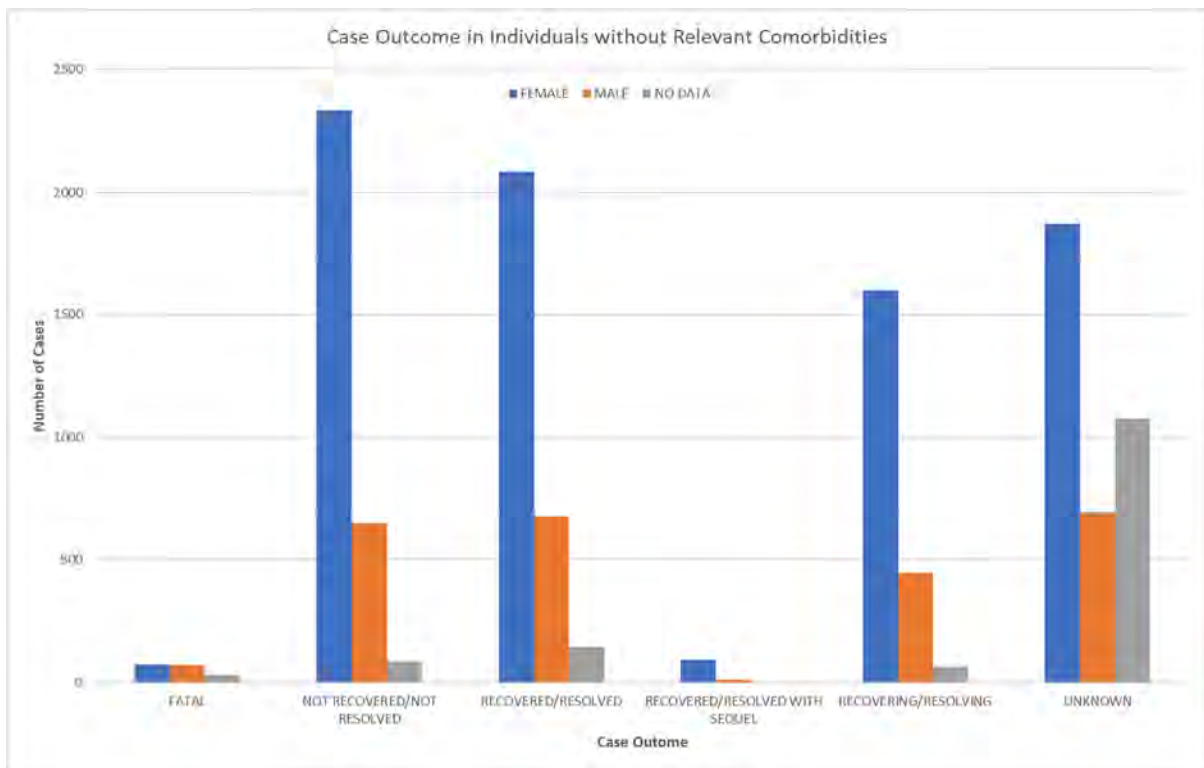
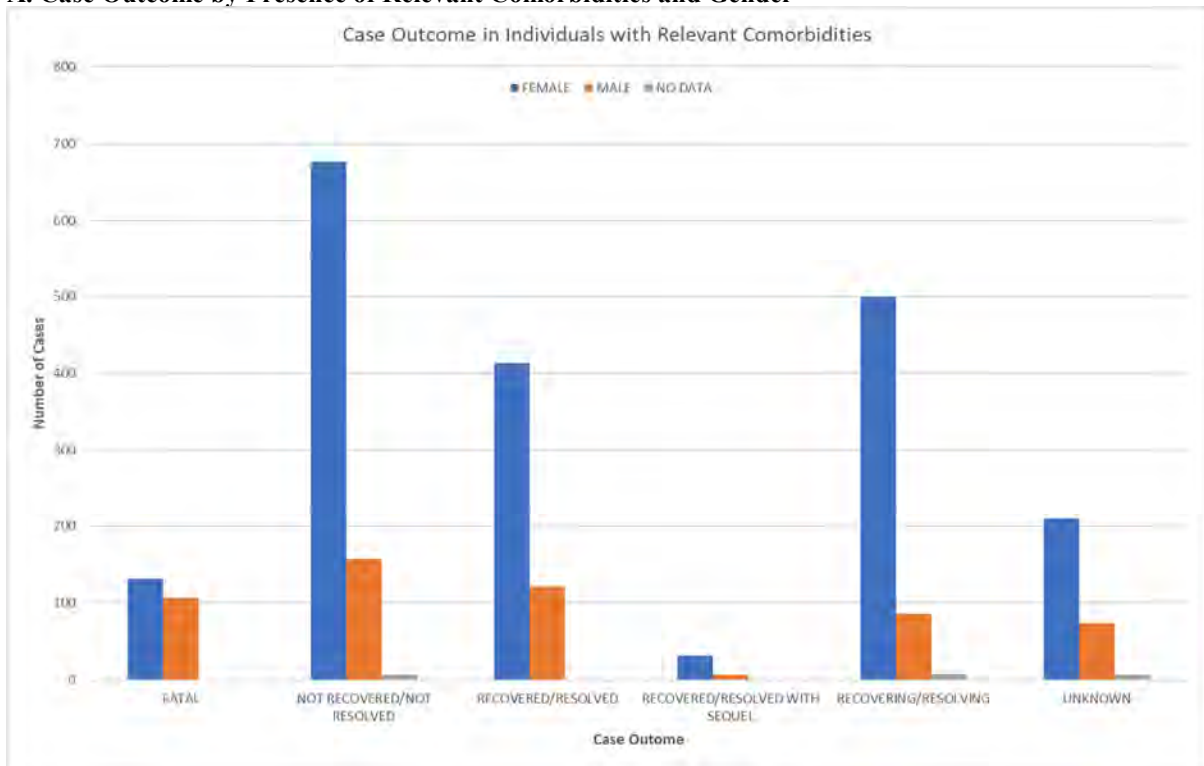
Figure 1. Case Outcome by Presence of Relevant Comorbidities



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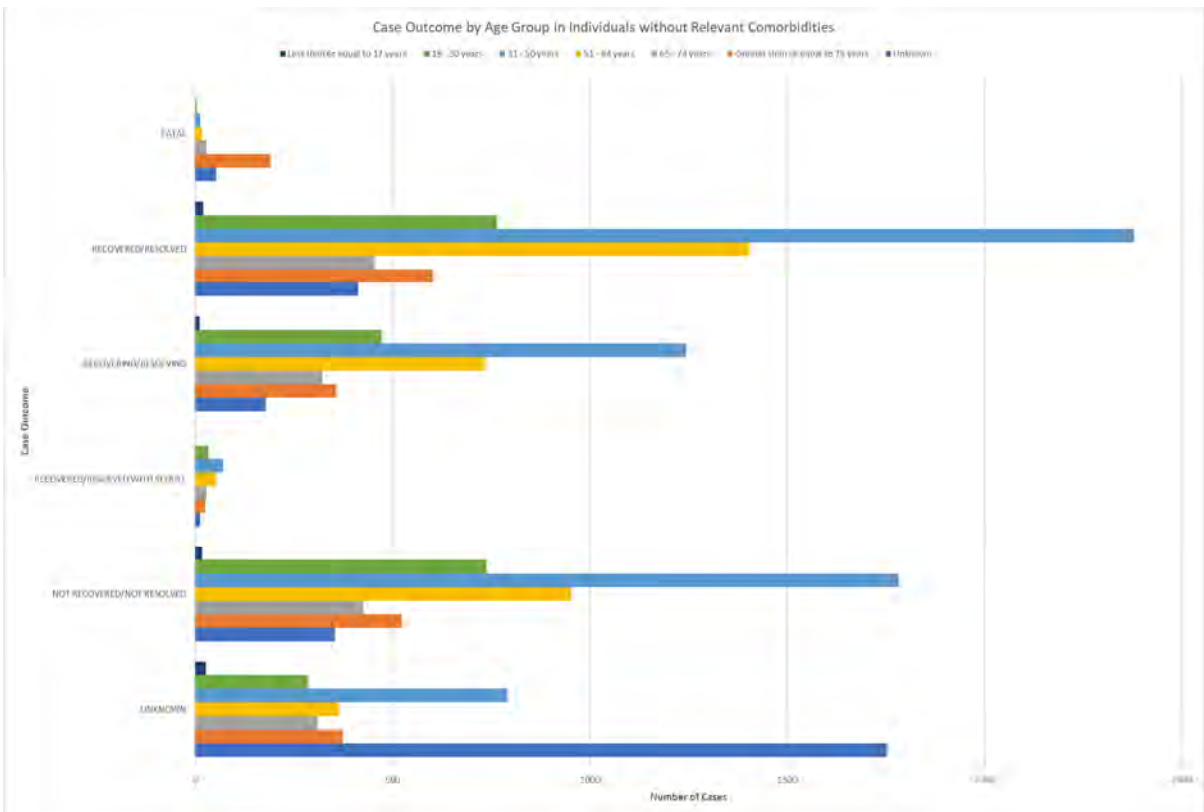
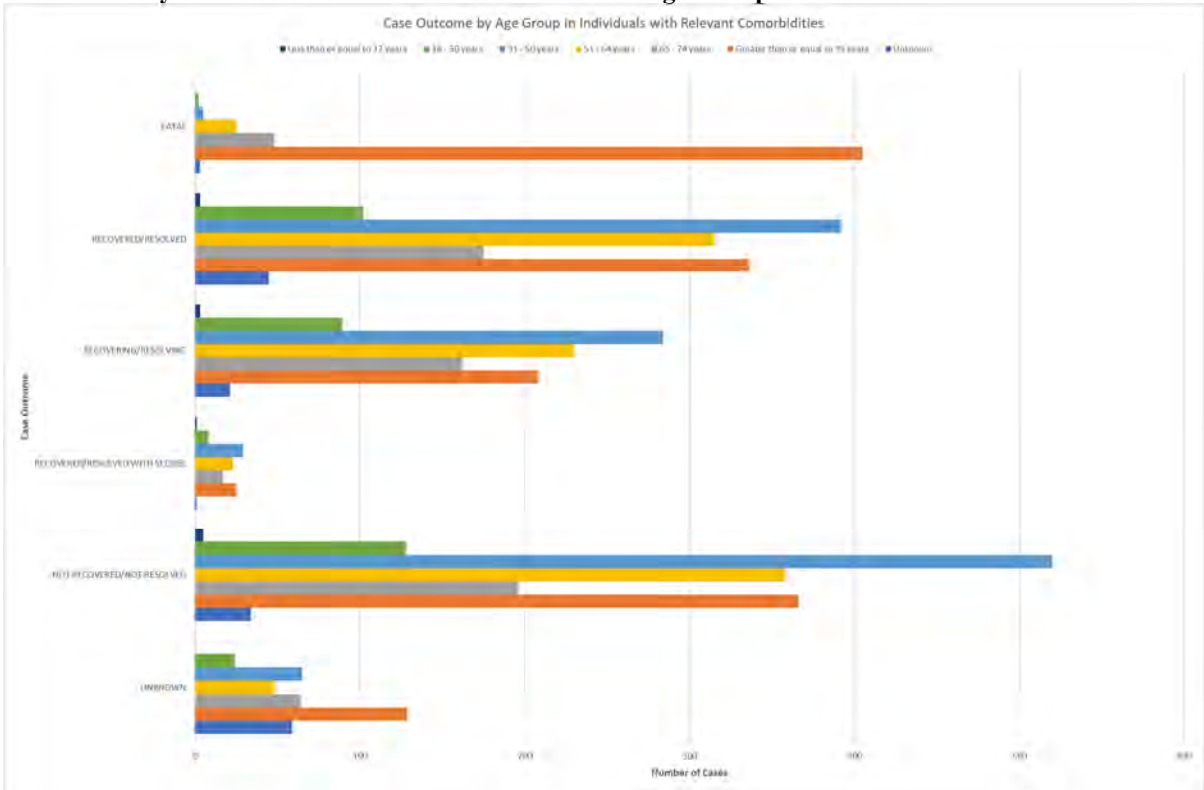
Figure 2. Case Outcome by Presence of Relevant Comorbidities, Gender and Age Group

A. Case Outcome by Presence of Relevant Comorbidities and Gender



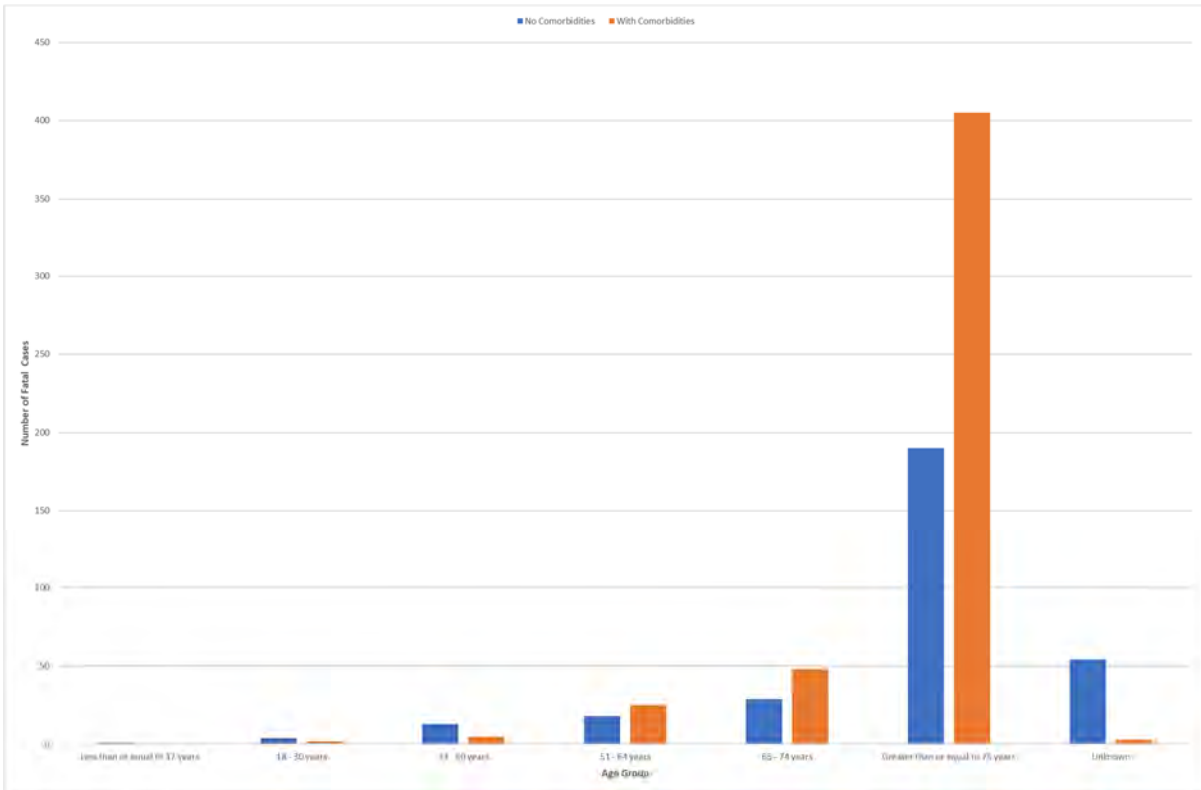
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B. Outcome by Presence of Relevant Comorbidities and Age Group



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

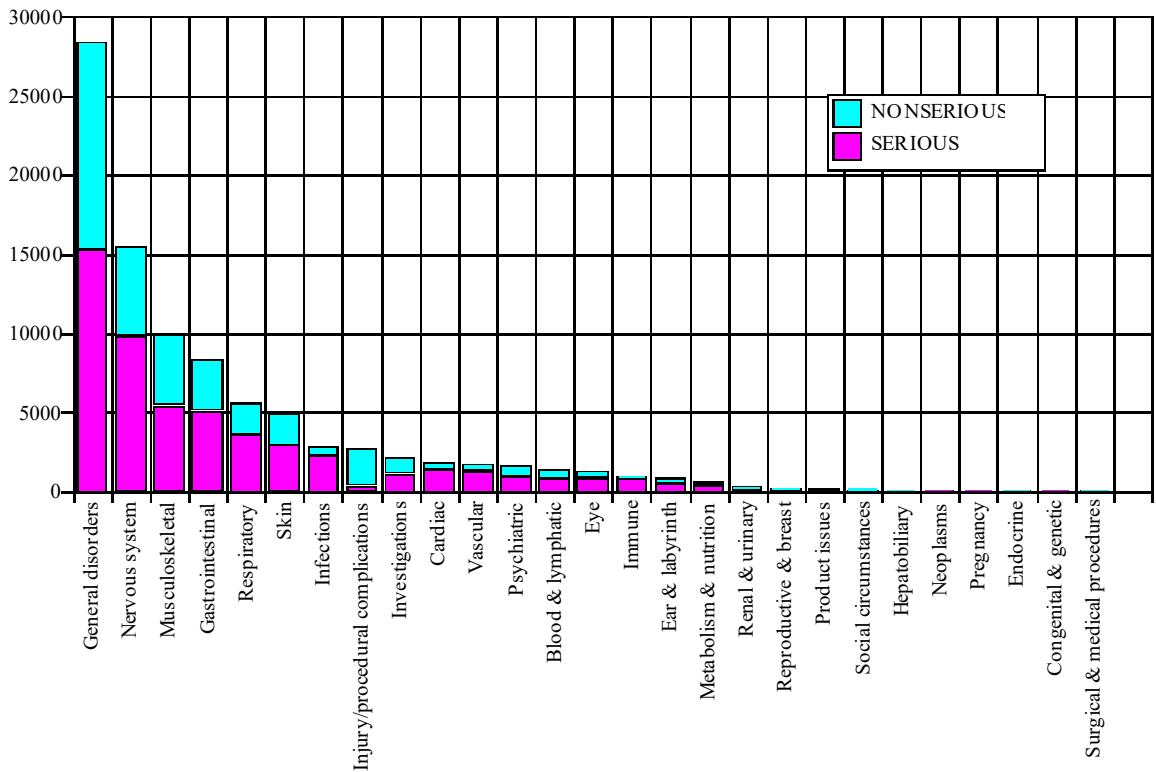


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ADVERSE EVENT DATA

As shown in Figure 4, the MedDRA SOCs containing the greatest number of events ($\geq 2\%$) were General disorders and administration site conditions (28,420), Nervous system disorders (15,446), Musculoskeletal and connective tissue disorders (9872), Gastrointestinal disorders (8274), Skin and subcutaneous tissue disorders (4919), Respiratory, thoracic and mediastinal disorders (5574), Infections and infestations (2879), Injury, poisoning and procedural complications (2722), Investigations (2120) and Cardiac disorders (1918). Of note, multiple adverse events may be reported in a single case.

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



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

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Table 6. Events Reported in $\geq 2\%$ * Cases

| | 01 February 2021 Through 28 February 2021 | Cumulatively Through 28 February 2021 |
|---|--|--|
| MedDRA SOC MedDRA PT | AEs (AERP%) N = 23558 | AEs (AERP%) N = 42086 |
| Blood and lymphatic system disorders | | |
| Lymphadenopathy ^a | 1101 (4.67%) | 1972 (4.69%) |
| Cardiac disorders | | |
| Tachycardia | 713 (3.03%) | 1098 (2.61%) |
| Gastrointestinal disorders | | |
| Nausea ^a | 2946 (12.51%) | 5182 (12.31%) |
| Diarrhoea ^b | 1132 (4.81%) | 1880 (4.47%) |
| Vomiting ^b | 1037 (4.40%) | 1698 (4.03%) |
| General disorders and administration site conditions | | |
| Pyrexia ^a | 4272 (18.13%) | 7666 (18.22%) |
| Fatigue ^a | 4226 (17.94%) | 7338 (17.44%) |
| Chills ^a | 2899 (12.31%) | 5514 (13.10%) |
| Vaccination site pain ^a | 2584 (10.97%) | 5181 (12.31%) |
| Pain ^a | 1825 (7.75%) | 3691 (8.77%) |
| Malaise ^a | 1697 (7.20%) | 2897 (6.88%) |
| Asthenia ^a | 1549 (6.58%) | 2285 (5.43%) |
| Drug ineffective ^c | 1032 (4.38%) | 2201 (5.23%) |
| Chest pain | 475 (2.02%) | 722 (1.72%) |
| Vaccination site erythema ^a | 471 (2.00%) | 930 (2.21%) |
| Infections and infestations | | |
| COVID-19 ^e | 1092 (4.64%) | 1927 (4.58%) |
| Injury, poisoning and procedural complications | | |
| Off label use ^c | 508 (2.16%) | 880 (2.09%) |
| Product use issue ^c | 474 (2.01%) | 828 (1.97%) |
| Musculoskeletal and connective tissue disorders | | |
| Myalgia ^a | 2903 (12.32%) | 4915 (11.68%) |
| Arthralgia ^a | 2101 (8.92%) | 3525 (8.38%) |
| Pain in extremity ^b | 2058 (8.74%) | 3959 (9.41%) |
| Back pain ^a | 473 (2.01%) | 809 (1.92%) |
| Nervous system disorders | | |
| Headache ^a | 5699 (24.19%) | 10131 (24.07%) |
| Dizziness | 2200 (9.34%) | 3720 (8.84%) |
| Paraesthesia | 875 (3.71%) | 1500 (3.56%) |
| Syncope | 540 (2.29%) | 710 (1.69%) |
| Hypoaesthesia | 531 (2.25%) | 999 (2.37%) |
| Respiratory, thoracic and mediastinal disorders | | |
| Dyspnoea ^d | 1406 (5.97%) | 2057 (4.89%) |
| Cough ^d | 676 (2.87%) | 1146 (2.72%) |
| Oropharyngeal pain | 551 (2.34%) | 948 (2.25%) |
| Skin and subcutaneous tissue disorders | | |
| Pruritus ^a | 813 (3.45%) | 1447 (3.44%) |
| Rash ^a | 784 (3.33%) | 1404 (3.34%) |
| Erythema ^a | 642 (2.73%) | 1044 (2.48%) |
| Hyperhidrosis | 529 (2.25%) | 900 (2.14%) |
| Total number of events | 52814 | 93104 |

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Table 6. Events Reported in $\geq 2\%$ * Cases

| | 01 February 2021 Through 28 February 2021 | Cumulatively Through 28 February 2021 |
|--------------------------------|--|--|
| MedDRA SOC MedDRA PT | AEs (AERP%) N = 23558 | AEs (AERP%) N = 42086 |

- a. Listed or consistent with listed AEs in current RSI;
- b. Added to the CDS after the data-lock point of this SMSR, on 02 March 2021;
- c. Listed per case processing conventions; for discussion of relevant cases of Drug ineffective/COVID-19 see [Table 11](#), *Lack of Efficacy* subsection;
- d. Consistent with anaphylactic reactions listed in the current RSI;

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

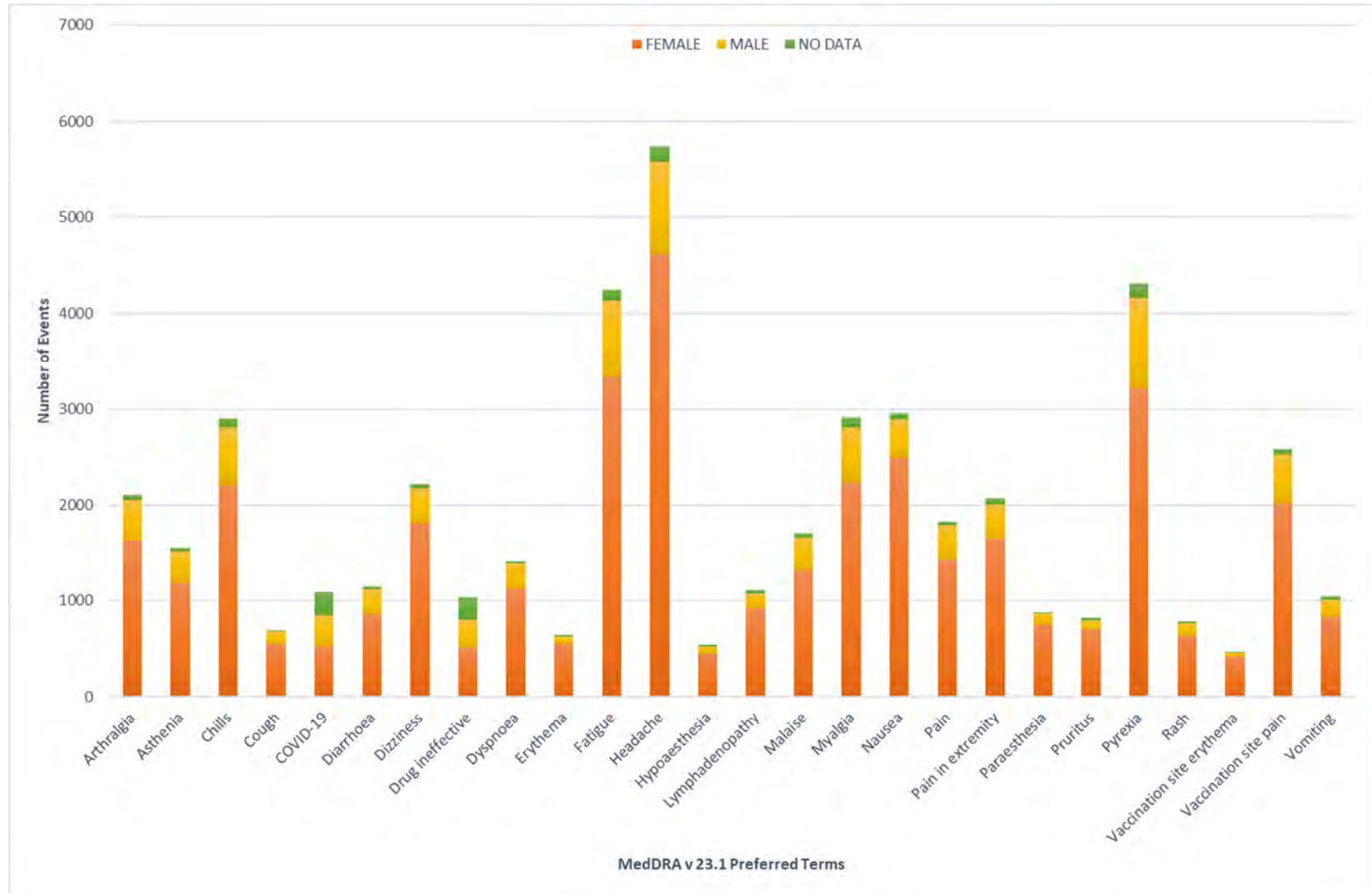
Most of the frequently reported events are listed or consistent with listed events as per the current RSI. Of note, the frequently reported events Dizziness, Paraesthesia, Syncope and Tachycardia, not listed as per the current RSIs, are signals addressed during the reporting period (see [Section 9.2](#)).

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

The distribution of the AEs reported in more than 2% of the cases by age group and by SOC is showed in [Figure 6](#) and [Figure 7](#). The largest number of events is reported overall in the 31-50 years age group.

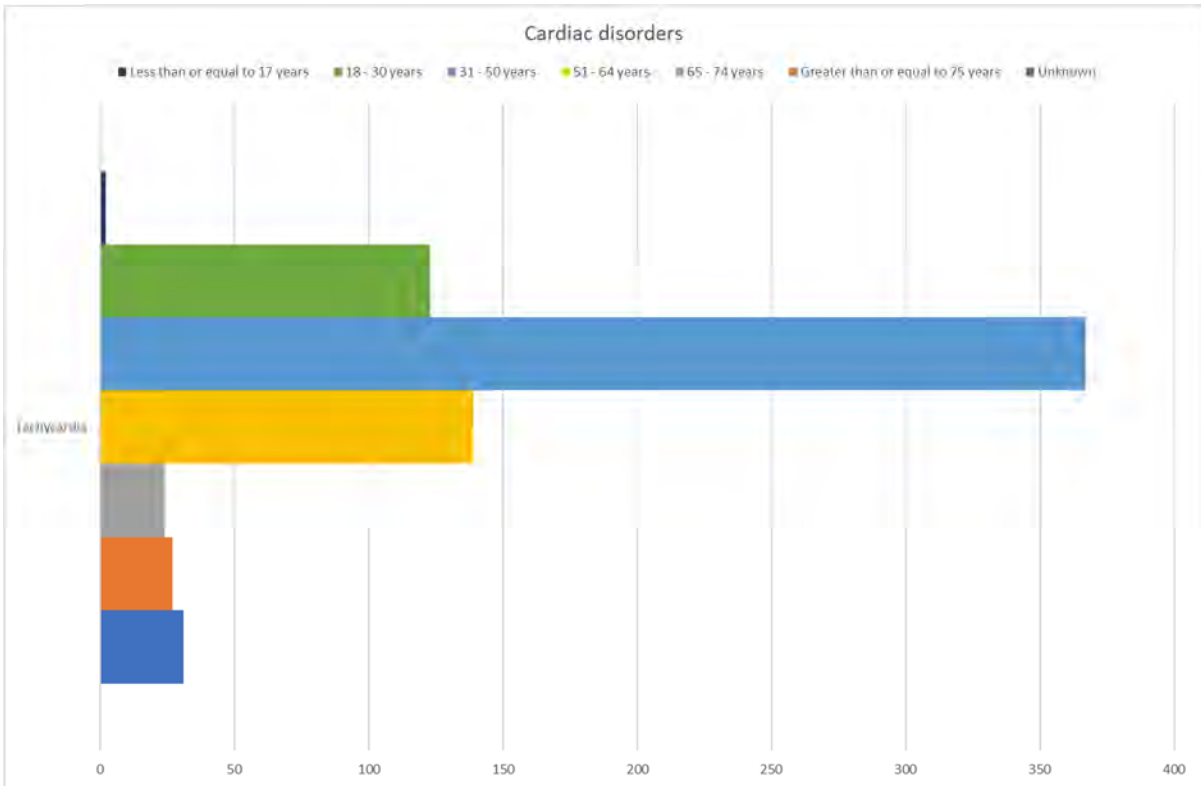
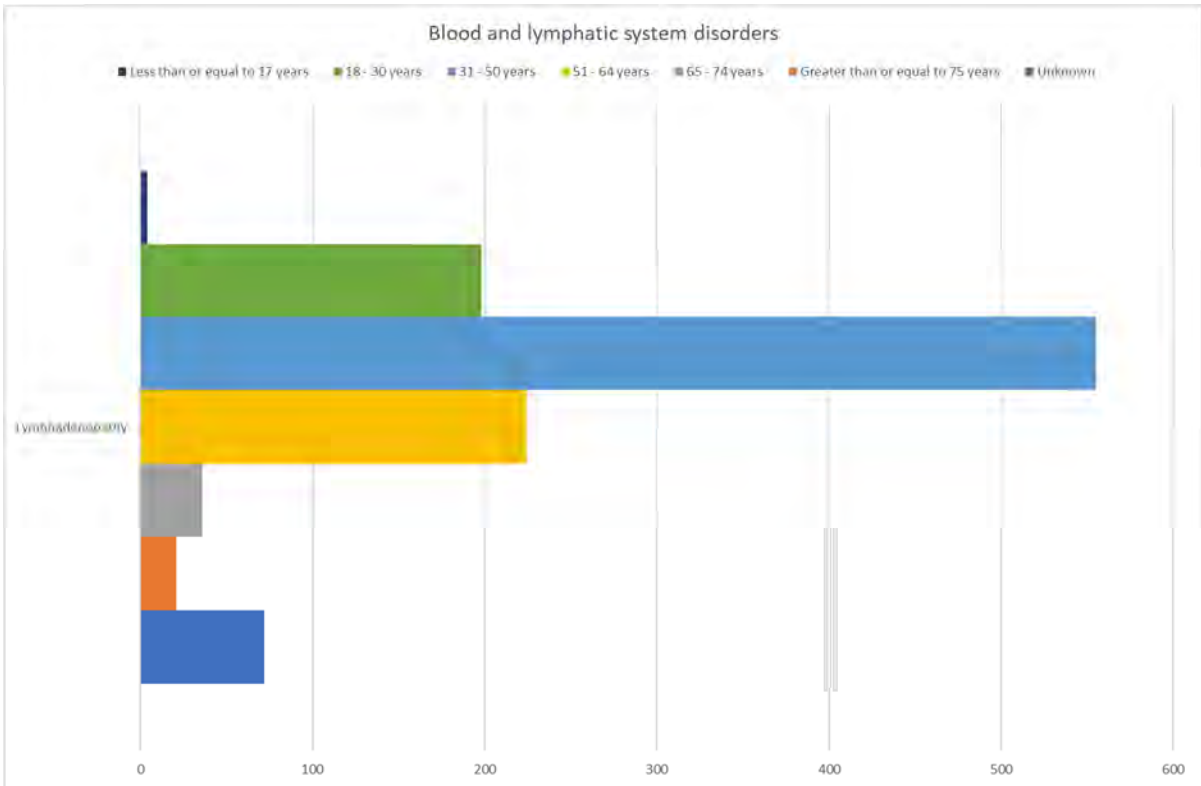
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Figure 5. Events Reported in $\geq 2\%$ Cases in the Interval Period by Gender

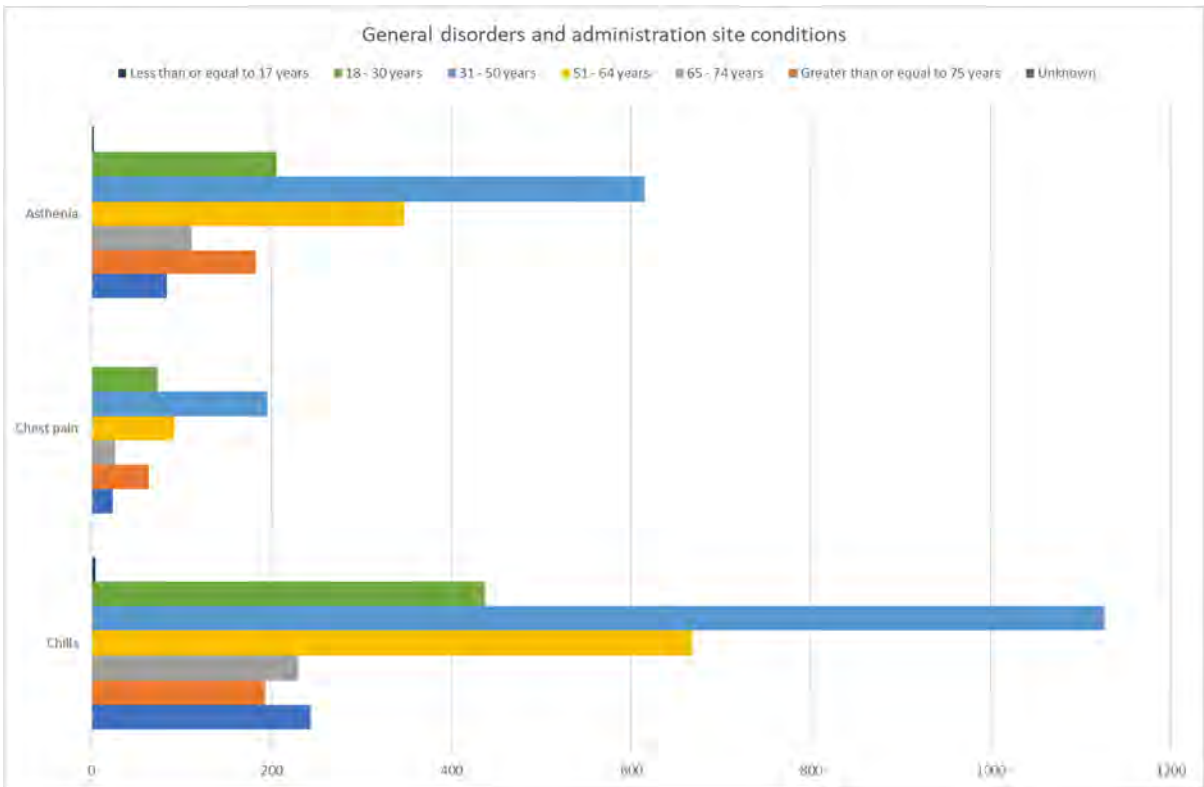
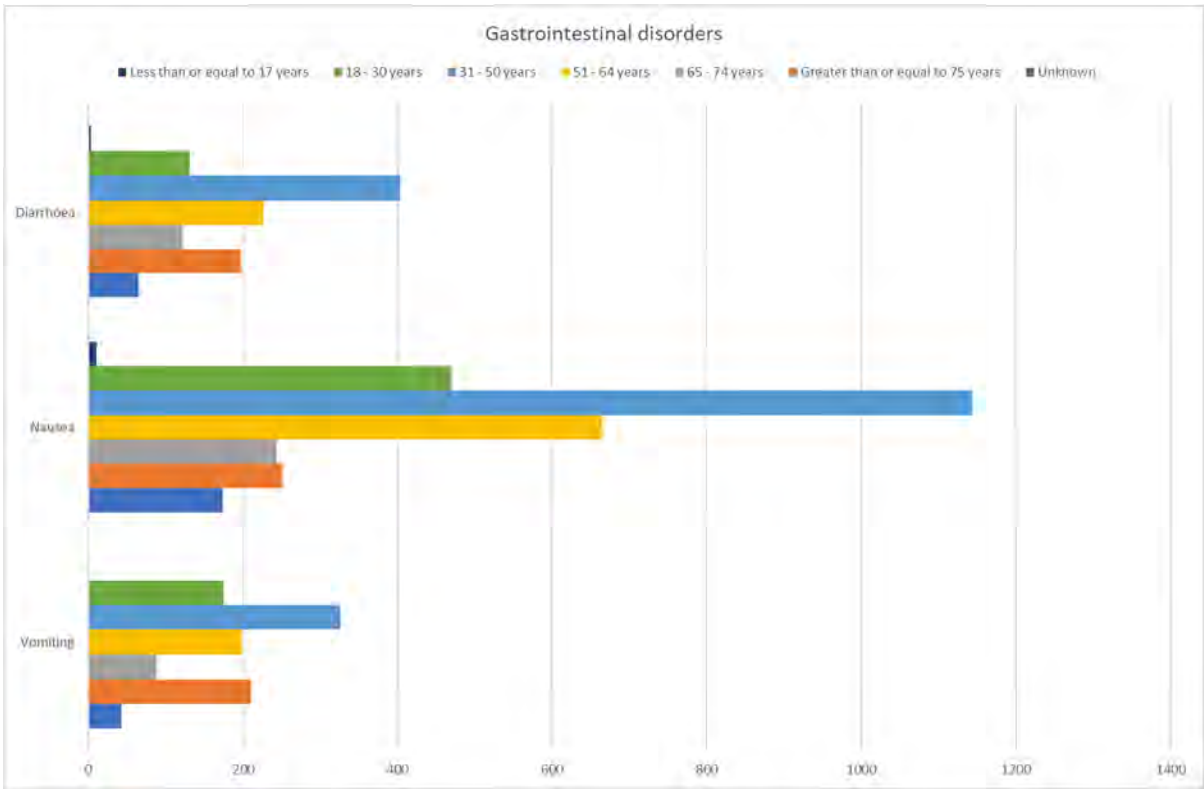


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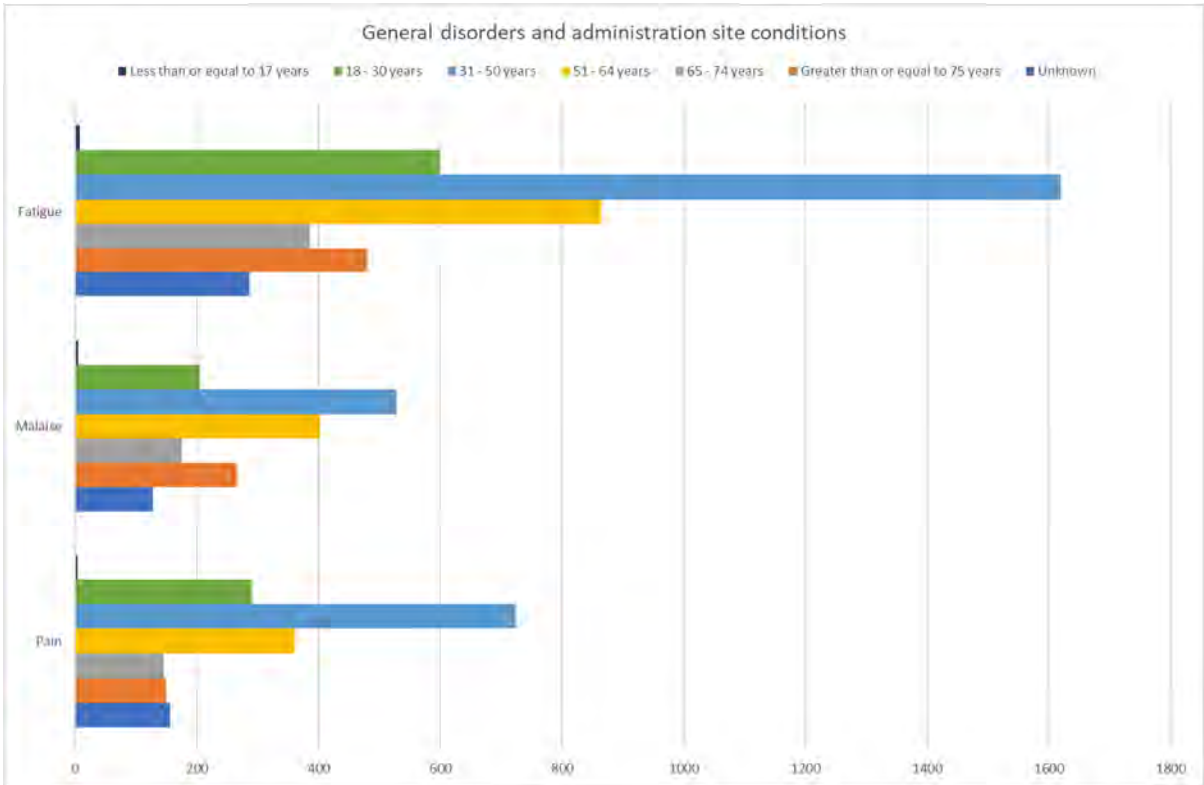
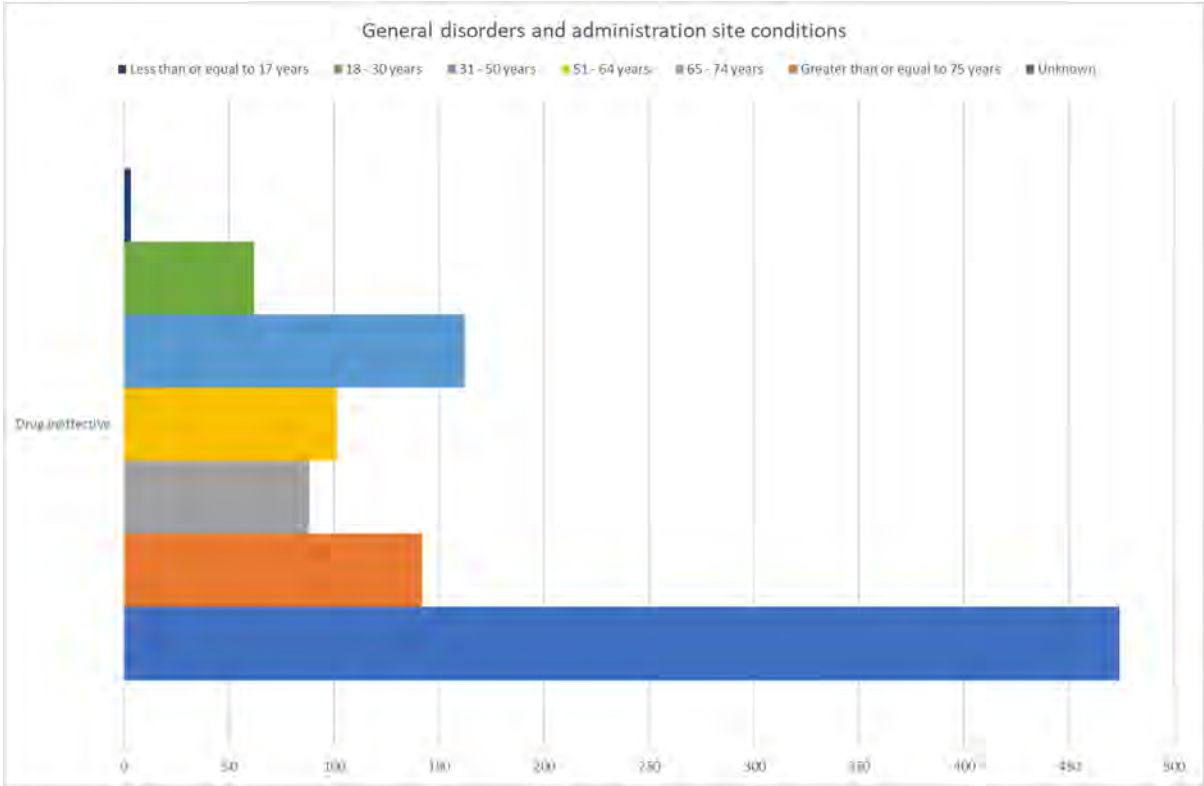
Figure 6. PT Reported in $\geq 2\%$ in the Interval Period - by SOC and Age Group



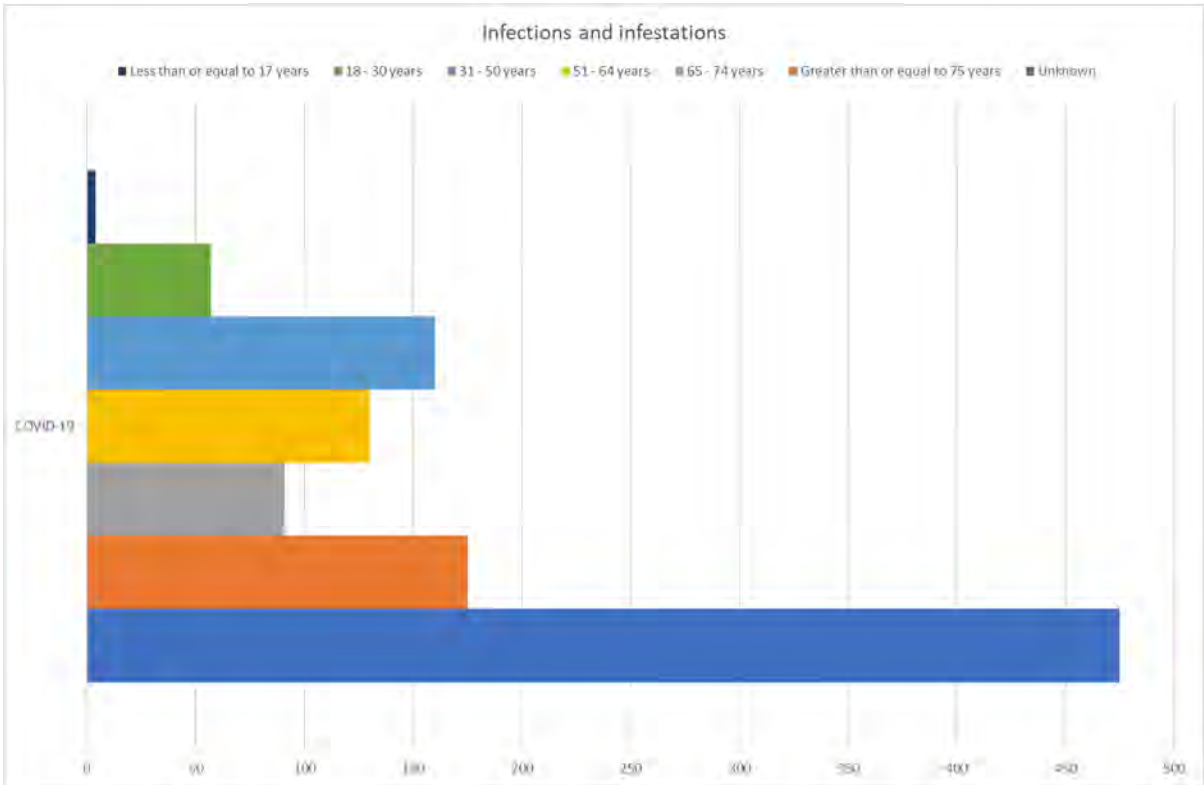
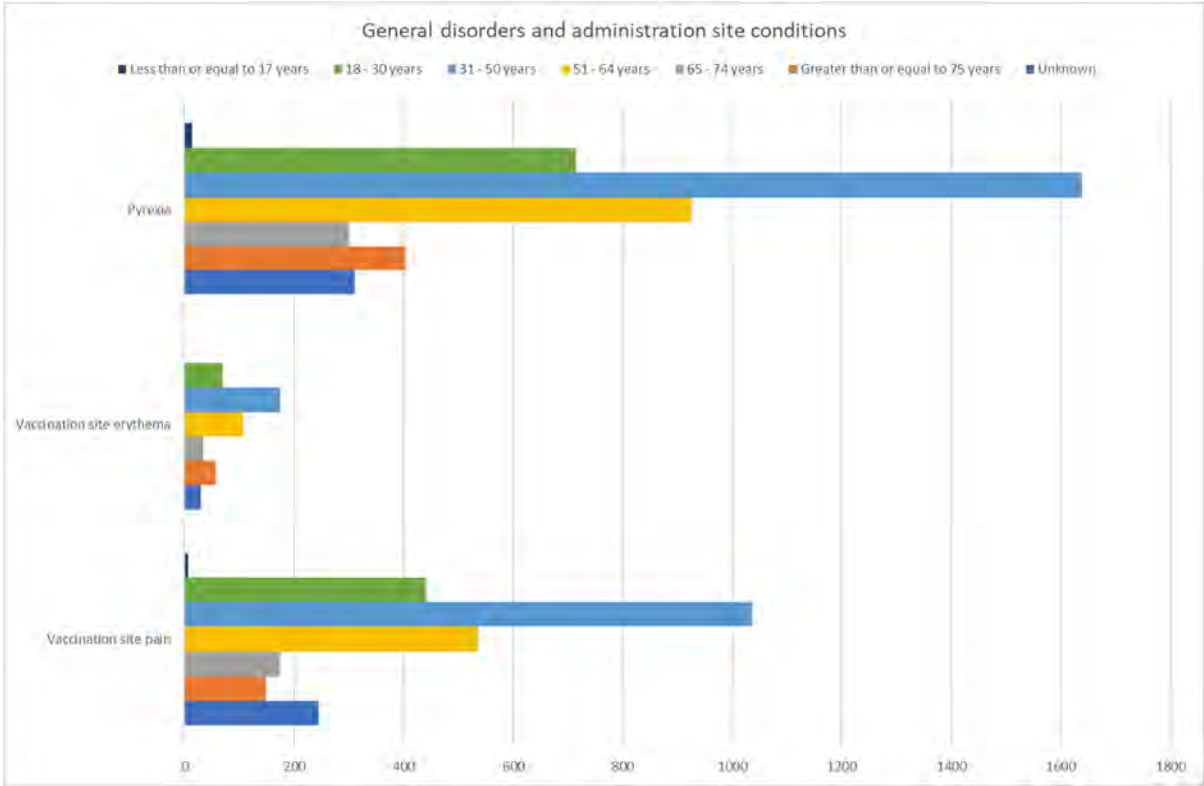
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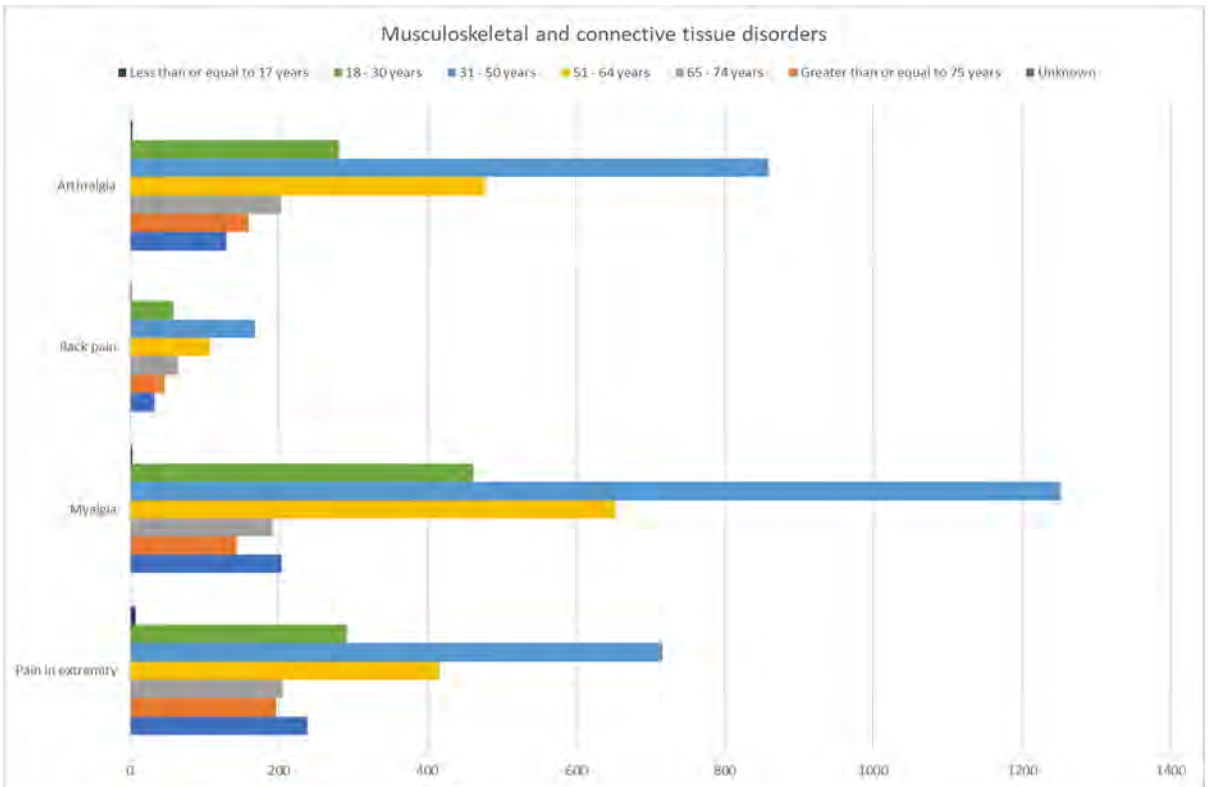
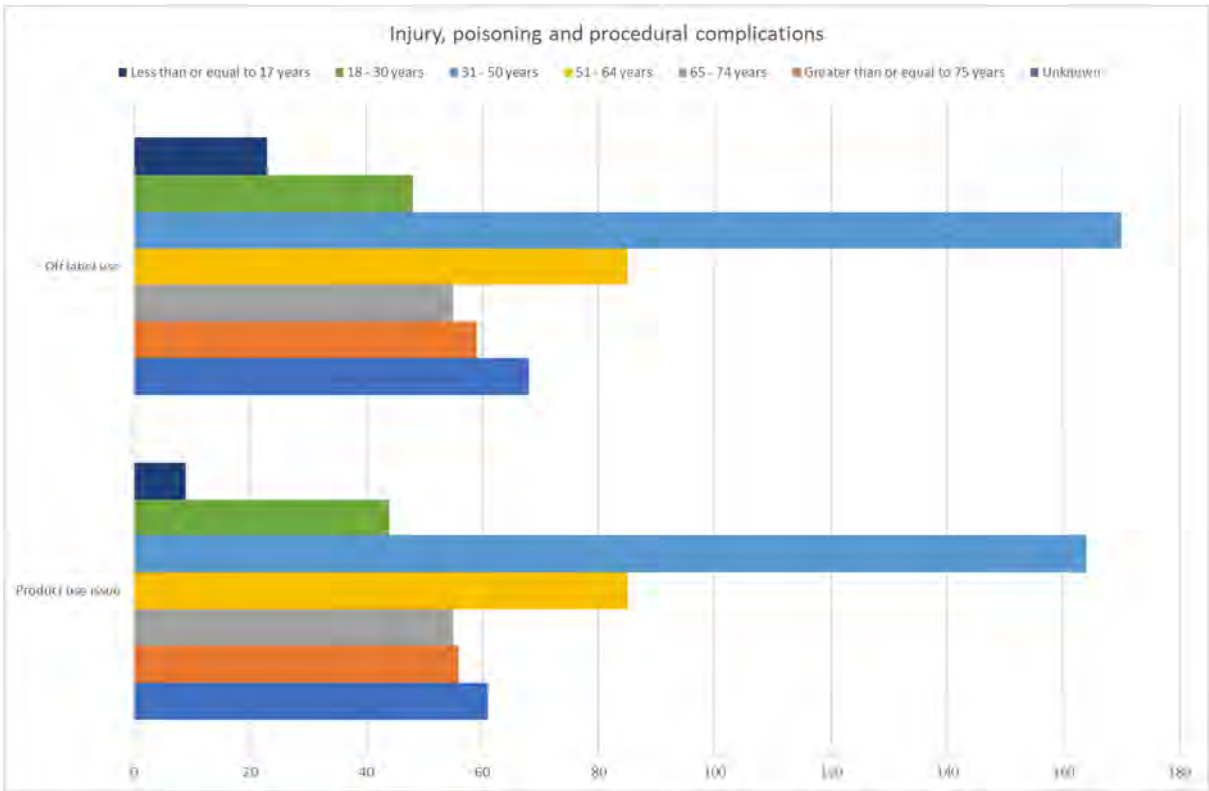
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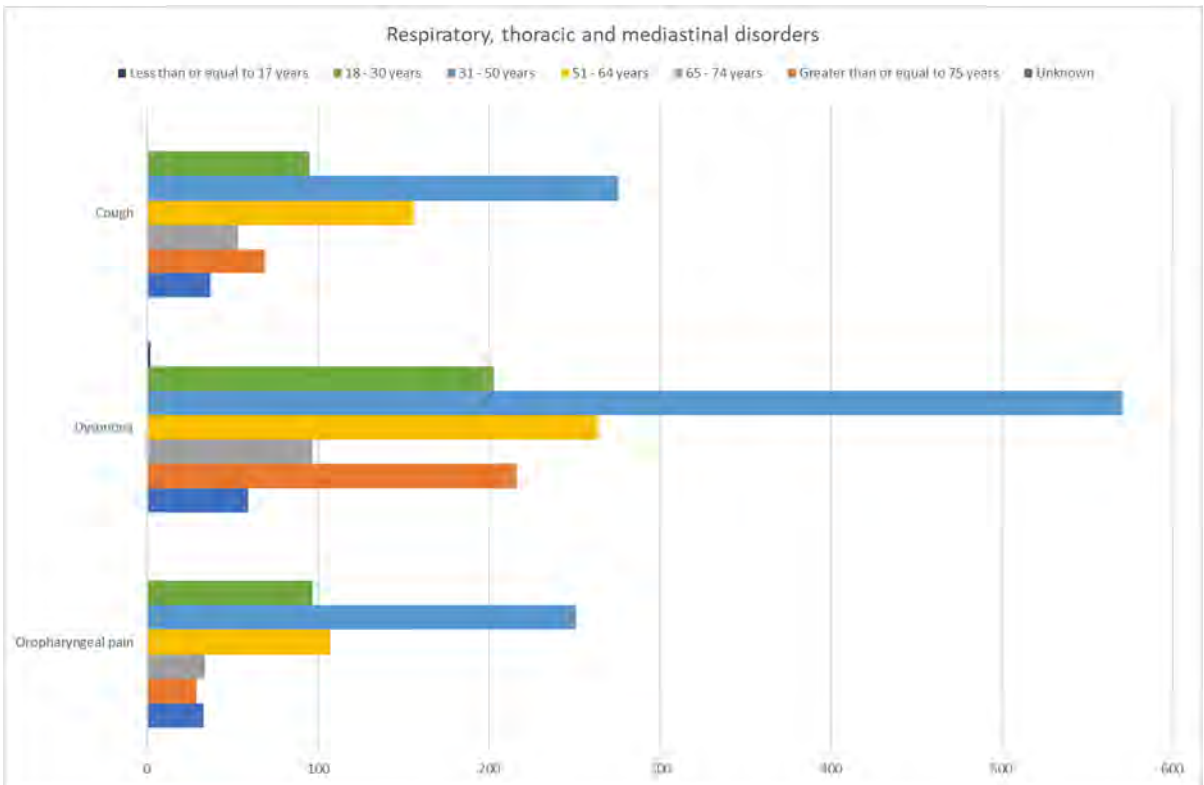
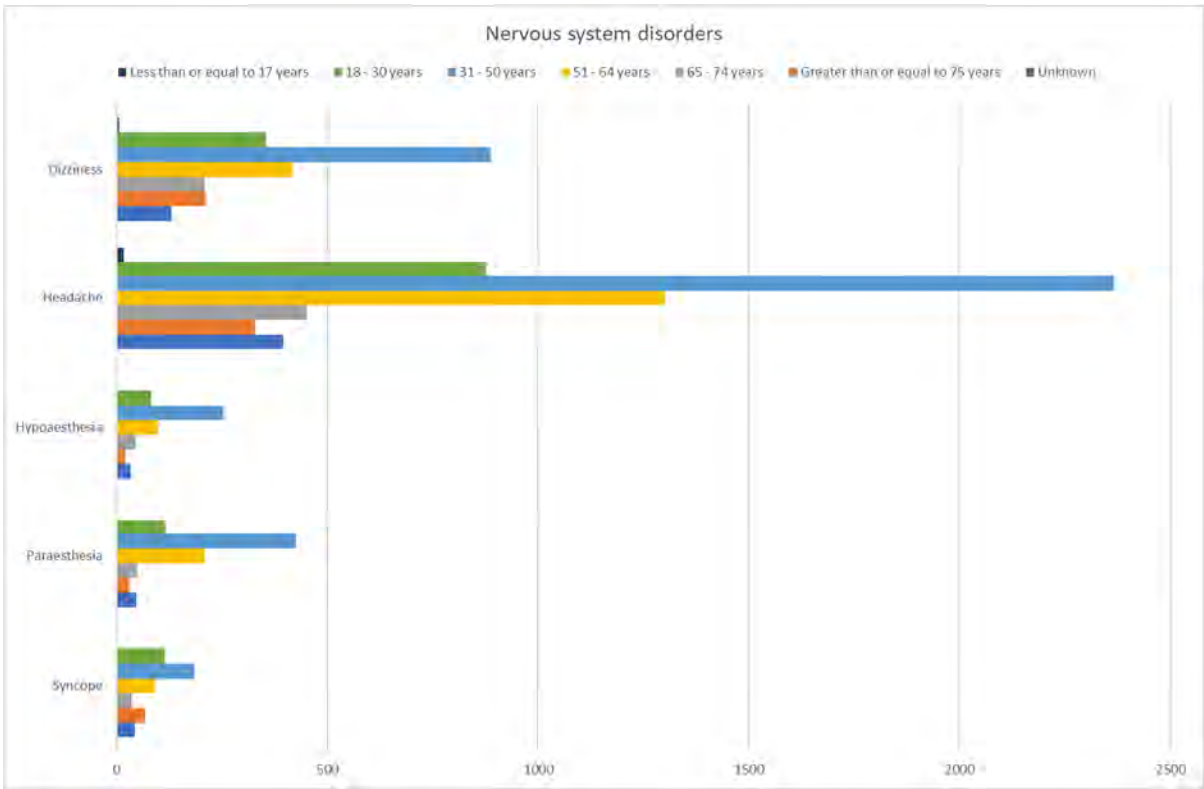
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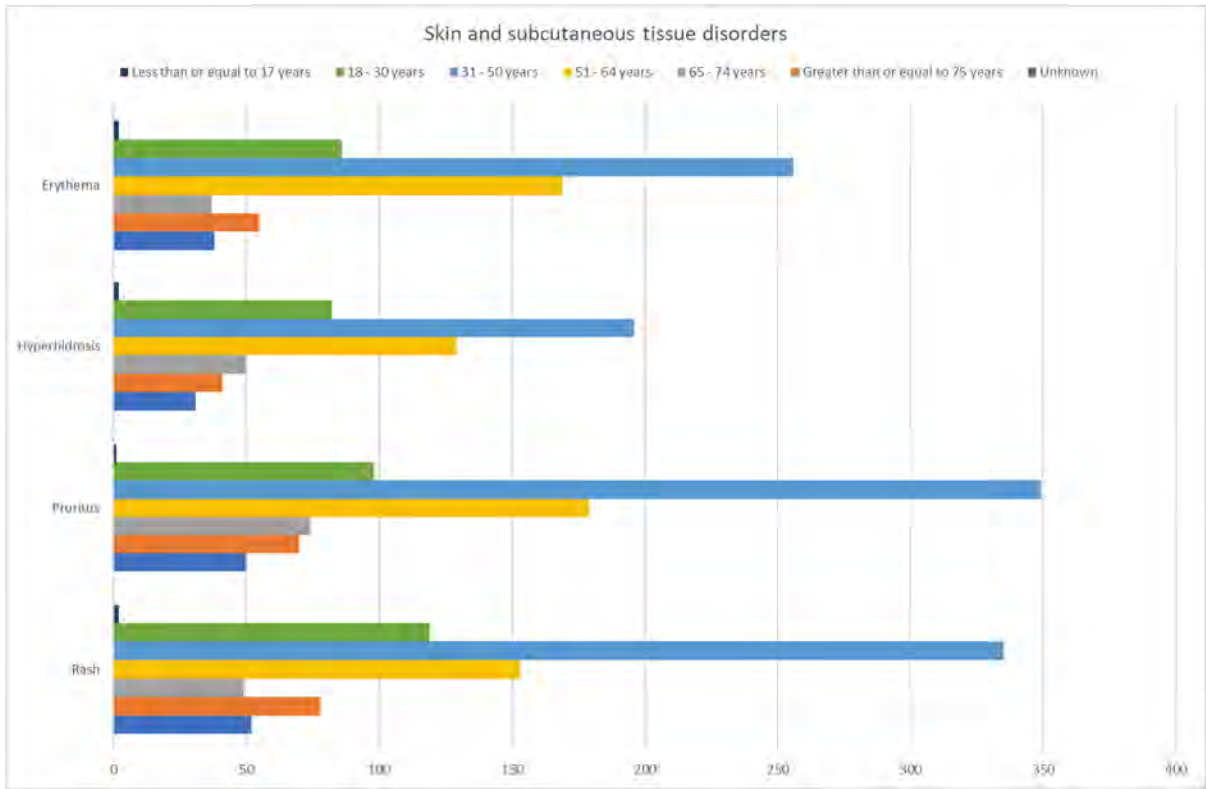
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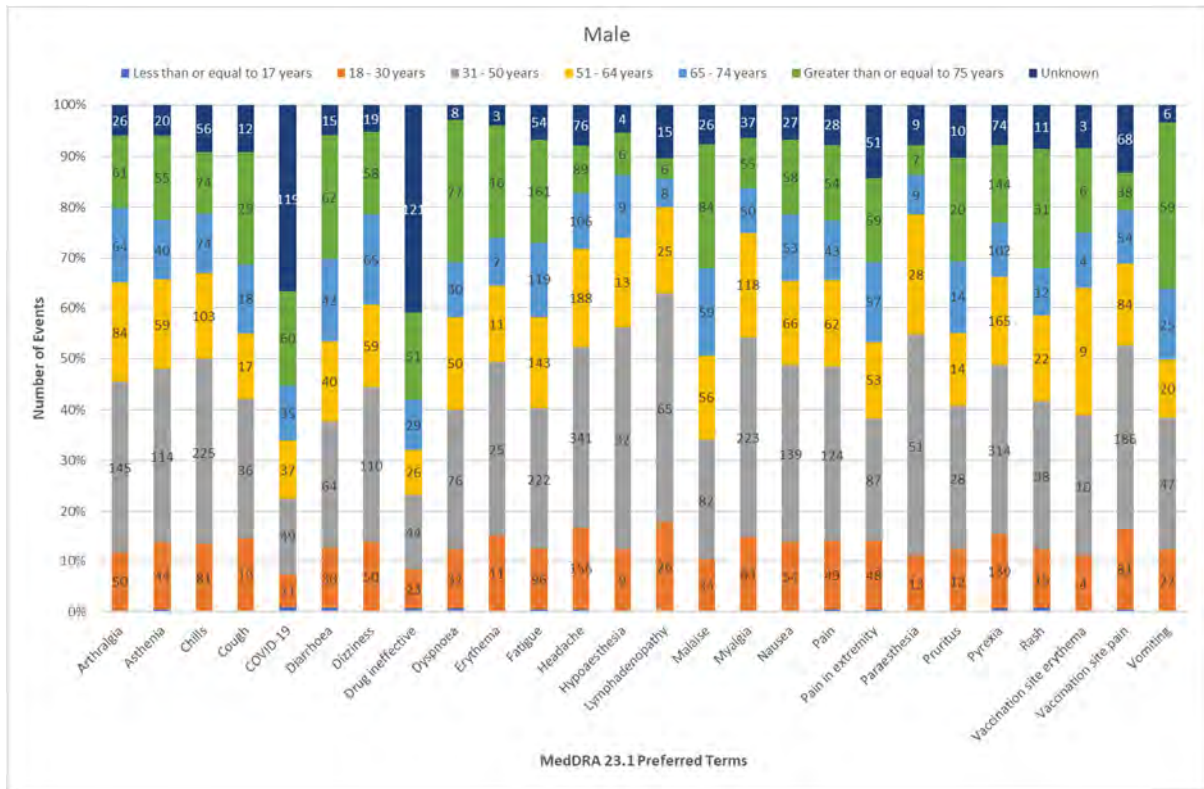
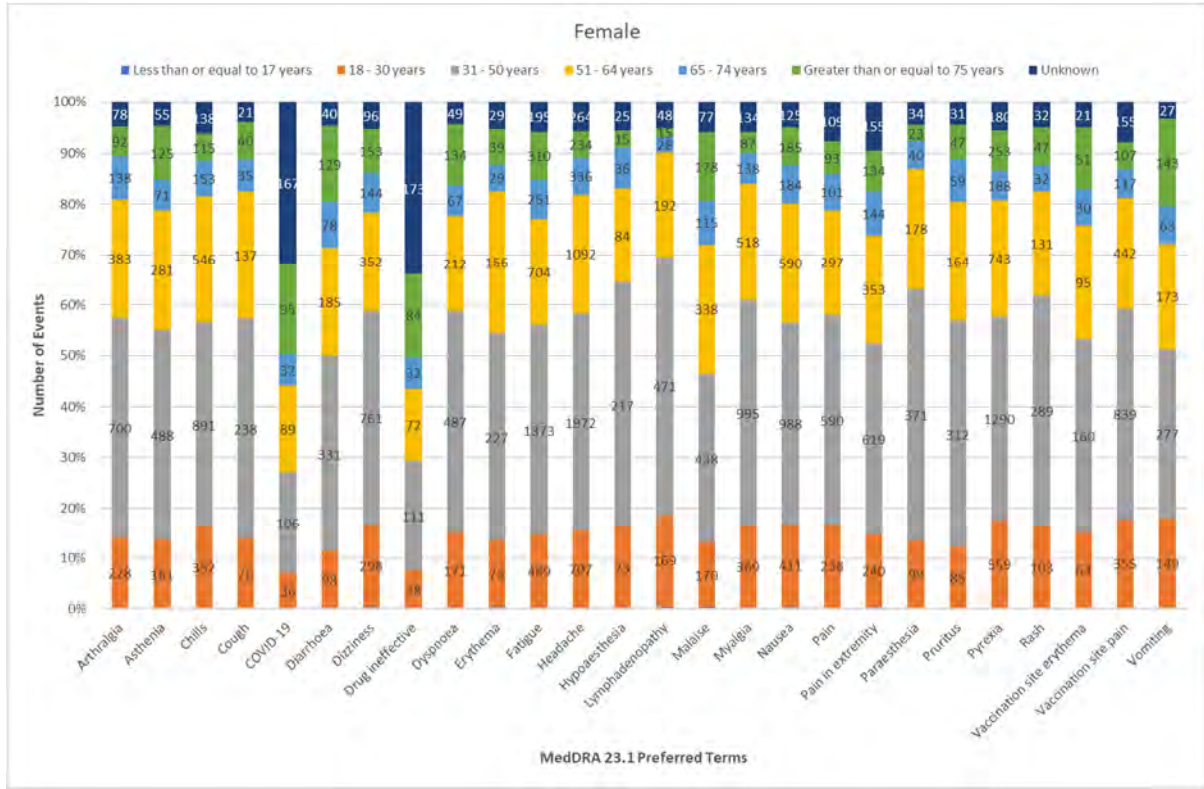


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Figure 7. Events Reported in $\geq 2\%$ in the Interval Period by Age Group within Gender



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As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1) received on the second SMSR, the MAH was requested to discuss the findings regarding side effects (particularly fever and muscle ache) reported more frequent and severe:

- a. *following the 1st dose;*
- b. *following the 2nd dose;*

in vaccinees that previously had a (PCR confirmed) COVID-19 infection, including any implications for the product information.

MAH Response

The available data on subjects in the Phase 2/3 portion of Study C4591001 with evidence of prior infection with SARS-CoV-2 as determined by NAAT or N-binding assay (at Visit 1) suggest no clinically meaningful difference with regard to clinical profile of the reported events. Out of a total safety population of approximately 44,000 subjects of both arms at the time of the analyses (14 November 2020), 545 BNT162b2-vaccinated subjects and 580 placebo recipients, were identified as baseline SARS-CoV-2 positive at Visit 1 and had safety data available for analysis.

Overall, there were no meaningful differences in the incidences or severity of reactogenicity, or incidences of AEs or SAEs between the baseline positive and negative subject groups. For any systemic reactions across all the measured reactions and doses, in the same reactogenicity baseline SARS-CoV-2 status subsets, 70.1% compared to 77.7% reported at least 1 systemic event in those positive or negative at baseline, respectively.

In participants positive at baseline for SARS-CoV-2, the reactogenicity reported at the first dose was generally higher than after the second dose. Fever was reported in 12.3% and 7.5% after Dose 1 and Dose 2, respectively, and muscle pain was reported 29.9% and 27.8% after Dose 1 and Dose 2, respectively. Overall, the rate of reactogenicity for each event measured was comparable to the rates for those negative at baseline for SARS-CoV-2. For example, muscle pain after any dose in baseline SARS-CoV-2 positive participants was 39.6% compared to 38.2% in individuals negative for SARS-CoV-2 at baseline, while fever after any dose in baseline SARS-CoV-2 positive participants was 16.9% as compared to 14.1% in baseline negative participants. Hence, for systemic events the rate of reactogenicity was higher after Dose 1 than Dose 2, but the overall rate was similar to the reactogenicity rates observed in participants negative for SARS-CoV-2.

With regard to the AE profile, among the safety data of ~38,000 participants³³ with AEs collected from Dose 1 to 1 month after Dose 2 and for which a median of 2 months of follow-up after Dose 2 was conducted, the frequency of AEs were 22.0% and 27.1% in those who were positive (n=545 BNT162b2, n=580 placebo) and negative (n=17,841 BNT162b2, n=17,808 placebo) at baseline, respectively. Of the AEs reported, 16.5% and 21.0% were related AEs in those positive and negative at baseline, respectively. Most of these events

³³ Population that met the requirement for the US EUA.

were local and systemic reactogenicity. SAEs were reported in 4 participants (0.7%) in the BNT162b2 recipients positive at baseline compared to 97 participants (0.5%) in participants negative at baseline.

The safety profile (ie, reactogenicity and AEs) did not show a clinically meaningful difference on the basis of baseline SARS-CoV-2 status and did not suggest any clinical concern about BNT162b2 vaccination in individuals previously exposed to SARS-CoV-2. As demonstrated by the data included in the MAA, overall Dose 2 had a higher frequency of systemic reactogenicity across all participants. Based on this analysis, the MAH did not recommend an update to the EU SmPC.

9. SIGNAL AND RISK EVALUATION

9.1. Literature Review

Please refer to [Appendix 6](#) for a summary description of the interval literature review that is performed for the purpose of signal detection. There were no literature articles identifying new safety topics that would represent signals for BNT162b2 during the reporting interval.

9.2. Overview of Signals During the Reporting Interval

Signals addressed during the reporting interval are presented below in Table 7.

Table 7. Overview of Signals

| Signal | Status | Category |
|----------------------------------|---------|---------------------------------|
| Vomiting | Closed | Identified Risk (Not Important) |
| Diarrhoea | Closed | Identified Risk (Not Important) |
| Eye pain/Eye swelling | Closed | No Risk |
| Delayed Syncope | Closed | No Risk |
| Hearing Loss and Tinnitus | Closed | No Risk |
| Immune thrombocytopenia | Closed | No Risk |
| Dizziness | Ongoing | Under evaluation |
| Facial paralysis | Ongoing | Under evaluation |
| Paraesthesia | Ongoing | Under evaluation |
| Herpes Zoster | Ongoing | Under evaluation |
| Tachycardia | Ongoing | Under evaluation |
| Vaccine stress-related responses | Ongoing | Under evaluation |

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

As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1) received on the second SMSR, the following cumulative overviews were performed for:

- Safety evaluation of Immune thrombocytopenia ([Appendix 3.2](#));
- Safety evaluation of Hearing loss and Tinnitus ([Appendix 3.3](#));
- Safety evaluation of Insomnia with discussion on duration ([Appendix 3.4](#));
- Safety evaluation of Dizziness ([Appendix 3.5](#));
- Safety evaluation of Guillain-Barré syndrome ([Appendix 3.6](#)).

9.3. Summary of Safety Concerns

Table 8 summarises the comprehensive list of important risks and missing information reflected in risk management and pharmacovigilance plans globally for BNT162b2 at the beginning of the reporting period. The pharmacovigilance and risk management activities implemented for the safety concerns by Pfizer on behalf of BioNTech are global.

Table 8. Safety Concerns

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

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

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

Please refer to [Appendix 5](#) for the list of the company’s AESIs for BNT162b2. Please refer to [Appendix 5.1](#) for the observed versus expected analysis for AESIs.^{34,35}

The company’s AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

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

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

9.5. Evaluation of Safety Concerns

Evaluation of new information collected from post-marketing data sources⁷ for BNT162b2 during the interval reporting period for important identified and important potential risks, AESIs, special situations and missing information is provided below in Section 9.5.1, [Section 9.5.2](#), [Section 9.5.3](#) and [Section 9.5.4](#).

9.5.1. Evaluation of Important Identified and Important Potential Risks

Table 9 below presents the evaluation of new information received during the interval reporting period from post-marketing data sources⁷ for the important identified and important potential risks of BNT162b2.

Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|---|--|
| Important Identified Risk | |
| Anaphylaxis ^c <i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria</i> | Number of cases from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm based on all terms in the SMQ: 1156 ³⁶ (4.9% compared to 3.4% of the total PM dataset of the previous SMSR), of which 907 were medically confirmed and 249 were non-medically confirmed; <ul style="list-style-type: none"> Number of events: 2868; |

³⁴ It should be noted that for the O/E analyses, the numbers of doses of vaccine administered had been estimated based on publicly available data from health authorities in various regions.

³⁵ As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1) sSpecific O/E analysis for arrhythmias, deafness, hypertension, tinnitus, sudden hearing loss were also included in [Appendix 5.1](#).

³⁶ One additional case was made invalid after the DLP due to lack of minimum valid criteria to process the case.

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Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) | | | | | | | | | | | | | | |
|------------------------------|--|------------------------------|-----------------|------|-----|------|-----|------|---|------|-----|------|-----|--------------|-------------|
| | <ul style="list-style-type: none"> • Country of incidence (>2%): UK (257), Mexico (138), US (135), Italy (105), Germany (103), France (51), Spain (49), Greece (35), Sweden (28), Austria and Portugal (25 each); • Subjects' gender: female (976), male (150) and unknown (30); • Subjects' age (n = 1100): ranged from 4 years (2 subjects) to 100 years (mean = 48.1 years, median = 46 years); • Most frequently reported individual PTs (≥2%): Dyspnoea (365), Anaphylactic reaction (360), Rash (189), Pruritus (172), Erythema (145), Cough (126), Respiratory distress (124), Urticaria (100), Hypotension (78), Swollen tongue (74), Swelling face (72), Anaphylactic shock (71), Lip swelling (69), Chest discomfort (66), Oedema (64), Flushing (56), Throat tightness (49), Pharyngeal swelling (48), Circulatory collapse (45), Swelling (40), Angioedema and Wheezing (38 each) and Bronchospasm (35), Blood pressure decreased (28), Type I hypersensitivity (27), Tongue oedema (25) and Face oedema (24); • Relevant event seriousness: serious (2203), non-serious (665); • Relevant event outcome:^d fatal (46), resolved/resolving (1741), resolved with sequelae (30), not resolved (203), unknown (857). <p>Cases (1156) were individually reviewed and assessed according to Brighton Collaboration (BC) case definition and level of diagnostic certainty as shown in the Table below.</p> <table border="1" data-bbox="662 1066 1412 1289"> <thead> <tr> <th>Brighton Collaboration Level</th> <th>Number of cases</th> </tr> </thead> <tbody> <tr> <td>BC 1</td> <td>212</td> </tr> <tr> <td>BC 2</td> <td>225</td> </tr> <tr> <td>BC 3</td> <td>7</td> </tr> <tr> <td>BC 4</td> <td>296</td> </tr> <tr> <td>BC 5</td> <td>416</td> </tr> <tr> <td><i>Total</i></td> <td><i>1156</i></td> </tr> </tbody> </table> <p>Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis, with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.</p> <p><u>BC Level 1 and 2 cases:</u> <u>Number of cases:</u> 437 (1467 events of interest) <u>Medical history</u> (n=239): the most frequently (≥2%) reported medical conditions included Hypersensitivity (51), Asthma (46), Food allergy (44), Drug hypersensitivity (40), Hypertension (22), Anaphylactic reaction (17), Seasonal allergy (16), Allergy to animal and COVID-19 (10 each) and Urticaria (9). <u>Number of vaccine doses</u> administered at the time of the event onset: 1 dose in 248 cases, 2 doses in 51 cases and number of doses was not specified in 138 cases. <u>Relevant PTs</u> (>2%): Dyspnoea (215), Rash (130), Erythema (103), Pruritus (102), Anaphylactic reaction (87), Respiratory distress (78), Urticaria (68), Cough (56), Hypotension (52), Swelling face (43), Swollen tongue (40), Throat tightness (33), Oedema (32), Pharyngeal</p> | Brighton Collaboration Level | Number of cases | BC 1 | 212 | BC 2 | 225 | BC 3 | 7 | BC 4 | 296 | BC 5 | 416 | <i>Total</i> | <i>1156</i> |
| Brighton Collaboration Level | Number of cases | | | | | | | | | | | | | | |
| BC 1 | 212 | | | | | | | | | | | | | | |
| BC 2 | 225 | | | | | | | | | | | | | | |
| BC 3 | 7 | | | | | | | | | | | | | | |
| BC 4 | 296 | | | | | | | | | | | | | | |
| BC 5 | 416 | | | | | | | | | | | | | | |
| <i>Total</i> | <i>1156</i> | | | | | | | | | | | | | | |

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Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------------|---|
| | <p>swelling (31), Lip swelling (30), Wheezing (29), Angioedema and Bronchospasm (27 each), Chest discomfort (24), Blood pressure decreased (20), Swelling (18), Anaphylactic shock (17), Flushing and Tongue oedema (15 each), Laryngeal oedema (14), Face oedema (13), Mouth swelling and Stridor (11 each), Rash pruritic (10), Sensation of foreign body and Type I hypersensitivity (9 each). <u>Relevant event outcome</u>: fatal (6), resolved/resolving (874), resolved with sequelae (9), not resolved (84), unknown (497).</p> <p><i>Fatal cases: 2</i></p> <ol style="list-style-type: none"> Country: US; Subject's gender and age: female subject aged 58 years; Medical history: hypersensitivity to penicillin, hypertension, obesity, sleep apnoea syndrome and type 2 diabetes mellitus; Vaccine dose: 1 Lot Number: EL9263 Event onset date: Day 0; (1 hour after receiving the vaccine); PTs: Acute pulmonary oedema, Anaphylactic reaction, Vomiting, Dyspnoea, Flushing and Illness. Acute pulmonary oedema and Anaphylactic reaction are reported with fatal outcome. Treatments: diphenhydramine hydrochloride, epinephrine, oxygen and cardiopulmonary resuscitation was performed. Autopsy: not performed. Country: Belgium Subject's age and gender: female subject aged 69 years; Medical history: Appendicitis, Cholecystectomy, Dementia with Lewy bodies; Urinary incontinence, Urinary tract infection and Vertigo positional Concomitant medications: enoxaparin, donepezil, benserazide/levodopa, melatonin, ascorbic acid/ ferrous sulfate, estriol and pantoprazole/sesquihydrate Vaccine dose: 1 Lot number: EM0477 Event onset date: Day 0 (1 hour after receiving the vaccine); PTs: Dyspnoea, Hypotension, Malaise, Anaphylactic reaction, COVID-19 pneumonia, Acute respiratory failure and Cardio-respiratory arrest. All events reported a fatal outcome. Treatments: adrenaline Autopsy: not specified if it was performed. <p>Discussion Anaphylaxis is an adverse reaction in Section 4.8 of the EU SmPC, in the CDS and local labels/fact sheets. It is also included as an Important identified risk in the EU RMP and in the US PVP.^c Based upon review of the available information, no additional change to the RSI is warranted at this time.</p> <p>On 08 February 2021, a cumulative review of all cases reporting serious hypersensitivity reactions suggestive of anaphylaxis using the Brighton Collaboration criteria and inclusive of Observed versus</p> |

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Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|---|--|
| | <p>Expected analysis was submitted to EMA in a LEG procedure as per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002) received on the first SMSR. Following EMA feedback, the response to the Post-Authorisation Measure LEG-022 Assessment will be submitted in conjunction with the current SMSR.</p> <p>Conclusion: Evaluation of BC cases Level 1 and 2 as well as 3 and 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</p> |
| Important Potential Risk | |
| <p>Vaccine-Associated Enhanced Disease (VAED) Including Vaccine-Associated Enhanced Respiratory Disease (VAERD)^{b,c}</p> | <p>VAED is a modified and/or severe presentation of an infectious disease affecting individuals exposed to the wild-type pathogen after having received vaccine designed to prevent infection.³⁷</p> <p>As noted by the Brighton Collaboration, there is currently no uniformly accepted definition of VAED (or VAERD) and the BC working group considers that a definitive case of VAED (Level 1 diagnostic certainty) cannot be ascertained with current knowledge of the mechanisms of pathogenesis of the condition; they have provided guidance on levels of diagnostic certainty of VAED cases based on various laboratory and clinical findings.</p> <p>No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue.</p> <p>The search criteria utilised to identify potential cases of VAED for this SMSR includes PTs indicating a lack of effect of the vaccine and medical disorders chosen because they are PTs potentially indicative of severe or atypical COVID-19.</p> <p>Overview</p> <ul style="list-style-type: none"> • Number of cases based on search strategy: 73 (0.3% of the total PM dataset, compared to 0.4% of the previous reporting period), all serious (of which 44 are medically confirmed)^h; • Country of incidence: UK (38), US (8), Germany (7), France, Spain (4 each), Italy (3), Denmark (2); the remaining 7 cases originated from 7 different countries. • Gender: female (40), males (26), unknown (7). |

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

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Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------------|---|
| | <ul style="list-style-type: none"> • Age: 23 to 100 years (n = 71), mean = 63.8, median = 68.0; • Respiratory system PTs: Dyspnoea (23), COVID-19 pneumonia (15), Respiratory failure (5), Hypoxia, Pulmonary embolism, (3 each), Tachypnoea (1). • Gastrointestinal system PTs: Diarrhoea (14), Vomiting (11), Abdominal pain (2); • Nervous system PTs: Seizure (6), Encephalopathy (1); • Other systems, relevant PTs: Arrhythmia, Cardiac failure, Acute kidney injury, Renal failure, Thrombocytopenia, Shock (1 each). • Case outcome: fatal (20), not resolved (34), resolved/resolving (14), unknown at the time of the reporting (4), resolved with sequelae (1). <p>COVID-19 positivity and severity of events</p> <ul style="list-style-type: none"> • Suspected COVID-19 infection (test not performed or negative or inconclusive): 21. • Confirmed COVID-19 infection: 52 (test positive). • Seriousness criteria for the total 73 cases: <ul style="list-style-type: none"> ○ Medically significant: 34 (of which 5 serious also for disability); ○ Hospitalization required (non-fatal/non-life threatening): 11; ○ Life threatening: 8; ○ Death: 20 (All subjects had COVID-19 test positive). <p>Seriousness criteria: medically significant (34)</p> <ul style="list-style-type: none"> • In 15, out of 34 cases where the seriousness criteria was “medically significant”, it was reported that the subjects had a COVID-19 positive test after vaccination, while 19 subjects had unconfirmed suspected COVID-19. These 34 subjects did not require hospitalization. • Age: 25 to 96 (n=15), Mean=56.3, Median=51. <p>Among the 15 COVID-19 positive subjects:</p> <ul style="list-style-type: none"> • 3 received the 1st vaccine dose. Latency to COVID-19 was 15, 16 and 50 days respectively. ○ 5 received the 1st and the 2nd vaccine doses. Latency to COVID-19 ranged from 1 to 15 days; in 1 case the subject tested positive for COVID-19 on the same day of the 2nd dose administration and 19 days after the 1st dose ○ 7 cases did not indicate the number of doses the subject had received. Latency to COVID 19 was reported for 6 subjects and ranged from 5 to 17 days post-vaccination. <p>The PTs reported more than twice in these 15 cases were: Drug ineffective (15), COVID-19 (13), Cough (7), Dyspnea, Pyrexia (6 each), Diarrhoea (5), Chest pain, Vomiting (4 each), Dizziness, Myalgia, SAR-CoV-2 test positive, and Tachycardia (2 each).</p> |

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Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------------|---|
| | <p>COVID-19 infection outcome: resolved/resolving (7), not resolved (4), unknown (4).</p> <p>Seriousness criteria: hospitalization (non-fatal, non-life threatening) (11)</p> <ul style="list-style-type: none"> Hospitalization occurred in 10 subjects, for 1 of them COVID-19 was not confirmed (inconclusive test). Age: 30 to 100 (n=9), Mean=63.9, Median=67: <p>Among the 10 COVID-19 positive subjects</p> <ul style="list-style-type: none"> 3 received the 1st vaccine dose. Latency to COVID-19 was reported for 1 subject (17 days). 2 received the 1st and the 2nd vaccine doses. Latency to COVID-19 was reported for 1 subject (10 days). 5 cases did not indicate the number of doses the subjects had received. Latency to COVID-19 was reported in all cases and ranged from 2 to 14 days post-vaccination. <p>The PTs reported more than twice in these 10 cases were: Drug ineffective (10), COVID-19 (8), Dyspnoea (4), Cough, COVID-19 pneumonia, Diarrhoea, Oxygen saturation decreased, Pneumonia (2 each).</p> <p>Covid-19 infection’s outcome: resolved/resolving (3), not resolved (3), unknown (4).</p> <p>Seriousness criteria: life threatening (8)</p> <ul style="list-style-type: none"> Hospitalization occurred in 3 of the 8 cases characterized as life-threatening; COVID-19 was suspected for 1 of the 8 subjects. Age: 52 to 88 (n=7), Mean=74.9, Median=81 <p>Among the 7 positive COVID-19 subjects:</p> <ul style="list-style-type: none"> 2 received the 1st vaccine dose. Latency to COVID-19 was reported for 1 subject (18 days). 1 received the 1st and the 2nd vaccine doses. Latency to COVID-19 unknown. 4 cases did not indicate the number of doses the subjects had received. Latency to COVID-19 was reported in 3 cases and ranged from 5 to 17 days post-vaccination. <p>The PTs reported more than twice in these 8 cases were: Drug ineffective (8), COVID-19 (5), COVID-19 pneumonia (4), Dyspnoea (2); Suspected COVID-19 (1) was the other term associated to the LOE PT.</p> <p>COVID-19 infection outcome: not resolved (6), resolved with sequelae (1), and unknown (Suspected COVID-19).</p> <p>Seriousness criteria: death (20)</p> <ul style="list-style-type: none"> Twenty (20) subjects died, all had a COVID-19 positive test after vaccination: |

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Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------------|---|
| | <ul style="list-style-type: none"> ○ Age: 63 to 92 years (n = 20), mean = 84.2, median = 85. ○ Countries of incidence: UK (5), Germany (4), Denmark, France, Spain, and US (2 each), Belgium, Czech Republic, and Italy (1 each). ○ Gender: female (9), male (11). ○ Medical history (n=16) of clinical significance included PTs in the following SOCs: <ul style="list-style-type: none"> ▪ Nervous system disorders: 11 (55.0%) [Cerebral infarction, Cerebrovascular accident, Cognitive disorder, Dementia, Dementia Alzheimer’s type (2 each), Cerebral thrombosis, Facial paralysis, Ischaemic stroke, Parkinson's disease, Vascular dementia (1 each)]; ▪ Cardiac disorders: 9 (45.0%) [Atrial fibrillation (5), Cardiac failure (2) Acute myocardial infarction, Angina pectoris, Bundle branch block left, Cardiomyopathy, Cardiovascular disorder, Coronary artery disease, Myocardial infarction (1 each)]; ▪ Metabolism and nutrition disorders: 9 (45.0%) [Type 2 diabetes mellitus (5), Diabetes mellitus (3), Dyslipidemia (2), Hypercalcemia, Insulin-requiring type 2 diabetes mellitus, Vitamin B12 deficiency (1 each)]; ▪ Renal and urinary disorders: 7 (35.0%) [Chronic kidney disease (5), Renal impairment (2 each), Renal cyst (1); ▪ Vascular disorders: 7 (35%) [Hypertension (7), Deep vein thrombosis (1); ● Latency of COVID-19 occurrence was reported for all cases and ranged from 2 to 41 days after vaccination: <ul style="list-style-type: none"> ○ 14 to 25 days after dose 1 (12); ○ 8 to 14 days after dose 2 (2); ○ 10 days after dose 2 (1); ○ 2 to 41 days after vaccination (dose number not reported) (6). ● Cause of death (n=20) reported more than once were: Drug ineffective (9), COVID-19 , COVID-19 pneumonia (8 each), Respiratory failure (4), Acute respiratory failure, Confusional state, Dyspnoea, Oxygen saturation decreased, Pulmonary embolism (2 each). <p>In 2 fatal cases, vaccination failure was reported (cross ref. with Section 9.5.3 – Lack of efficacy):</p> <ul style="list-style-type: none"> ● A 63-year-old female subject, with type 2 diabetes, arterial hypertension, chronic renal failure and recent closed fracture of multiple cervical vertebrae, was admitted to intensive care unit for acute respiratory failure (onset of symptoms 5 days before) caused by untyped bacterial pneumonia; on the same day, 14 days after the 2nd vaccine dose, she had a positive SAR-CoV-2 PCR rapid test; however, chest X-Ray was not |

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Table 9. Risks Evaluation for BNT162b2

| Safety Risk | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------------|--|
| | <p>suggestive of COVID-19 pneumonia; she died within 24 hours due to septic shock and multi-organ failure. Vaccination failure was coded in this case due to coding convention criteria.</p> <ul style="list-style-type: none"> An 85-year-old female subject, with unspecified thyroid disorder and on psychotropic drugs for unspecified diagnosis and food supplements, developed vomiting and “aggravated food intake”, 7 days after the 2nd dose. She was transferred to the hospital, where she was diagnosed with massive pulmonary embolism with saturation 50%; the day after, she had a positive PCR COVID-19 test and she died on the same day. Pulmonary embolism in this COVID-19 positive subject may be due to COVID-19 or to an unspecified or unknown underlying medical condition. <p>VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 52 subjects with test-confirmed COVID-19 following one or both doses of the vaccine. 33 of the 52 cases were severe, resulting in hospitalization or death. None of the 52 cases could be definitively considered as having VAED/VAERD.</p> <p>Conclusion: In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine Surveillance will continue.</p> |

- Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- As per both the EU RMP Version 1.0, dated 21 December 2020 and the US PVP, Version 0.3, dated 20 January 2021;
- Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children;
- Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events.
- As per the EU RMP Version 1.0, dated 21 December 2020; the US PVP was updated during the reporting period with the finalization of the US PVP, Version 0.3, dated 20 January 2021, to include Anaphylaxis as an Important identified risk.
- Subjects with age ranged between 18 and 64 years;
- Subjects with age equal to or above 65 years.
- Note that 24 additional cases, retrieved with this search strategy, have been excluded from the discussion because, upon review, they cannot be considered true lack of efficacy cases: 23 cases, where the PT Drug ineffective was coded, reported that the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 1 case the PT Drug ineffective has been removed after DLP because the subject experienced COVID-19 like symptoms but the COVID-19 test (PCR) was negative.

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9.5.2. Evaluation of AESIs

Table 10 below presents the evaluation of new information received during the interval reporting period from post-marketing data sources⁷ with regard to the AESIs for BNT162b2. Where applicable, observed versus expected analysis is provided in [Appendix 5.1](#).

Table 10. AESIs Evaluation for BNT162b2

| AESIs^a Category | Post-Marketing Cases Evaluation^b Total Number of Cases in the Reporting Period (N=23558) |
|--|--|
| Anaphylactic Reactions <i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria</i> | Please refer to the Risk 'Anaphylaxis' in Table 9 . |
| Cardiovascular AESIs <i>Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia</i> | <ul style="list-style-type: none"> • Number of cases: 924 (3.9% of the total PM dataset, compared to 2.4% in the previous reporting period), of which 768 are medically confirmed and 156 are non-medically confirmed; • Country of incidence: Mexico (185), UK (128), France (121), Italy (109), Germany (65), US (56), Spain (43), Greece (33), Portugal (32), Ireland (17), Sweden (15), Poland (13), Netherlands (11), Austria and Finland (10 each), Belgium (9), Czech Republic, Hungary and Norway (8 each), Croatia and Romania (7 each), Latvia (4), Canada, Denmark and Israel (3 each); the remaining 16 cases were distributed among 12 other countries; • Subjects' gender: female (717), male (193) and unknown (14); • Subjects' age (n = 886): ranged from 17 to 102 years (mean = 50.4 years, median = 47 years); • Subjects' age group (n = 894): Adult^c (703), Elderly^d (190) and Adolescent^e (1); • Number of relevant events: 956, of which 677 serious, 279 non-serious; in the cases reporting relevant serious events, subject's age ranges from 17 to 102 years (mean = 54.5 years, median = 49.5 years); • Reported relevant PTs: Tachycardia (713), Arrhythmia* (83), Cardiac failure* (61), Myocardial infarction* (55), Acute myocardial infarction* (19), Cardiac failure acute* (10), Cardiogenic shock* and Postural orthostatic tachycardia syndrome* (6 each) and Coronary artery disease* (3); • Relevant event onset latency (n = 826): Range from <24 hours to 21 days, median <24 hours; • Relevant event outcome:^f fatal (83), resolved/resolving (515), resolved with sequelae (11), not resolved (89) and unknown (260); • In 73 cases out of 924 cases (involving 41 female and 32 male subjects with ages ranged from 35 to 97 years, mean 76.8 years, median 81 years), 34 of which had fatal outcome, the subject's medical history was significant for the specific events of Cardiac failure (34), Myocardial infarction (17), Coronary artery disease (11), Arrhythmia (9), Tachycardia (4), Acute myocardial infarction and Postural orthostatic tachycardia syndrome (3 each), |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|---|--|
| | <p>Cardiogenic shock and Stress cardiomyopathy (1 each). More than 1 relevant medical history event was reported in 9 cases;</p> <ul style="list-style-type: none"> • Additionally, in 94 out of 924 cases, the subject’s medical history was significant for other cardiac disorders, with the following conditions reported most frequently (>2 cases): Atrial fibrillation (40), Myocardial ischaemia (14), Cardiovascular disorder (6), Angina pectoris (5), Hypertensive heart disease (4), Cardiac disorder, Palpitations and Supraventricular tachycardia (3 each); • In 65 out of 924 cases, the subjects’ medical history was significant for COVID-19 or suspected COVID-19. <p>* Observed/Expected analysis was performed for Acute myocardial infarction/Myocardial infarction, Arrhythmia, Cardiac failure/Cardiac failure acute, Cardiogenic shock, Coronary Artery disease and Postural orthostatic tachycardia syndrome (see Appendix 5.1).</p> <p>Conclusion: Tachycardia is an ongoing signal (see Appendix 3 and Appendix 3.1). No other cardiovascular signals have emerged from the review of post-authorisation data. The review of cases and O/E analysis do not raise new concerns. Surveillance will continue.</p> |
| <p>COVID-19 AESIs <i>Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmiaⁱ</i></p> | <ul style="list-style-type: none"> • Number of cases: 1630 (6.9% of the total PM dataset, compared to 7.6% in the previous reporting period), of which 1067 are medically confirmed and 563 are non-medically confirmed; • Country of incidence: US (412), UK (323), Germany (233), France (153), Italy (76), Spain (62), Romania (41), Belgium (37), Poland (35), Mexico and Portugal (32 each), Sweden (29), Austria (25), Greece (23), Israel (22), Denmark (17), Czech Republic (14), Hungary (13), Ireland (11), Canada (5), Netherlands, Switzerland and United Arab Emirates (4 each), Costa Rica, Slovakia and Slovenia (3 each); the remaining 14 cases were distributed among 10 other different countries; • Subjects’ gender: female (874), male (468) and unknown (288); • Subjects’ age group (n= 1039): Adult^c (645), Elderly^d (390), Infant^g (2), Adolescent^e and Child^h (1 each); • Number of relevant events: 1760, of which 1325 serious, 435 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1092), Suspected COVID-19 (142), Ageusia* and SARS-CoV-2 test positive (114 each), Anosmia* (91), SARS-CoV-2 antibody test negative (67), COVID-19 pneumonia and SARS-CoV-2 antibody test positive (38 each), Asymptomatic COVID-19 (22), Exposure to SARS-CoV-2 (18), Coronavirus infection (10), Coronavirus test positive (4), Occupational exposure to SARS-CoV-2 (3), SARS-CoV-2 antibody test and SARS-CoV-2 test negative (2 each); • Relevant event onset latency (n = 1115): Range from <24 hours to 50 days, median 6 days; • Relevant event outcome: fatal (98), not resolved (312), resolved/resolving (333), resolved with sequelae (4) and unknown (1014). |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|--|--|
| | <p>* Observed/Expected analysis was performed for Ageusia and Anosmia (see Appendix 5.1).</p> <p>Conclusion: No safety signals have emerged based on a review of these cases, however the lower level of the confidence interval exceeds 1 for the cumulative and interval risk periods in the Observed versus Expected analysis. Anosmia and ageusia will be reviewed and discussed in the next SMSR.</p> |
| <p>Dermatological AESIs <i>Search criteria: PT Chillblains; Erythema multiformeⁱ</i></p> | <ul style="list-style-type: none"> • Number of cases: 15 cases (0.06% of the total PM dataset, compared to 0.01% in the previous reporting period), of which 12 are medically confirmed and 3 are non-medically confirmed; • Country of incidence: UK (5), France and Poland (2 each), and the remaining 6 cases were distributed among 6 other different countries; • Subjects' gender: female (14) and unknown (1); • Subjects' age group (n=15): Adult^c (14), Elderly^d (1); • Number of relevant events: 15 events, 13 serious, 2 non-serious • Reported relevant PTs: Erythema multiforme* (11) and Chillblains* (4) • Relevant event onset latency (n = 14): Range from <24 hours to 17 days, median 4 days; • Relevant event outcome: resolved/resolving (6), not resolved and unknown (5 each). <p>* Observed/Expected analysis was performed for Chillblains and Erythema multiforme (see Appendix 5.1).</p> <p>Conclusion: No safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue</p> |
| <p>Haematological AESIs <i>Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia,^j Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms^k</i></p> | <ul style="list-style-type: none"> • Number of cases: 612 (2.6% of the total PM dataset),^k of which 330 medically confirmed and 282 non-medically confirmed; • Country of incidence: UK (229), US (149), France (45), Italy (35), Germany (30), Spain (23), Mexico (12), Poland (9), Netherlands (8), Ireland, Portugal and Sweden (7 each), Denmark and Finland (6 each), Austria, Israel and Norway (5 each), Croatia (4), Greece (3), Belgium, Cyprus, Hungary and Latvia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=592): female (442) and male (150); • Subjects' age group (n=555): Adult^c (339), Elderly^d (216); • Number of relevant events: 721, of which 519 serious, 202 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (75), Contusion (71), Vaccination site bruising (46), Haemorrhage* (34), Petechiae (33), Vaccination site haemorrhage (31), Haematochezia and Vaccination site haematoma (26 each), Conjunctival haemorrhage and Thrombocytopenia* (24 each), Haematoma (20), Menorrhagia (19), Rectal haemorrhage (18), Immune thrombocytopenia* and Vaginal haemorrhage (17 each), Haematemesis, Haemoptysis and Neutropenia (15 each); |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|---|---|
| | <ul style="list-style-type: none"> • Relevant event onset latency (n = 534): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome:^f fatal (16), resolved/resolving (268), resolved with sequelae (14), not resolved (174) and unknown (251). <p>As per EMA PRAC assessment report received on the second SMSR, a cumulative overview of all cases reporting Immune thrombocytopenia/Thrombocytopenia, using Search strategy of HLT Thrombocytopenias and SMQ Haematopoietic thrombocytopenia (narrow and broad), was conducted and included in Appendix 3.2.</p> <p>* Observed/Expected analysis was performed for Haemorrhage, Immune thrombocytopenia and Thrombocytopenia (see Appendix 5.1).</p> <p>Conclusion: No other signals for the hematological AESIs have emerged based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue.</p> |
| <p>Hepatic AESIs <i>Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury</i></p> | <ul style="list-style-type: none"> • Number of cases: 52 cases (0.2% of the total PM dataset, compared to 0.1% of the previous reporting period), of which 38 medically confirmed and 14 non-medically confirmed; • Country of incidence: UK (11), US (9), France (7), Italy (5), Germany (4), Mexico and Spain (3 each), Austria, Belgium and Iceland (2 each) and Denmark, Greece, Ireland and Slovakia (1 each); • Subjects' gender: female (35), male (16) and unknown (1); • Subjects' age group (n=47): Adult^c (28), Elderly^d (19); • Number of relevant events: 69, of which 36 serious, 33 non-serious; • Reported relevant PTs: Alanine aminotransferase increased (11), Transaminases increased (8), Hepatic pain (7), Liver function test increased (6), Aspartate aminotransferase increased, Gamma-glutamyltransferase increased and Liver function test abnormal (5 each), Hepatic enzyme increased (4), Blood alkaline phosphatase increased, Blood bilirubin increased and Hypertransaminasaemia (3 each), Ascites and Liver injury* (2 each) and Deficiency of bile secretion, Hepatic function abnormal, Hepatomegaly, Hyperbilirubinaemia and Liver tenderness (1 each); • Relevant event onset latency (n = 46): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (2), resolved/resolving (15), resolved with sequelae (1), not resolved (11) and unknown (40). <p>* Observed/Expected analysis was performed for Liver injury (see Appendix 5.1).</p> <p>Conclusion: No safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue.</p> |
| <p>Facial Paralysis</p> | <p><i>As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1) received on the second SMSR, the</i></p> |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|---|--|
| <p><i>Search criteria: PTs Facial paralysis, Facial paresis</i></p> | <p><i>MAH was requested to thoroughly follow-up cases reporting facial paralysis including the outcome and if recovered the days till recovery to estimate the total duration of this ADR. Once a reliable estimate of duration is available from case reports, the MAH is requested to include information of duration of facial paralysis complaints in the product information. The MAH was also requested to indicate when the results of the assessments of the facial paralysis cases in the clinical study data will be available.</i></p> <p>A cumulative case series evaluation of this topic, with cases assessed according to BC case definition and criteria, was included in the second SMSR (reporting period 01-31 January 2021) and will be repeated as warranted.</p> <p>A review of the interval cases reported during the current reporting period follows.</p> <ul style="list-style-type: none"> • Number of cases: 323^l (1.4% of the total PM dataset, compared to 0.7% of previous reporting period), 228 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (83), US (65), Italy (37), France (27), Spain (17), Germany (11), Sweden (10), Ireland (9), Israel (8), Austria (7), Finland (6), Cyprus, Hungary and Portugal (5 each), Mexico (4), Canada and Croatia (3 each), Malta, Netherlands, Norway, Poland and Romania (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (209), male (103), unknown (11); • Subjects' age group (n=304): Adult^c (221), Elderly^d (82), Infant (1); ^{e,n} • Number of relevant events:^m 323, of which 319 serious, 4 non-serious; • Reported relevant PTs: Facial paralysis (283), Facial paresis (40); • Relevant event onset latency (n = 286): Range from <24 hours to 29 days, median 2 days; • Relevant event outcome: resolved/resolving (138), resolved with sequelae (1), not resolved (129) and unknown (55); • Duration of events till resolution was reported in 39 out of 67 occurrences with outcome of resolved; it ranged from 10 minutes to 1 month and 3 days, with a median value of 1 day. <p>* Please see Appendix 5.1 for Observed versus Expected analysis of Facial paralysis/Facial paresis (Bell's palsy).</p> <p>Interval conclusion: No new significant safety information was identified based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue.</p> <p>Update to case series review presented in the second SMSR (reporting period 01-31 January 2021): The 139 spontaneous reports resulting from the MedDRA version 23.1 search of the MAH safety database for PTs <i>Facial paralysis</i> or <i>Facial paresis</i> were reviewed for any updates in outcome resulting from follow-up activity through 26 February 2021</p> |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|--|---|
| | <p>(As-of date 27 February 2021). Thirty of the 139 reports were reversioned due to updates and 2 reports were made invalid. The 30 reversioned reports were reviewed to understand the nature of the updates. Of the 30 reversioned reports, 4 reports had a change in outcome:</p> <p>AER (b) (6), PT Facial paralysis was changed to Facial paresis and outcome changed from Not recovered to Recovering</p> <p>AER (b) (6), PT Facial paralysis outcome changed from Not recovered to Recovering</p> <p>AER (b) (6), PT Facial paralysis outcome changed from Unknown to Not recovered</p> <p>AER (b) (6), PT Facial paralysis outcome changed from Not recovered to Unknown</p> <p>These updates based on follow-up do not substantially change the MAH’s evaluation or conclusion. Follow-up efforts to obtain detail, including outcome for AEs, especially AESIs, reported for the vaccine are in place. Evaluations of facial palsy will continue to consider duration of facial paresis/paralysis and will propose updates to labeling language regarding facial palsy if warranted.</p> <p>Overall Conclusion: Taking all available information into consideration, including the unblinded clinical study C4591001 data (DLP 14 November 2020), the post-authorisation data and the comparison of observed case reports to the expected number of events (O/E analyses), the available information does not support a conclusion of a causal association between Bell’s palsy and the vaccine. This topic will continue to be monitored. Causality assessment will be further evaluated following availability of additional data from the remaining clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell’s palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June 2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.</p> |
| <p>Immune-Mediated/Autoimmune AESIs <i>Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLTG (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity</i></p> | <ul style="list-style-type: none"> • Number of cases: 710 (3.0% of the total PM dataset, compared to 2.5% of the previous reporting period), of which 518 medically confirmed and 192 non-medically confirmed; • Country of incidence (>10 cases): UK (174), US (107), France (68), Italy (63), Germany (48), Sweden (33), Spain (31), Mexico (30), Greece (22), Austria (16), Czech Republic (14), Denmark (11). The remaining 93 cases were from 25 different countries. • Subjects’ gender (n=682): female (526), male (156). • Subjects’ age group (n=664): Adult^c (510), Elderly^d (152) Adolescent^e (2). • Number of relevant events: 730, of which 582 serious, 148 non-serious. |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|--|--|
| | <ul style="list-style-type: none"> • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (374), Neuropathy peripheral* (35), Pericarditis* (23), Myocarditis* (20), Encephalitis* (16), Dermatitis Bullous (12), Dermatitis, Psoriasis (11 each); • Relevant event onset latency (n = 580): Range from <24 hours to 30 days, median 1 day. • Relevant event outcome:^f resolved/resolving (359), not resolved (166), fatal (7), resolved with sequelae (15) and unknown (184). <p>* Please see Appendix 5.1 for Observed/Expected analysis performed for Autoimmune thyroiditis, Encephalitis, Myasthenia gravis, Myelitis, Myocarditis, Neuropathy peripheral, Pericarditis, Type 1 diabetes mellitus.</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases. The lower level of the confidence interval exceeds 1 for the cumulative and interval risk periods in the Observed versus Expected analysis for Myasthenia gravis and Peripheral neuropathy and these events will be reviewed and discussed in the next SMSR. Surveillance will continue.</p> |
| <p>Musculoskeletal AESIs <i>Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial;^o Chronic fatigue syndrome; Polyarthrits; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis^l</i></p> | <ul style="list-style-type: none"> • Number of cases: 2151 (9.1% of the total PM dataset, compared to 8.2% of the previous reporting period), of which 1121 medically confirmed and 1030 non-medically confirmed; • Country of incidence: UK (827), US (340), Italy (241), Mexico (201), Portugal (70), Germany (54), France (46), Greece (44), Czech Republic (30), Latvia (28), Poland (27), Spain and Sweden (20 each), Ireland (19), Austria, Belgium and Finland (18 each), Israel (15), Netherlands (14), Denmark (13), Romania (10), Bulgaria and Croatia (9 each), Cyprus (8), Canada, Hungary and Norway (6 each), Estonia and Serbia (5 each), Iceland, Puerto Rico and Slovakia (3 each), Costa Rica, Lithuania, Malta, Saudi Arabia and Slovenia (2 each); the remaining 5 cases originated from 5 different countries; • Subjects' gender (n=2089): female (1653), male (436); • Subjects' age group (n=2027): Adult^c (1656), Elderly^d (371); • Number of relevant events: 2173, of which 1179 serious, 994 non-serious; • Reported relevant PTs: Arthralgia (2101), Arthritis (40), Rheumatoid arthritis* (20), Polyarthrits* (5), Chronic fatigue syndrome* (3), Polyneuropathy* (2) and Arthritis bacterial and Post viral fatigue syndrome* (1 each); • Relevant event onset latency (n = 1798): Range from <24 hours to 32 days, median 1 day; • Relevant event outcome:^f resolved/resolving (1103), resolved with sequelae (27), not resolved (533) and unknown (522). <p>* Observed/Expected analysis was performed for Rheumatoid arthritis, Polyarthrits, Chronic fatigue syndrome, Polyneuropathy and Post viral fatigue syndrome (see Appendix 5.1).</p> |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|--|---|
| | <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue.</p> |
| <p>Neurological AESIs (including demyelination) <i>Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy;^j Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy</i></p> | <ul style="list-style-type: none"> • Number of cases: 394 (1.7% of the total PM dataset, compared to 0.9% of the previous reporting period), of which 296 medically confirmed and 98 non-medically confirmed. • Country of incidence (>10 cases): UK (110), US (41), Germany (40), Italy (28), Mexico (26), France (24), Spain (18), Poland (17), Netherlands (15), Israel (11). The remaining 64 cases were from 23 different countries. • Subjects' gender (n=377): female (253), male (124). • Subjects' age group (n=378): Adult^e (256), Elderly^d (122); • Number of relevant events: 426, of which 409 serious, 17 non-serious. • Most frequently reported relevant PTs (≥2 occurrences) included: Seizure* (159), Epilepsy (73), Generalised tonic-clonic seizure* (26), Guillain-Barre syndrome* (20), Febrile convulsion*, Trigeminal neuralgia (14), Fibromyalgia* (12), Status epilepticus (11), Myelitis transverse* and Tonic convulsion* (9 each), Optic neuritis* (8), Ataxia (7), Encephalopathy*, Petit mal epilepsy and Tonic clonic movements (6 each), Multiple sclerosis relapse* (5), Foaming at mouth (4), Aura, Narcolepsy*, Partial seizures and Tongue biting (3 each) and Bad sensation, Clonic convulsion, Leukoencephalopathy, Meningitis*, Meningitis aseptic*, Myokymia, Postictal state and Seizure like phenomena (2 each); • Relevant event onset latency (n = 342): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (13), resolved/resolving (211), resolved with sequelae (8), not resolved (71) and unknown (125); upon review, in the 11 cases reporting overall 13 neurological events with fatal outcome, the outcome of these neurological events was not relevant as the subjects died due to multiple or different causes; • Most frequently reported relevant medical history (> 1 occurrence) Epilepsy (39), Seizure (14), Cerebrovascular accident (8), Fibromyalgia (7), Trigeminal neuralgia (4), Cerebral haemorrhage, Cerebral infarction (3 each), Cerebral palsy, Generalised tonic-clonic seizure, Myoclonus, Partial seizures, Petit mal epilepsy, Transient ischaemic attack (2 each). <p>* Observed/Expected analysis was performed for Encephalopathy, Guillain-Barre syndrome, Fibromyalgia, Meningitis, Multiple sclerosis, Myelitis transverse, Narcolepsy, Optic neuritis and Seizure/Seizure disorders (see Appendix 5.1). A safety evaluation of Guillain-Barre syndrome was also conducted (see Appendix 3.6).</p> <p>Conclusion: No new safety signals have emerged from review of the cases. The lower level of the confidence interval exceeds 1 for the cumulative and interval risk periods in the Observed versus Expected analysis for Meningitis and Transverse myelitis and these events will</p> |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|---|---|
| | be reviewed and discussed in the next SMSR. Surveillance will continue. |
| <p>Other AESIs <i>Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive</i></p> | <ul style="list-style-type: none"> • Number of cases: 4597 (19.5% of the total PM dataset, compared to 20.3% of the previous reporting period), of which 2650 were medically confirmed and 1947 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (1475), US (716), Italy (586), Portugal (198), Mexico (191), France (176), Germany (145), Spain (135), Sweden (117), Denmark (92), Greece (82), Poland (79), Czech Republic (72), Finland (49), Austria (47), Latvia, Norway (45 each), Belgium (40), Israel (38), Hungary (36), Croatia (34), Ireland (32), Romania (24) Netherlands (22). The remaining 121 cases were from 21 different countries; • Subjects' gender (n=4441): female (3427), male (1014); • Subjects' age group (n=4312): Adult^c (3496), Elderly^d (803), Adolescent^e, Child^h (5 each), Infant^g (3); • Number of relevant events: 4666, of which 2691 serious, 1975 non-serious; • Most frequently reported relevant PTs (≥5 occurrences) included: Pyrexia (4272), Herpes zoster* (179), Inflammation (93), Oral herpes (50), Multiple organ dysfunction syndrome* (12), Ophthalmic herpes zoster* (10), Herpes simplex (8), Herpes virus infection (7), Herpes ophthalmic (6), Herpes zoster reactivation* (5); • Relevant event onset latency (n = 2498): Range from <24 hours to 32 days, median 1 day; • Relevant events outcome:^f fatal (69), resolved/resolving (2953), resolved with sequelae (50), not resolved (752) and unknown (877). <p>* Among multiple different events grouped under this Other AESIs category, Observed/Expected analysis was performed on specific PTs relevant for Herpes zoster disorders and Multiple organ dysfunction syndrome (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue.</p> |
| <p>Pregnancy Related AESIs <i>Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia</i></p> | <p>For relevant cases, please refer to the subsection <i>Use in Pregnancy and While Breast Feeding</i> in Table 12.</p> |
| <p>Renal AESIs <i>Search criteria: PTs Acute kidney injury; Renal failure.</i></p> | <ul style="list-style-type: none"> • Number of cases: 45 cases (0.2% of the total PM dataset, compared to 0.1% of the previous reporting period), of which 36 medically confirmed, 9 non-medically confirmed; |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|--|--|
| | <ul style="list-style-type: none"> • Country of incidence: France (12), Germany (10), UK (6), Spain (4), Belgium and US (3 each), Italy (2) and Austria, Canada, Denmark, Finland and Luxembourg (1 each); • Subjects' gender: female (29), male (16); • Subjects' age group (n=45): Adult^c (6), Elderly^d (39); • Number of relevant events: 45, all serious; • Reported relevant PTs: Acute kidney injury* (24) and Renal failure* (21); • Relevant event onset latency (n = 28): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (15), resolved/resolving (7), not resolved (11) and unknown (12). <p>* Observed/Expected analysis performed for Acute kidney injury and Renal failure (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Surveillance will continue.</p> |
| <p>Respiratory AESIs <i>Search criteria: Lower respiratory tract infections NEC (HLT) (Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome</i></p> | <ul style="list-style-type: none"> • Number of cases: 100 cases (0.4% of the total PM dataset, compared to 0.2% of the previous reporting interval), of which 82 medically confirmed; • Countries of incidence: France (17), Germany (12), United Kingdom (12), Spain (11), Italy (8), Belgium, United States (7 each), Denmark 6), Norway (5), Czech Republic, Iceland (3 each); the remaining 9 cases originated from 6 different countries. • Subjects' gender (n=60): male (40). • Subjects's age group (n=97): Elderly^d (63), Adult^c (33), Adolescent^e (1). • Number of relevant events: 100 serious events, 6 non-serious. • Reported relevant PTs: Hypoxia, Respiratory failure (35 each), Respiratory disorder (26), Acute respiratory distress syndrome (7), Chronic respiratory syndrome (2), Severe acute respiratory syndrome (1). • Relevant event onset latency (n=80): range from < 24 hours to 18 days. • Relevant events outcome: fatal (30), Resolved/resolving (41), not recovered (11) and unknown (24). • Out of these 100 cases, only 2 (1 fatal and 1 medically significant) in which the PT Respiratory failure (2) was reported in a context of vaccine lack of efficacy (PT: Drug ineffective) , were also reviewed among the potential relevant cases for the Risk 'VAED Including VAERD' in Table 9. <p>* Observed/Expected analysis performed for Acute respiratory distress syndrome (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Surveillance will continue.</p> |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|--|--|
| <p>Thromboembolic Events <i>Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism</i></p> | <ul style="list-style-type: none"> • Number of cases: 114 (0.5% of the total PM dataset, compared to 0.2% of the previous reporting period), of which 86 medically confirmed and 28 non-medically confirmed; • Country of incidence: UK (23), France (20), US (18), Germany (11), Spain (6), Denmark, Italy and Sweden (5 each), Belgium, Canada, Cyprus and Netherlands (2 each); the remaining 13 cases originated from 13 different countries; • Subjects' gender (n= 112): female (69), male (43); • Subjects' age group (n=106): Adult^e (55), Elderly^d (51); • Number of relevant events: 127, of which 125 serious, 2 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism* (48), Thrombosis (28), Deep vein thrombosis* (23), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Thrombophlebitis and Venous thrombosis (3 each) and Blue toe syndrome and Microembolism (2 each); • Relevant event onset latency (n = 95): Range from <24 hours to 28 days, median 5 days; • Relevant event outcome: fatal (9), resolved/resolving (44), resolved with sequelae (4), not resolved (41) and unknown (29). <p>* Observed/Expected analysis performed for Deep vein thrombosis and Pulmonary embolism (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases and of the Observed versus Expected analysis performed Surveillance will continue.</p> |
| <p>Stroke^p <i>Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents (Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)</i></p> | <ul style="list-style-type: none"> • Number of cases: 193 (0.8% of the total PM dataset)^p, of which 120 medically confirmed and 73 non-medically confirmed; • Country of incidence: US (46), UK (42), France (28), Germany (16), Norway (12), Netherlands and Spain (11 each), Sweden (6), Italy (3), Belgium, Denmark, Finland and Poland (2 each); the remaining 10 cases originated from 10 different countries; • Subjects' gender (n= 191): female (133), male (58); • Subjects' age group (n=186): Adult^e (38), Elderly^d (147), Child^{h,q} (1); • Number of relevant events: 209, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: <ul style="list-style-type: none"> ○ PTs indicative of Ischaemic stroke: Cerebrovascular accident (111), Ischaemic stroke (30), Cerebral infarction (12), Cerebral thrombosis and Ischaemic cerebral infarction (3 each) and Basal ganglia stroke, Cerebral ischaemia, Cerebral venous sinus thrombosis and Thrombotic stroke (2 each); ○ PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (19), Haemorrhagic stroke (7), Cerebral haematoma and Subarachnoid haemorrhage (4 each); • Relevant event onset latency (n = 164): Range from <24 hours to 41 days, median 2 days; |

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|---|---|
| | <ul style="list-style-type: none"> • Relevant event outcome: fatal and resolved/resolving (44 each), resolved with sequelae (7), not resolved (49) and unknown (65). <p>* Observed/Expected analysis was performed for Stroke disorders (see Appendix 5.1).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases, or of the Observed versus Expected analysis performed. Surveillance will continue.</p> |
| <p>Vasculitic Events <i>Search criteria: Vasculitides HLT</i></p> | <ul style="list-style-type: none"> • Number of cases: 26 cases (0.1% of the total PM dataset, compared to 0.01% of the previous reporting period), of which 21 medically confirmed and 5 non-medically confirmed; • Country of incidence: UK (10), France (4), Portugal (3), Spain and US (2 each) and Cyprus, Germany, Hungary, Italy and Slovakia (1 each); • Subjects' gender: female (21), male (5); • Subjects' age group (n=25): Adult^c (13), Elderly^d (12); • Number of relevant events: 28, of which 21 serious, 7 non-serious; • Reported relevant PTs: Vasculitis* (12), Cutaneous vasculitis* (4), Vasculitic rash* (3), Behcet's syndrome, Giant cell arteritis and Hypersensitivity vasculitis (2 each) and Palpable purpura, Peripheral ischaemia* and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 20): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: resolved/resolving (12), not resolved (9) and unknown (7). <p>* Observed/Expected analysis was performed for Vasculitis and Cutaneous vasculitis disorders (see Appendix 5.1).</p> <p>No new significant safety information was identified based on a review of these cases, or of the Observed versus Expected analysis. Surveillance will continue.</p> |

- a. For the complete list of the AESIs, please refer to Appendix 5;
- b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- c. Subjects with age ranged between 18 and 64 years;
- d. Subjects with age equal to or above 65 years;
- e. Subjects with age ranged between 12 and less than 18 years;
- f. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
- g. Subjects with age ranged between 1 (28 days) and 23 months;
- h. Subjects with age ranged between 2 and 11 years;
- i. To increase clinical relevance of the review, compared to previous SMSR these PTs were moved to COVID-19 category;
- j. To increase clinical relevance of the review, compared to previous SMSR this PT was moved from the Immune-mediated/Autoimmune Category to its appropriate specific body system category;
- k. As per EMA PRAC assessment report received on the second SMSR, EMA has requested an analysis of haemorrhagic disorders through review of PTs present in a specific SMQ query in addition to the PTs Haemorrhage and Haemorrhagic disorder already included in the AESIs/TME list; comparison with reporting

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Table 10. AESIs Evaluation for BNT162b2

| AESIs ^a Category | Post-Marketing Cases Evaluation ^b Total Number of Cases in the Reporting Period (N=23558) |
|--------------------------------|---|
|--------------------------------|---|

proportion of Haematological events reported in the previous reporting period is therefore not applicable for this Category;

- l. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy (BC Category 5) because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
- m. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
- n. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell’s palsy 1 day following vaccination that had not resolved at the time of the report;
- o. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;
- p. New search strategy was implemented since this third SMSR for Stroke to include, in addition to the PT Cerebrovascular accident already included in the AESIs/TME List, other reported PTs that are indicative of stroke and were not in the previous search strategy, and to differentiate between ischemic and hemorrhagic strokes; for this reason the comparison with the reporting proportion of previous reporting period is not applicable for this AESI category;
- q. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.

9.5.3. Evaluation of Special Situations

Table 11 below presents the evaluation of new information received during the current reporting period from post-marketing data sources for BNT162b2 in relation to special situations (Death, Lack of Efficacy and Vaccine Interactions).

Table 11. Evaluation of Special Situations for BNT162b2

| Topic | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------|--|
| Death | <p>Overview</p> <ul style="list-style-type: none"> • Number of fatal cases: 794³⁸ (3.4% of the total PM dataset, compared to 2.8% of the total PM cases received in the previous reporting period) of which 652 were medically confirmed and 142 non-medically confirmed; • Country of incidence: the majority were from France (140), Germany (132), UK (99), Norway (65), Sweden (56), US (48), Netherlands (44), Belgium (41), Denmark (29), Spain (23); the remaining 117 cases occurred in 21 other countries. • Subject Gender: females (423), males (303), unknown (68); |

³⁸ During the current reporting interval there were 8 additional cases reporting subjects’ death. However, they were excluded from further analysis in this subsection as the death was mentioned as an incidental information only in 3 cases, with none of the reported events presenting a fatal outcome; 2 cases were excluded as it was made invalid; and 3 cases reported foetal death and are reviewed in [Table 12](#) under *Use in Pregnancy and While Breast Feeding*.

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Table 11. Evaluation of Special Situations for BNT162b2

| Topic | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------|--|
| | <ul style="list-style-type: none"> • Subjects' Age: 19 to 103 years (n = 722), mean = 82.7, median = 86; • Adults (68), Elderly (672), subjects with unknown age (54); • Causes of death most frequently reported (≥2% of total fatal cases): Death (239), COVID-19 (70), Sudden death (68), General physical health deterioration (63), Pyrexia (51), Dyspnoea (42), Drug ineffective (37), Cardiac failure (35), Cardiac arrest, Pneumonia (26 each), Oxygen saturation decreased (25), Myocardial infarction (23), Cerebrovascular accident (20), Respiratory failure, Vomiting (19 each), Malaise (18), and COVID-19 pneumonia (16). • PTs most frequently reported (>2% events): Death (240), COVID-19 (94), Pyrexia (85), Sudden death (73), Dyspnoea, General physical health deterioration (70 each), and Drug ineffective (68). • Concomitant medications were reported in 343 out of 794 cases and the most frequently present (≥2%) are listed below: Paracetamol (97), Furosemide (71), Acetylsalicylic acid (52), Oxazepam (41), Apixaban (38), Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride (34), Atorvastatin, Mirtazapine (31 each), Omeprazole (29), Bisoprolol Fumarate (27), Bisoprolol, Colecalciferol (26 each), Pantoprazole, Ramipril (24 each), Amlodipine, Levothyroxine Sodium, Potassium Chloride, Zopiclone (23 each), Pantoprazole Sodium Sesquihydrate (22), Calcium Carbonate/Colecalciferol (21), Folic Acid, Lansoprazole (20 each), Risperidone (19), and Fentanyl (16). • Lot/Batch Number (#) information by Country was available in 514 cases with no related quality issues identified during investigations of the impacted lot/batch numbers. The list of Lot/Batch #s most frequently reported (>2% of total fatal cases) is presented hereinafter: <ul style="list-style-type: none"> ○ Lot # EM0477 in 130 cases from France (41), Germany (32), Netherlands (19), Norway (16), Belgium (12), Spain (6), Ireland (3), and Denmark (1). ○ Lot # EJ6795 in 70 cases from France (29), Norway (22), Sweden (11), Netherlands (3), Germany, Finland (2 each), and Poland (1). ○ Lot # EJ6796 in 49 cases from Germany (20), Norway (7), France (6), Sweden (5), Austria (4), Spain (3), Belgium, Finland, Hungary, and Iceland (1 each). ○ Lot/Batch # EJ6788 in 41 cases from France (38), Germany (2), and Netherlands (1). ○ Lot # EJ6797 in 29 cases from Denmark (14), Austria, Italy (5 each), Germany (3), Slovakia, and Slovenia (1 each). ○ Lot # EJ6134 in 26 cases from Sweden (7), Denmark (4), Netherlands, Finland (3 each), Hungary, France, Belgium (2), Slovenia, Slovakia, and Austria (1 each). ○ Lot # EK9788 in 21 cases from Germany (9), Denmark (5), France (3), Poland (2), Belgium, and Italy (1 each). ○ Lot # EL1484 in 21 cases from Sweden (12), Italy (6), Portugal (2), and Hungary (1). ○ Lot # EL1491 in 17 cases from Germany (5), Austria (3), Croatia, Poland, Spain (2 each), Czech Republic, Finland, and Greece (1 each). |

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Table 11. Evaluation of Special Situations for BNT162b2

| Topic | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|------------------|--|
| | <ul style="list-style-type: none"> • Time to onset of fatal events was reported for 602 subjects and ranged from the day of vaccination to 41 days after vaccination: <ul style="list-style-type: none"> ○ Same day to 3 days after vaccination: 327 cases ○ 4-7 days after vaccination: 155 cases ○ 8-14 days after vaccination: 83 cases ○ 15-41 days after vaccination: 37 cases • Number of vaccine doses administered at the time of the subjects' death: in 390 cases the death occurred after the administration of the first dose, in 108 cases the fatal outcome was observed after the administration of the second dose whereas in the remaining cases (296) it was not specified if the subjects received the first or the second vaccine dose at the time of the fatal events. • Test for COVID-19 was reported for 234 subjects as follows: in 118 cases subjects tested positive (72 after 1st vaccine dose, 7 after 2nd vaccine dose and in 39 there was no information available about the dose they received), in 107 were negative, 2 cases reported prior history of positive COVID-19 test, and in 7 cases test results were unknown. <p>Analysis</p> <p>Most of the cases reporting a fatal outcome (74.9%) were in subjects over 75 years of age. This reflects one of the priority groups targeted for vaccination by many regions and countries, including Europe and the US, that is, elderly (with various lower age cut-offs across countries), because of their higher risk of severe disease and mortality if infected with SARS-CoV-2.^{12,13}</p> <p>Among the total of 794 cases with a fatal outcome, when the medical history was provided (in 624 cases), the majority had multiple concomitant comorbidities. The most frequently reported medical conditions included cardiac and vascular disorders (eg Hypertension, Atrial fibrillation, Cardiac failure, Cerebrovascular accident, Myocardial ischaemia, Myocardial infarction). Other frequently reported significant medical histories included Dementia/Dementia Alzheimer's type, Chronic kidney disease, Renal failure, Diabetes mellitus/Type 2 diabetes mellitus, and Chronic obstructive pulmonary disease. Some of the subjects (16.5%) who received the vaccine already had general physical deterioration, were bedridden, were living in residential institutions, or on palliative care. No specific pattern regarding underlying conditions or cause of death have been identified. Further reports will continue to be closely monitored.</p> <p>Please see Appendix 5.1 for Observed versus Expected analysis of Death.</p> <p>Conclusion: No new risks were identified following review of the signal of death, particularly in the comorbid elderly population.</p> |
| Lack of Efficacy | <p>Company conventions for coding cases indicative of lack of efficacy:</p> <ul style="list-style-type: none"> • The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine was revised on 12 February 2021, as shown below: PT "Vaccination failure" is coded when ALL of the following criteria are met: <ul style="list-style-type: none"> ○ The subject has received the appropriate series of two doses based on the labeling. ○ At least 7 days have elapsed since the second dose of vaccine has been administered. ○ The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: |

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Table 11. Evaluation of Special Situations for BNT162b2

| Topic | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) | | | | | | | | | |
|--|---|--|--|---------------------------------|--|-------------------------|----------------------------|-----------------------------|---|--|
| | <ul style="list-style-type: none"> ○ The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., “the vaccine did not work”, “I got COVID-19”. ○ It is unknown: <ul style="list-style-type: none"> ▪ Whether the subject has received the appropriate series of two doses in correct timing based on the labeling instructions; ▪ How many days have passed since the first dose (including unspecified number of days like a”a few days”, “some days”, etc.); ▪ If 7 days have passed since the second dose of the vaccine administration; ○ The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. <p>Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, this is considered a potential lack of efficacy even if the vaccination course is not complete.</p> <p>This is the summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:</p> <table border="1" data-bbox="508 982 1414 1178"> <thead> <tr> <th data-bbox="508 982 808 1037">1st dose (day 1-13)</th> <th data-bbox="808 982 1109 1037">From day 14 post 1st dose to day 6 post 2nd dose</th> <th data-bbox="1109 982 1414 1037">Day 7 post 2nd dose</th> </tr> </thead> <tbody> <tr> <td data-bbox="508 1037 808 1121">Code only the events describing the SARS-CoV-2 infection</td> <td data-bbox="808 1037 1109 1121">Code “Drug ineffective”</td> <td data-bbox="1109 1037 1414 1121">Code “Vaccination failure”</td> </tr> <tr> <td data-bbox="508 1121 808 1178">Scenario Not considered LOE</td> <td data-bbox="808 1121 1109 1178">Scenario considered LOE as “Drug ineffective”</td> <td data-bbox="1109 1121 1414 1178">Scenario considered LOE as “Vaccination failure”</td> </tr> </tbody> </table> <p>Lack of efficacy cases</p> <ul style="list-style-type: none"> • Number of cases³⁹: 856 (3.6 % of the total PM dataset, compared to 7.2% of the previous reporting period) of which 572 were medically confirmed and 284 non -medically confirmed; • Number of lack of efficacy events: 856 [PT: Drug ineffective (840) and Vaccination failure (16)]. • Country of incidence: US (233), UK (180), Germany (120), France (80), Italy (52), Belgium, Romania (28 each), Poland (20), Spain (19), Austria , Israel (16 each), Greece (14), Portugal (9), Denmark (7), Mexico (6), Czech Republic, Sweden (4 each); the remaining 20 cases originated from 11 different countries. | 1 st dose (day 1-13) | From day 14 post 1 st dose to day 6 post 2 nd dose | Day 7 post 2 nd dose | Code only the events describing the SARS-CoV-2 infection | Code “Drug ineffective” | Code “Vaccination failure” | Scenario Not considered LOE | Scenario considered LOE as “Drug ineffective” | Scenario considered LOE as “Vaccination failure” |
| 1 st dose (day 1-13) | From day 14 post 1 st dose to day 6 post 2 nd dose | Day 7 post 2 nd dose | | | | | | | | |
| Code only the events describing the SARS-CoV-2 infection | Code “Drug ineffective” | Code “Vaccination failure” | | | | | | | | |
| Scenario Not considered LOE | Scenario considered LOE as “Drug ineffective” | Scenario considered LOE as “Vaccination failure” | | | | | | | | |

³⁹ One hundred and ninety-six (196) additional cases retrieved in this dataset were excluded from the analysis; upon review, 188 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after DLP because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 2 cases have been invalidated in the safety database after DLP.

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Table 11. Evaluation of Special Situations for BNT162b2

| Topic | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|-------|---|
| | <ul style="list-style-type: none"> • COVID-19 infection was confirmed in 791 cases, suspected in 64 cases, in 1 case it was reported that the first dose was no effective (no other information). • COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (100), not resolved (121) or unknown (591) at the time of the reporting; there were 44 cases where a fatal outcome was reported (see also <i>Death</i> section above in this table). <p><i>Drug ineffective cases (840)⁴⁰</i></p> <ul style="list-style-type: none"> • Drug ineffective seriousness: serious (833), non-serious (7)⁴¹; • Lack of efficacy term was reported: <ul style="list-style-type: none"> ○ after the 1st dose in 427 cases ○ after the 2nd dose in 106 cases ○ in 307 cases it was unknown after which dose the lack of efficacy occurred. • Latency of lack of efficacy term reported after the first dose was known for 119 cases: <ul style="list-style-type: none"> ○ Within 0 and 7 days: 1 subject; ○ Within 14 and 21 days: 104 subjects; ○ Within 23 and 50 days: 14 subjects; • Latency lack of efficacy term reported after the second dose was known for 50 cases: <ul style="list-style-type: none"> ○ Within 0 and 7 days: 28 subjects; ○ Within 8 and 21 days: 17 subjects; ○ Within 23 and 36 days: 5 subjects. • Latency of lack of efficacy term reported in cases (307) where the number of doses administered was not provided, was known in 194 cases: <ul style="list-style-type: none"> ○ Within 0 and 7 days after vaccination: 121 subjects. ○ Within 8 and 14 days after vaccination: 46 subjects. ○ Within 15 and 44 days after vaccination: 27 subjects. <p>According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 840 cases where lack of efficacy was reported after the 1st dose or the 2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.</p> <p><i>Vaccination failure cases (16)</i></p> <ul style="list-style-type: none"> • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose; • Latency of lack of efficacy term was known for all cases: <ul style="list-style-type: none"> ○ Within 7 and 14 days: 10 subjects; ○ Within 15 and 29 days: 6 subjects. <p>COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections occurred in these 16 cases.</p> |

⁴⁰ There were 837 PTs Drug ineffective; in 3 additional cases the LOE PT has been recoded from Vaccination failure to Drug ineffective after DLP.

⁴¹ Event seriousness of PTs, indicative of possible lack of therapeutic effect captured at the DLP, was upgraded to serious as per case processing convention at completion of the case.

Table 11. Evaluation of Special Situations for BNT162b2

| Topic | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|----------------------|--|
| | Conclusion: No new safety signals have emerged based on a review of these cases. |
| Vaccine Interactions | <ul style="list-style-type: none"> Number of cases: 7 (0.03% of the total PM dataset, compared to 0.08% of the previous reporting period) of which, 4 cases were medically confirmed and 3 cases were non-medically confirmed. Country of incidence: US (3), Portugal, Spain, Switzerland, UK (1 each). Subject Gender: Female (4) and Male (3); Subjects' Age: 32 to 80 years; (n=7); mean=50.6; median 49.0; Relevant reported interaction PTs: Drug interaction (6) and Alcohol interaction (1); Relevant event seriousness: Serious (4) and Non-serious (3); Relevant event outcome: Resolved/Resolving (2), Not resolved (1), and Unknown (4); Co-reported events coded to the PTs (>1 event): Headache, Off-label use, and Product use issue (2). Reported Interacting Agents: adalimumab, alcohol, clozapine, insulin, lamotrigine, ocrelizumab, paroxetine, PEG, and warfarin. <p>Conclusion: there is no indication of a safety signal of interference of immune response of vaccines noted based on a review of these cases.</p> |

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

9.5.4. Evaluation of Missing Information

Table 12 below summarises the evaluation of new information received during the current reporting period from post-marketing data sources⁷ in relation to the Missing information associated with the use of BNT162b2.

Table 12. Evaluation of Missing Information for BNT162b2

| Missing Information | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|--|---|
| Use in Pregnancy and While Breast Feeding ^b | <ul style="list-style-type: none"> Number of cases: 153^c (0.6% of the total PM dataset, compared to 1.4% of the previous reporting period) of which 74 were medically confirmed and 79 were non-medically confirmed; Country of incidence: UK (50), US (38), Germany (15), Canada (8), Italy (7), Israel (6), Ireland, Mexico (5 each), Hungary (4), Portugal (3), Czech Republic, Poland (2 each), Belgium, Denmark, Estonia, Finland, Latvia, Lithuania, Romania, and Spain (1 each). <p><u>Pregnancy cases:</u> 121 cases including:</p> <ul style="list-style-type: none"> 117 mother cases and 4 fetus/baby cases representing 117 unique pregnancies (the 4 fetus/baby cases were linked to 3 mother cases; 1 mother case involved twins) Pregnancy outcomes for the 117 pregnancies were reported as spontaneous abortion^d (18), spontaneous abortion with intrauterine death, premature birth with neonatal death (2 each), spontaneous abortion with neonatal death (1), and no outcome was provided for 95 pregnancies (note that 2 different outcomes were reported for the twins and both were counted) |

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Table 12. Evaluation of Missing Information for BNT162b2

| Missing Information | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|--|--|
| | <ul style="list-style-type: none"> • 47 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (35), Exposure during pregnancy (11), and Maternal exposure timing unspecified (1). Trimester of exposure was reported in 7 of these cases: 1st trimester (5 cases), 2nd trimester, and 3rd trimester (1 case each) • 70 mother cases, 15 non-serious and 55 serious, reported additional clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Spontaneous abortion (17), Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (24), Pain in extremity (13), Fatigue (12), Nausea, Pyrexia, Vaccination site pain (8 each), Chills, Myalgia, Pain (7 each), Arthralgia, and Asthenia (6 each). Trimester of exposure was reported in 17 of these cases: 1st trimester (13 cases), 2nd trimester (3 cases), 3rd trimester (1 case). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. <p><u>Breast feeding baby cases:</u> 31, of which:</p> <ul style="list-style-type: none"> • 25 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical events; • 6 cases, 3 serious and 3 non-serious, reported 7 additional clinical events that occurred in the infant/child exposed to vaccine via breastfeeding; these events coded to the PTs Illness (2), Diarrhoea, Pain, Pyrexia, Rash, and Urticaria (1 each). <p><u>Breast feeding mother cases:</u></p> <ul style="list-style-type: none"> • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia. <ul style="list-style-type: none"> • <u>Conclusion:</u> There were no safety signals that emerged from the review of these cases of use in pregnancy and while and breast feeding. |
| Use in Immunocompromised Patients ^c | <ul style="list-style-type: none"> • Number of cases: 941 (4.0% of the total PM dataset, compared to 2.1% of the previous reporting period) of which 369 were medically confirmed and 572 non-medically confirmed; • Case Seriousness: Serious (758), Non-Serious (183); • Country of incidence: UK (534), US (175), France (78), Italy (18), Germany (15), Denmark and Spain (11 each), Norway and Sweden (10 each), Austria and Portugal (9 each), Belgium (7), Czech Republic, Israel and Netherlands (6 each), Greece (5), Ireland (4), Estonia, Finland and Slovakia (3 each), Bulgaria, Hungary, Malta, Mexico and Poland (2 each); the remaining 8 cases originated from 8 different countries; • Gender: females (705), males (221) and unknown (15); |

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Table 12. Evaluation of Missing Information for BNT162b2

| Missing Information | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|--|---|
| | <ul style="list-style-type: none"> • Age (n = 891) ranged from 18 to 100 years, mean = 57.7 years, median = 57 years; • Relevant patients' medical histories most frequently reported (≥20 cases) coded to the PTs: Immunodeficiency (273), Breast cancer (119), Neoplasm malignant (58), Chemotherapy (56), Neoplasm (51), Radiotherapy (42), Prostate cancer (34), Hysterectomy (33), Thyroidectomy (32), Splenectomy (31), Lymphoma (24), Chronic lymphocytic leukaemia (23) and Renal transplant (20); • Of the 4561 events overall reported, the most frequent clinical events (≥60 occurrences) coded to the PTs: Headache (241), Fatigue (225), Pyrexia (145), Nausea (141), Myalgia and Pain in extremity (112 each), Chills (106), Dizziness (102), Malaise (98), Vaccination site pain (87), Pain (85), Arthralgia (69), Dyspnoea (66) and Diarrhoea (60); • Case outcome: fatal (36, see Table 11, <i>Death</i>), resolved/resolving (442), resolved with sequelae (23), not resolved (359) and unknown (81). <p>Conclusion: The most frequently reported clinical events observed in immunocompromised subjects were consistent with those observed in the overall population. The reporting proportion of unresolved cases (38.2%) and cases resolved with sequelae (2.4%) in patients in immunocompromised subjects is slightly higher compared to the reporting proportion observed in the overall population (27.2% for outcome of not resolved, 1.4% for outcome of resolved with sequelae), while the reporting proportion of cases with fatal outcome in immunocompromised subjects (3.8%) is similar to the reporting proportion of cases with fatal outcome in the overall population (3.4%).</p> <p>No safety signals have emerged that would be considered specific to this population.</p> |
| Use in Patients With Autoimmune or Inflammatory Disorders ^e | <ul style="list-style-type: none"> • Number of cases: 1490 (6.3% of the total PM dataset, compared to 6.1% of the previous reporting period) of which 721 were medically confirmed and 769 non-medically confirmed; • Case Seriousness: Serious (1009), Non-Serious (481); • Country of incidence: UK (586), US (403), France (84), Italy (76), Sweden (35), Germany (32), Portugal (31), Spain (27), Austria (26), Denmark (21), Czech Republic (19), Croatia (17), Ireland (15), Finland (14), Greece (13), Hungary and Israel (12 each), Norway (7), Canada and Romania (6 each), Belgium, Malta and Netherlands (5 each), Cyprus, Mexico and Poland (4 each), Bulgaria, Estonia, Slovakia and Slovenia (3 each) and Iceland and Latvia (2 each); the remaining 5 cases originated from 5 different countries; • Gender: Females (1269), Males (195) and Unknown (26); • Age (n = 1416) ranged from 18 to 104 years, mean = 52.9 years, median = 51.5 years; • Relevant subjects' medical histories most frequently reported (>20 cases) coded to the PTs: Hypothyroidism (295), Rheumatoid arthritis (209), Arthritis (120), Autoimmune thyroiditis (105), Crohn's disease (74), Colitis ulcerative (69), Thyroid disorder (67), Inflammatory bowel disease (65), Multiple sclerosis (59), Type 1 diabetes mellitus (58), Coeliac disease (53), Psoriasis (48), Systemic lupus erythematosus (41), Psoriatic arthropathy (39), Autoimmune disorder (31), Sjogren's syndrome and Raynaud's phenomenon (28 each) and Ankylosing spondylitis (24); • Of the 6819 events overall reported, the most frequent (≥65 occurrences) coded to the PTs: Headache (434), Fatigue (357), Pyrexia (247), Nausea (232), Arthralgia (214), Vaccination site pain (197), Chills (196), Myalgia (174), Dizziness (163), Pain in extremity (160), Pain (134), Malaise (111), Diarrhoea |

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Table 12. Evaluation of Missing Information for BNT162b2

| Missing Information | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|--|--|
| | <p>(109), Asthenia (99), Paraesthesia (76), Lymphadenopathy (75), Dyspnoea (66) and Vomiting (65);</p> <ul style="list-style-type: none"> Case outcome: fatal (13 see Table 11, Death), resolved/resolving (765), resolved with sequelae (34), not resolved (555) and unknown (123). <p>Conclusion: The most frequently reported clinical events observed in subjects with autoimmune or inflammatory disorders were consistent with those observed in the overall population. The reporting proportion of unresolved cases (37.2%) and cases resolved with sequelae (2.3%) in subjects with autoimmune or inflammatory disorders is slightly higher compared to the reporting proportion observed in the overall population (27.2% for outcome of not resolved, 1.4% for outcome of resolved with sequelae), while the reporting proportion of cases with fatal outcome in subjects with autoimmune or inflammatory conditions (0.9%) is below the reporting proportion of cases with fatal outcome in the overall population (3.4%). No safety signals have emerged that would be considered specific to this population</p> |
| <p>Use in Frail Patients With Co-morbidities (e.g. COPD, Diabetes, Chronic Neurological Disease, Cardiovascular Disorders)^c</p> | <ul style="list-style-type: none"> Number of cases: 2521^f (10.7% of the total PM dataset, compared to 9.2% of the previous reporting period) of which 1602 were medically confirmed and 919 non-medically confirmed; Case Seriousness: Serious (2008), Non-Serious (513); Country of incidence: UK (735), US (492), France (337), Sweden (149), Germany (126), Spain (113), Italy (80), Norway (76), Denmark (63), Finland (40), Netherlands (37), Austria (36), Ireland and Portugal (35 each), Belgium (33), Greece (18), Czech Republic (17), Canada and Switzerland (10 each), Israel (9), Hungary (8), Croatia, Iceland and Romania (7 each), Malta and Mexico (6 each), Estonia (5), Cyprus and Latvia (4 each), United Arab Emirates (3), Luxembourg and Serbia (2 each); the remaining 9 cases originated from 9 different countries; Gender: Females (1719), Males (774) and Unknown (28); Age (n = 2457) ranged from 5 to 106 years, mean = 66.5 years, median = 72 years; Relevant subjects' medical histories most frequently reported (>20 cases) coded to the PTs: Asthma (880), COPD (242), Dementia (240), Cardiac failure (179), Dementia Alzheimer's type (151), Chronic kidney disease (125), Cognitive disorder (90), Parkinson's disease (73), Pulmonary embolism (63), Renal failure (59), Vascular dementia (45), Cardiac failure congestive (28) and Bronchiectasis (26); Of the 10317 events overall reported, the most frequent (≥100 occurrences) coded to the PTs: Pyrexia (430), Headache (427), Fatigue (390), Dyspnoea (284), Nausea (268), Chills (225), Malaise (201), Dizziness (194), Myalgia (189), Vaccination site pain (167), Pain in extremity (157), Pain (152), Vomiting (147), Arthralgia (143), Asthenia (142), Diarrhoea (118), Death (107) and Cough (100); all these events were consistent with the most frequent events observed in the overall population except for Death; Case outcome: fatal (438, see Table 11, Death), resolved/resolving (1158), resolved with sequelae (47), not resolved (693) and unknown (185). <p>Conclusion: The reporting proportion of not resolved cases (27.5%) and cases resolved with sequelae (1.9%) in frail subjects is similar to the reporting proportion observed in the overall population (27.2% for outcome of not resolved, 1.4% for outcome of resolved with sequelae).</p> |

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Table 12. Evaluation of Missing Information for BNT162b2

| Missing Information | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|---|---|
| | <p>The reporting proportion of cases reporting fatal outcome (17.4%) in frail subjects is higher than the reporting proportion of cases reporting fatal outcome in the overall population (3.4%). This is expected, considering that most of the cases reporting a fatal outcome (82.9%) among the frail subjects involved subjects over 75 years of age who, due to their advanced age and underlying comorbidities, are more likely to die than younger individuals. Underlying comorbidities are likely to be contributory to their deaths.</p> <p><i>As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1) received on the second SMSR, the MAH was requested to discuss if there is a higher risk on worsened outcome in the particularly frail or elderly patients with underlying morbidities, who are reporting diarrhoea and/or vomiting.</i></p> <p>The reporting proportion of cases reporting Diarrhoea and/or Vomiting (9.4%) in these frail or elderly subjects with underlying morbidities is similar to the reporting proportion observed in the overall population (8.2%); there was no difference in the incidence of serious occurrences (63.8% in frail or elderly subjects with underlying morbidities versus 61.3% of serious occurrences in the overall population) and in the reporting proportion of cases in which these events had an outcome of not resolved or resolved with sequelae, respectively 16.4% and 1.3% in frail subjects, versus 18.3% and 1.6% in the overall population. The reporting proportion of cases in which Diarrhoea and/or Vomiting had a fatal outcome is higher (10.1%) in frail subjects than in the overall population (1.7%); the cases with fatal outcome involved 24 subjects with age ranged from 74 to 96 years (mean 87.5 years, median 89 years) and they had multiple underlying co-morbidities that are likely to be contributory to their deaths.</p> <p>Conclusion: Overall, no risks based on subject frailty have been identified for the vaccine. Pfizer recognizes that severe vomiting and diarrhea may have negative clinical consequences, especially in medically frail subjects. As with all vaccinations, the full safety and efficacy profile of the vaccine should be considered in the context of the health of the individual subject when determining the benefit risk of vaccination.</p> |
| Interaction With Other Vaccines ^c | There were no cases reporting an interaction with other vaccines during the reporting interval (please refer to Table 11 , <i>Vaccine Interactions</i>). |
| Long-Term Safety Data | Not applicable |
| Use in Paediatric Individuals <16 Years of Age ^g | <ul style="list-style-type: none"> • Number of cases: 26^h (0.1% of the total PM dataset, as in the previous reporting period), of which 11 were medically confirmed and 15 were non-medically confirmed, and indicative of administration in paediatric subjects <16 years of age; • Country of incidence: UK (19), US (4), Germany (2), Israel (1); • Cases Seriousness: Serious (16), Non-Serious (10); • Gender: Females (20), Males (3), Unknown (3); • Age (n=26) ranged from 2 months to 15 years, mean = 6.2, median = 5; • Case outcome: resolved/resolving (10), not resolved, and unknown (8 each). • Of the 92 reported events, <ul style="list-style-type: none"> ○ The most frequently reported events (>1 case) were coded to the PTs Product administered to patient of inappropriate age (20, see Section 7 Medication Errors), Off label use (12), Product use |

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Table 12. Evaluation of Missing Information for BNT162b2

| Missing Information | Post-Marketing Cases Evaluation ^a Total Number of Cases in the Reporting Period (N=23558) |
|------------------------------------|--|
| | <p>issue (4), Fatigue, Nausea, Pyrexia (3 each), COVID-19, Facial paralysis, Headache, Lymphadenopathy, Swelling, and Vaccination site pain (2 each)</p> <ul style="list-style-type: none"> ○ There were 26 unlisted events reported in 9 cases: <ul style="list-style-type: none"> ▪ These events coded to the PTs Facial paralysis, Swelling (2 each), Blepharospasm, Cellulitis, Cerebrovascular accident, Chest discomfort, Diarrhoea,ⁱ External ear pain, Feeling hot, Hypertension, Mastitis, Muscle spasms, Myoclonus, Neuralgia, Pain in extremity,ⁱ Pain in jaw, Paraesthesia, Paraesthesia oral, Peripheral swelling, Poor quality sleep, Post laminectomy syndrome, Rhinorrhoea, Vaccination site pruritus, and Wheezing (1 each). ▪ All of these cases were received from the MHRA and provided limited information (i.e., medical history, concomitant medications, actions taken, or clinical outcome not provided). <p>No new significant safety information was identified based on a review of these cases.</p> |
| Vaccine effectiveness ^g | Relevant cases for vaccine effectiveness during the reporting interval are reviewed in Table 11 , <i>Lack of Efficacy</i> . |

- a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- b. Missing information as per both the EU-RMP Version 1.0, dated 21 December 2020 and the US PVP, Version 0.3, dated 20 January 2021;
- c. Five cases were excluded from the analysis; pregnancy was not confirmed in 4 cases and 1 case was invalid for unidentifiable reporter;
- d. Birth type of spontaneous abortion was added to 7 cases after the data-lock point;
- e. Missing information as per the EU-RMP Version 1.0, dated 21 December 2020;
- f. One additional case was excluded from the discussion as found as invalid upon review;
- g. Missing information as per the US PVP, Version 0.3, dated 20 January 2021; were excluded from analysis as the data reported (e.g., clinical details, height, weight, etc.) were not consistent for paediatric subjects;
- h. Upon review, 27 cases were excluded from analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects; other paediatric cases, including the one involving a 2-month-old subject, might be reported with a miscoded pediatric age however, since they reported limited details and no follow-up is possible for clarification, they were conservatively discussed in this section;
- i. Added to the CDS after the data-lock point of this SMSR, on 02 March 2021.

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10. OVERALL BENEFIT-RISK EVALUATION

10.1. Benefits

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.

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

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

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for in total 2,214 person-years for the COVID-19 mRNA Vaccine and in total 2,222 person-years in the placebo group. There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g. asthma, body mass index (BMI) \geq 30 kg/m², chronic pulmonary disease, diabetes mellitus, hypertension).

The vaccine efficacy information is presented in Table 13.

Table 13. Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population

| First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection* | | | |
|--|---|---|---|
| Subgroup | COVID-19 mRNA Vaccine N ^a = 18,198 Cases n1 ^b Surveillance time ^c (n2 ^d) | Placebo N ^a = 18,325 Cases n1 ^b Surveillance time ^c (n2 ^d) | Vaccine efficacy % (95% CI) ^f |
| All subjects ^e | 8 2.214 (17,411) | 162 2.222 (17,511) | 95.0 (90.0, 97.9) |
| 16 to 64 years | 7 1.706 (13,549) | 143 1.710 (13,618) | 95.1 (89.6, 98.1) |
| 65 years and older | 1 0.508 (3848) | 19 0.511 (3880) | 94.7 (66.7, 99.9) |
| 65 to 74 years | 1 0.406 (3074) | 14 0.406 (3095) | 92.9 (53.1, 99.8) |

Table 13. Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population

| First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection* | | | |
|--|---|---|--|
| Subgroup | COVID-19 mRNA Vaccine N ^a = 18,198 Cases n1 ^b Surveillance time ^c (n2 ^d) | Placebo N ^a = 18,325 Cases n1 ^b Surveillance time ^c (n2 ^d) | Vaccine efficacy % (95% CI) ^f |
| 75 years and older | 0 0.102 (774) | 5 0.106 (785) | 100.0 (-13.1, 100.0) |

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

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

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

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

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

10.2. Risks

Based on pharmacovigilance monitoring activities, since first authorisation, anaphylaxis has been recognised as an important identified risk. Hypersensitivity reactions (other than Anaphylaxis) Diarrhoea, Pain in extremity (arm) and Vomiting were also assessed as identified risks (not important for the purpose of inclusion in the Risk Management Plans and Pharmacovigilance Plans) and added as adverse reactions to the labeling.

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

10.3. Overall Benefit-Risk

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

11. CONCLUSION AND ACTIONS

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

PREPARED BY PFIZER INC

CDS EFFECTIVE DATE: 12-FEB-2021

Date of Superseded CDS: NA

COVID-19 mRNA Vaccine

CORE DATA SHEET

VERSION 1

PFIZER CONFIDENTIAL

1

FDA-CBER-2021-5683-1081259

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1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

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

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

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

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

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM^{2,3}

Concentrate for solution for injection.

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

Active immunization to prevent coronavirus disease 2019 (COVID-19) disease caused by SARS-CoV-2 virus, in individuals 16 years of age and older.⁴

4.2. Posology and method of administration

Posology

Individuals 16 years of age and older

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

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

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

For further information on efficacy, see Section 5.1.

Pediatric population

The safety and efficacy of TRADENAME in individuals under 16 years of age have not yet been established.

Geriatric population

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

Method of administration

Administer TRADENAME intramuscularly in the deltoid muscle after dilution.

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

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

Irrespective of the type of syringe and needle:

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

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

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Traceability

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

General recommendations

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

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

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

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

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

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

No interaction studies have been performed.

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

4.6. Fertility, pregnancy and lactation

Pregnancy

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

Lactation

It is unknown whether TRADENAME is excreted in human milk.

Fertility

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

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4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Summary of safety profile

The safety of TRADENAME was evaluated in participants 16 years of age and older in 2 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.¹² Study BNT162-01 (Study 1) enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) enrolled approximately 44,000 participants, 12 years of age or older.¹²

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

The most frequent adverse reactions in participants 16 years of age and older (in order from highest to lowest frequencies) were pain at the injection site (>80%),¹⁴ fatigue (>60%),¹³ headache (>50%),¹³ myalgia and chills (>30%),¹³ arthralgia (>20%),¹³ pyrexia¹³ and injection site swelling¹⁴ (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A lower frequency of reactogenicity events was associated with greater age.¹⁵

Table 1. Adverse Drug Reactions^{13,14,16}

| System Organ Class | Adverse Drug Reactions |
|--|---|
| Blood and lymphatic system disorders | Lymphadenopathy |
| Immune system disorders | Anaphylaxis Hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema) |
| Nervous system disorders | Headache |
| Gastrointestinal disorders | Nausea |
| Musculoskeletal and connective tissue disorders | Arthralgia Myalgia |
| General disorders and administration site conditions | Pyrexia Chills Malaise Fatigue Injection site pain Injection site swelling Injection site redness |

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

4.9. Overdose

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

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacological class, therapeutic class

Vaccines

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

Mechanism of action

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

Efficacy in participants 16 years of age and older

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

In the Phase 2/3 portion approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of COVID-19 mRNA Vaccine or placebo separated by 21 days. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19 disease.^{12,27}

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

Table 2. Demographics (Population for the Primary Efficacy Endpoint)^{a,22}

| | TRADENAME (N=18,242) n (%) | Placebo (N=18,379) n (%) |
|---|---|---|
| Sex | | |
| Male | 9318 (51.1) | 9225 (50.2) |
| Female | 8924 (48.9) | 9154 (49.8) |
| Age (years) | | |
| Mean (SD) | 50.6 (15.70) | 50.4 (15.81) |
| Median | 52.0 | 52.0 |
| Min, max | (12, 89) | (12, 91) |
| Age group | | |
| 12 to 15 years | 46 (0.3) | 42 (0.2) |
| 16 to 17 years | 66 (0.4) | 68 (0.4) |
| 16 to 64 years | 14,216 (77.9) | 14,299 (77.8) |
| 65 to 74 years | 3176 (17.4) | 3226 (17.6) |
| ≥75 years | 804 (4.4) | 812 (4.4) |
| Race | | |
| White | 15,110 (82.8) | 15,301 (83.3) |
| Black or African American | 1617 (8.9) | 1617 (8.8) |
| American Indian or Alaska Native | 118 (0.6) | 106 (0.6) |
| Asian | 815 (4.5) | 810 (4.4) |
| Native Hawaiian or other Pacific Islander | 48 (0.3) | 29 (0.2) |
| Other ^b | 534 (2.9) | 516 (2.8) |
| Ethnicity | | |
| Hispanic or Latino | 4886 (26.8) | 4857 (26.4) |
| Not Hispanic or Latino | 13,253 (72.7) | 13,412 (73.0) |
| Not reported | 103 (0.6) | 110 (0.6) |
| Comorbidities^c | | |
| Yes | 8432 (46.2) | 8450 (46.0) |
| No | 9810 (53.8) | 9929 (54.0) |

- a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.
- b. Includes multiracial and not reported.
- c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease.
 - Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
 - Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

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- Obesity (body mass index ≥ 30 kg/m²)
- Diabetes (Type 1, Type 2, or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

Efficacy against COVID-19 disease

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

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 disease including those with 1 or more comorbidities that increase the risk of severe COVID-19 disease [e.g., asthma, body mass index (BMI) ≥ 30 kg/m², chronic pulmonary disease, diabetes mellitus, hypertension].^{23,24}

The vaccine efficacy information is presented in Table 3.

Table 3. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

| First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection^{*,34} | | | |
|---|---|---|--|
| Subgroup | TRADENAME N^a=18,198 Cases n^{1b} Surveillance Time^c (n^{2d}) | Placebo N^a=18,325 Cases n^{1b} Surveillance Time^c (n^{2d}) | Vaccine Efficacy % (95% CI) |
| All participants ^e | 8 2.214 (17,411) | 162 2.222 (17,511) | 95.0 (90.3, 97.6) ^f |
| 16 to 64 years | 7 1.706 (13,549) | 143 1.710 (13,618) | 95.1 (89.6, 98.1) ^g |
| ≥ 65 years | 1 0.508 (3848) | 19 0.511 (3880) | 94.7 (66.7, 99.9) ^g |
| 65 to 74 years | 1 0.406 (3074) | 14 0.406 (3095) | 92.9 (53.1, 99.8) ^g |
| ≥ 75 years | 0 0.102 (774) | 5 0.106 (785) | 100.0 (-13.1, 100.0) ^g |

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| First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection²⁸ | | | |
|---|---|---|--|
| Subgroup | TRADENAME N^a=19,965 Cases n1^b Surveillance Time^c (n2^d) | Placebo N^a=20,172 Cases n1^b Surveillance Time^c (n2^d) | Vaccine Efficacy % (95% CI) |
| All participants ^e | 9 2.332 (18,559) | 169 2.345 (18,708) | 94.6 (89.9, 97.3) ^f |
| 16 to 64 years | 8 1.802 (14,501) | 150 1.814 (14,627) | 94.6 (89.1, 97.7) ^g |
| ≥65 years | 1 0.530 (4044) | 19 0.532 (4067) | 94.7 (66.8, 99.9) ^g |
| 65 to 74 years | 1 0.424 (3239) | 14 0.423 (3255) | 92.9 (53.2, 99.8) ^g |
| ≥75 years | 0 0.106 (805) | 5 0.109 (812) | 100.0 (-12.1, 100.0) ^g |

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting). Abbreviations: NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

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

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

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The subgroup analyses of vaccine efficacy including important demographic characteristics is presented in Table 4.

Table 4. Subgroup Analyses of Vaccine Efficacy - Participants Without Evidence of Infection Prior to 7 Days After Dose 2 - Evaluable Efficacy Population³³

| Subgroup | TRADENAME N ^a =18,198 | Placebo N ^a =18,325 | Vaccine Efficacy % (95% CI) |
|---------------------------|---|---|--------------------------------|
| | Cases n1 ^b Surveillance Time ^c (n2 ^d) | Cases n1 ^b Surveillance Time ^c (n2 ^d) | |
| Sex | | | |
| Female | 5 1.090 (8536) | 81 1.114 (8749) | 93.7 (84.7, 98.0) |
| Male | 3 1.124 (8875) | 81 1.108 (8762) | 96.4 (88.9, 99.3) |
| Ethnicity | | | |
| Hispanic or Latino | 3 0.605 (4764) | 53 0.600 (4746) | 94.4 (82.7, 98.9) |
| Not Hispanic or Latino | 5 1.596 (12,548) | 109 1.608 (12,661) | 95.4 (88.9, 98.5) |
| Race | | | |
| Black or African American | 0 0.165 (1502) | 7 0.164 (1486) | 100.0 (31.2, 100.0) |
| White | 7 1.889 (14,504) | 146 1.903 (14,670) | 95.2 (89.8, 98.1) |
| All others ^f | 1 0.160 (1405) | 9 0.155 (1355) | 89.3 (22.6, 99.8) |

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

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The subgroup analyses of vaccine efficacy by risk status in participants is presented in Table 5.

Table 5. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population²³

| Efficacy Endpoint Subgroup | TRADENAME N ^a =18,198 | Placebo N ^a =18,325 | Vaccine Efficacy % (95% CI ^e) |
|--|---|---|--|
| | Cases n ^{1b} Surveillance Time ^c (n2 ^d) | Cases n ^{1b} Surveillance Time ^c (n2 ^d) | |
| First COVID-19 occurrence from 7 days after Dose 2 | | | |
| At risk ^f | | | |
| Yes | 4 1.025 (8030) | 86 1.025 (8029) | 95.3 (87.7, 98.8) |
| No | 4 1.189 (9381) | 76 1.197 (9482) | 94.7 (85.9, 98.6) |
| Age group (years) and at risk | | | |
| 16 to 64 and not at risk | 4 0.962 (7671) | 69 0.964 (7701) | 94.2 (84.4, 98.5) |
| 16 to 64 and at risk | 3 0.744 (5878) | 74 0.746 (5917) | 95.9 (87.6, 99.2) |
| ≥65 and not at risk | 0 0.227 (1701) | 7 0.233 (1771) | 100.0 (29.0, 100.0) |
| ≥65 and at risk | 1 0.281 (2147) | 12 0.279 (2109) | 91.7 (44.2, 99.8) |
| Obese ^g | | | |
| Yes | 3 0.763 (6000) | 67 0.782 (6103) | 95.4 (86.0, 99.1) |
| No | 5 1.451 (11,406) | 95 1.439 (11,404) | 94.8 (87.4, 98.3) |
| Age group (years) and obese | | | |
| 16 to 64 and not obese | 4 1.107 (8811) | 83 1.101 (8825) | 95.2 (87.3, 98.7) |
| 16 to 64 and obese | 3 0.598 (4734) | 60 0.609 (4789) | 94.9 (84.4, 99.0) |
| ≥65 and not obese | 1 0.343 (2582) | 12 0.338 (2567) | 91.8 (44.5, 99.8) |
| ≥65 and obese | 0 0.165 (1265) | 7 0.173 (1313) | 100.0 (27.1, 100.0) |

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

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Table 5. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population²³

| Efficacy Endpoint Subgroup | TRADENAME N ^a =18,198 | Placebo N ^a =18,325 | Vaccine Efficacy % (95% CI ^e) |
|----------------------------|---|---|--|
| | Cases n1 ^b Surveillance Time ^c (n2 ^d) | Cases n1 ^b Surveillance Time ^c (n2 ^d) | |

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

- a. N = number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of participants at risk for the endpoint.
- e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
- f. At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥ 30 kg/m²).
- g. Obese is defined as BMI ≥ 30 kg/m².

Efficacy against severe COVID-19

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

Efficacy against severe COVID-19 (as defined by the study protocol*) occurring after the first dose was 88.9% (95% CI: 20.1, 99.7) (1 case in COVID-19 mRNA Vaccine group and 9 cases in placebo group), with an estimated vaccine efficacy of 75.0% (95% CI: -152.6, 99.5) (1 case in COVID-19 mRNA Vaccine group and 4 cases in placebo group) against severe COVID-19 occurring at least 7 days after Dose 2.³⁶

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

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

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

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproduction and developmental toxicity.^{10,11}

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients^{2,3}

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

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

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

Cholesterol

Potassium chloride

Potassium dihydrogen phosphate

Sodium chloride

Disodium hydrogen phosphate dihydrate

Sucrose

Water for injections

6.2. Incompatibilities

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

6.3. Shelf life

Unopened vial

6 months at -90 °C to -60 °C.

Once removed from the freezer, the unopened vaccine can be stored for up to 5 days at 2 °C to 8 °C, and up to 2 hours at temperatures up to 30 °C, prior to use.

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

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

Diluted medicinal product

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

6.4. Special precautions for storage^{2,25}

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

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

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

Thawed vials can be handled in room light conditions.

When you are ready to thaw or use the vaccine

- Open-lid vial trays, or vial trays containing less than 195 vials removed from frozen storage (<-60 °C) may be at room temperature (<25 °C) for up to 3 minutes to remove vials or for transfer between ultra-low-temperature environments.
- Once a vial is removed from the vial tray, it should be thawed for use.
- After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transportation

If local redistribution of unopened vials is needed, and full trays containing vials cannot be transported at -90 °C to -60 °C, available data support transportation of 1 or more thawed vials at 2 °C to 8 °C for up to 12 hours. Any hours used for transport of unopened vials at 2 °C to 8 °C count against the 120-hour limit for storage at 2 °C to 8 °C.²⁹

If local redistribution of diluted medicinal product in vials or syringes is needed, available data support physical and chemical stability during transportation between 2 °C and 30 °C for up to 6 hours. Any hours used for transport of diluted medicinal product in vials or syringes at 2 °C to 30 °C count against the 6-hour limit for storage at 2 °C to 30 °C. Microbiological risks, particularly for prepared dosing syringes, are the responsibility of the preparer during transportation of diluted medicinal product.³⁰

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

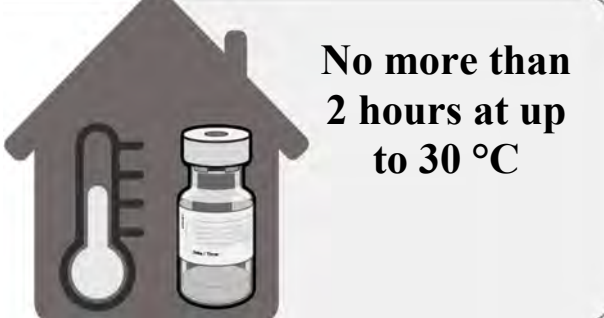
6.5. Nature and contents of container

Information to be provided by local subsidiary.

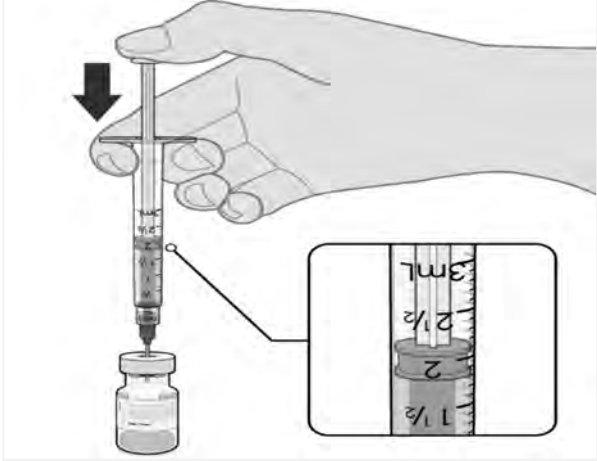
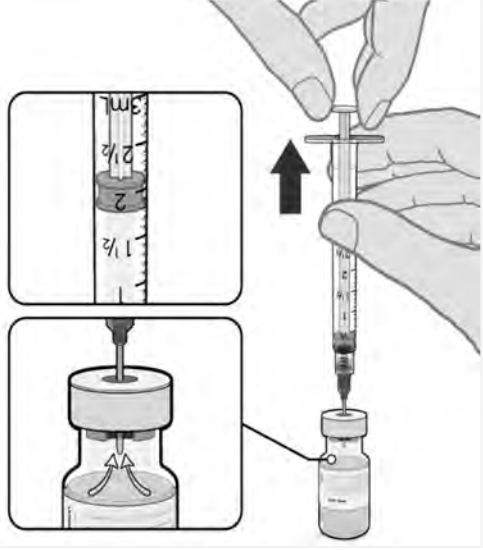
6.6. Special precautions for disposal and other handling^{2,3,26,35}

Handling instructions

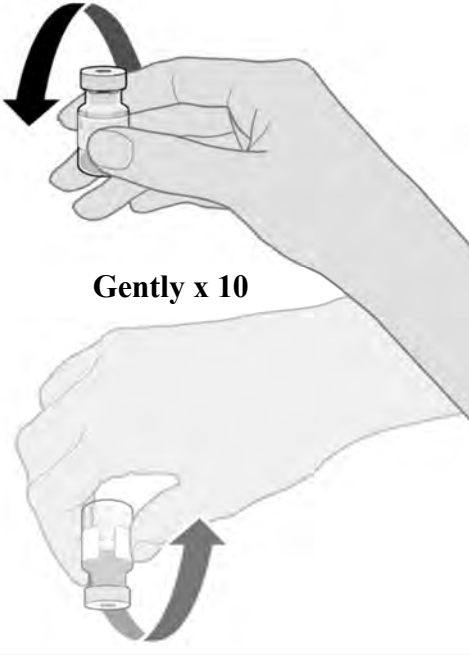

TRADENAME should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

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

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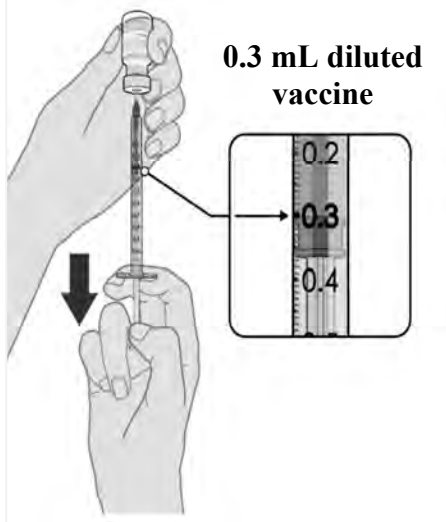
| DILUTION | |
|--|--|
|  <p>1.8 mL of 0.9% sodium chloride injection</p> | <ul style="list-style-type: none">• The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques. |
|  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

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

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PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY



- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of TRADENAME.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters.

If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 6 hours after dilution.

Disposal

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

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24. Baseline Charlson Comorbidities – ~38,000 Subjects for Phase 2/3 Analysis – Safety Population
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31. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status -- ~38000 Subjects for Phase 2/3 Analysis – Safety Population
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APPENDIX 2 Interval Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non-Medically Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class

PF-07302048 - ALL

Reporting Period: 01-FEB-2021 Through 28-FEB-2021
Total Number of Cases: 23558 (100%) (ALL) / 23558 (OVERALL)
Total Number of Adverse Events (PT): 91934 (ALL)

NON CT

Total Number of Cases: 23558
Total Number of Adverse Events (PT): 91934

| | | Number of Cases | Percentage (%) |
|-------------------------------------|---|-----------------|----------------|
| Sex | | | |
| | FEMALE | 17040 | 72.3 % |
| | MALE | 5317 | 22.6 % |
| | NO DATA | 1201 | 5.1 % |
| Age Range | | | |
| Min = 0.06 Years | 0 to 27 days | 3 | 0.0 % |
| Max = 107.0 Years | 28 days to 23 months | 26 | 0.1 % |
| | 2 to 11 years | 34 | 0.1 % |
| Mean = 52.6 | 12 to 17 years | 28 | 0.1 % |
| Median = 50.0 | 18 - 30 years | 2654 | 11.3 % |
| Standard Deviation = 19.52 | 31 - 50 years | 7579 | 32.2 % |
| n = 20433 | 51 - 64 years | 4526 | 19.2 % |
| | 65 - 74 years | 2234 | 9.5 % |
| | Greater than or equal to 75 years | 3544 | 15.0 % |
| | Unknown | 2927 | 12.4 % |
| | N/A - age range only applies to post-birth patients | 3 | 0.0 % |
| Country Where Event Occurred | | | |
| | UNITED KINGDOM | 7824 | 33.2 % |
| | UNITED STATES | 4711 | 20.0 % |
| | ITALY | 1884 | 8.0 % |
| | FRANCE | 1395 | 5.9 % |
| | GERMANY | 1182 | 5.0 % |
| | PORTUGAL | 695 | 3.0 % |
| | MEXICO | 585 | 2.5 % |
| | SPAIN | 563 | 2.4 % |
| | SWEDEN | 521 | 2.2 % |
| | GREECE | 520 | 2.2 % |
| | DENMARK | 429 | 1.8 % |
| | CZECH REPUBLIC | 287 | 1.2 % |
| | AUSTRIA | 267 | 1.1 % |
| | POLAND | 259 | 1.1 % |
| | NORWAY | 240 | 1.0 % |
| | IRELAND | 222 | 0.9 % |
| | FINLAND | 216 | 0.9 % |
| | BELGIUM | 193 | 0.8 % |
| | ISRAEL | 192 | 0.8 % |

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| | | Number of Cases | Percentage (%) |
|-------------------------------------|--------------------------------------|-----------------|----------------|
| Country Where Event Occurred | | | |
| | NETHERLANDS | 169 | 0.7 % |
| | ROMANIA | 157 | 0.7 % |
| | HUNGARY | 124 | 0.5 % |
| | CROATIA | 123 | 0.5 % |
| | CANADA | 121 | 0.5 % |
| | LATVIA | 114 | 0.5 % |
| | ESTONIA | 63 | 0.3 % |
| | SLOVENIA | 61 | 0.3 % |
| | CYPRUS | 53 | 0.2 % |
| | SLOVAKIA | 52 | 0.2 % |
| | BULGARIA | 49 | 0.2 % |
| | ICELAND | 40 | 0.2 % |
| | SWITZERLAND | 37 | 0.2 % |
| | MALTA | 31 | 0.1 % |
| | COSTA RICA | 26 | 0.1 % |
| | PUERTO RICO | 24 | 0.1 % |
| | SERBIA | 22 | 0.1 % |
| | UNITED ARAB EMIRATES | 18 | 0.1 % |
| | CHILE | 17 | 0.1 % |
| | LITHUANIA | 17 | 0.1 % |
| | SAUDI ARABIA | 12 | 0.1 % |
| | LUXEMBOURG | 11 | 0.0 % |
| | QATAR | 4 | 0.0 % |
| | ECUADOR | 3 | 0.0 % |
| | JORDAN | 3 | 0.0 % |
| | SINGAPORE | 3 | 0.0 % |
| | ANGOLA | 2 | 0.0 % |
| | BAHRAIN | 2 | 0.0 % |
| | HOLY SEE (VATICAN CITY STATE) | 2 | 0.0 % |
| | JAPAN | 2 | 0.0 % |
| | KUWAIT | 2 | 0.0 % |
| | NORTHERN MARIANA ISLANDS | 2 | 0.0 % |
| | FRENCH POLYNESIA | 1 | 0.0 % |
| | GIBRALTAR | 1 | 0.0 % |
| | LEBANON | 1 | 0.0 % |
| | OMAN | 1 | 0.0 % |
| | PANAMA | 1 | 0.0 % |
| | TURKS AND CAICOS ISLANDS | 1 | 0.0 % |
| | UNITED STATES MINOR OUTLYING ISLANDS | 1 | 0.0 % |
| Source | | | |
| | Clinical Study | 211 | 0.9 % |
| | Literature - Non Study | 1 | 0.0 % |
| | Solicited | 4 | 0.0 % |
| | Spontaneous | 23342 | 99.1 % |



| | | Number of Cases | Percentage (%) |
|-------------------------------|---|-----------------|----------------|
| Case Seriousness | | | |
| | SERIOUS | 15984 | 67.8 % |
| | NONSERIOUS | 7574 | 32.2 % |
| HP/Medically Confirmed | | | |
| | Yes | 13389 | 56.8 % |
| | No | 10169 | 43.2 % |
| Special Populations | Pregnant/Breastfeeding Women | | |
| | Yes | 158 | 0.7 % |
| | Pediatric Non EIU | | |
| | Yes | 73 | 0.3 % |
| | Elderly | | |
| | Yes | 5778 | 24.5 % |
| | Race/Ethnicity | | |
| | ASIAN - HISPANIC OR LATINO | 1 | 0.0 % |
| | ASIAN - NO DATA | 71 | 0.3 % |
| | ASIAN - NOT HISPANIC OR LATINO | 109 | 0.5 % |
| | BLACK - HISPANIC OR LATINO | 8 | 0.0 % |
| | BLACK - NO DATA | 112 | 0.5 % |
| | BLACK - NOT HISPANIC OR LATINO | 83 | 0.4 % |
| | BLACK - OTHER | 1 | 0.0 % |
| | CAUCASIAN - HISPANIC OR LATINO | 101 | 0.4 % |
| | CAUCASIAN - NO DATA | 1785 | 7.6 % |
| | CAUCASIAN - NOT HISPANIC OR LATINO | 1338 | 5.7 % |
| | NATIVE AMERICAN - HISPANIC OR LATINO | 5 | 0.0 % |
| | NATIVE AMERICAN - NO DATA | 14 | 0.1 % |
| | NATIVE AMERICAN - NOT HISPANIC OR LATINO | 10 | 0.0 % |
| | NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA | 6 | 0.0 % |
| | NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO | 10 | 0.0 % |
| | NO DATA - HISPANIC OR LATINO | 130 | 0.6 % |
| | NO DATA - NO DATA | 19715 | 83.7 % |
| | NO DATA - NOT HISPANIC OR LATINO | 40 | 0.2 % |
| | NO DATA - OTHER | 19 | 0.1 % |

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

PF-07302048 - ALL

Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23558 (100%) (ALL) / 23558 (OVERALL)

Total Number of Adverse Events (PT): 91934 (ALL)

NON CT

Total Number of Cases: 23558

Total Number of Adverse Events (PT): 91934

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------|--|-----------------|
| Headache | Nervous system disorders | 5699 (24.19%) |
| Pyrexia | General disorders and administration site conditions | 4272 (18.13%) |
| Fatigue | General disorders and administration site conditions | 4226 (17.94%) |
| Nausea | Gastrointestinal disorders | 2946 (12.51%) |
| Myalgia | Musculoskeletal and connective tissue disorders | 2903 (12.32%) |
| Chills | General disorders and administration site conditions | 2899 (12.31%) |
| Vaccination site pain | General disorders and administration site conditions | 2584 (10.97%) |
| Dizziness | Nervous system disorders | 2200 (9.34%) |
| Arthralgia | Musculoskeletal and connective tissue disorders | 2101 (8.92%) |
| Pain in extremity | Musculoskeletal and connective tissue disorders | 2058 (8.74%) |
| Pain | General disorders and administration site conditions | 1825 (7.75%) |
| Malaise | General disorders and administration site conditions | 1697 (7.20%) |
| Asthenia | General disorders and administration site conditions | 1549 (6.58%) |
| Dyspnoea | Respiratory, thoracic and mediastinal disorders | 1406 (5.97%) |
| Diarrhoea | Gastrointestinal disorders | 1132 (4.81%) |
| Lymphadenopathy | Blood and lymphatic system disorders | 1101 (4.67%) |
| COVID-19 | Infections and infestations | 1092 (4.64%) |
| Vomiting | Gastrointestinal disorders | 1037 (4.40%) |
| Drug ineffective | General disorders and administration site conditions | 1032 (4.38%) |
| Paraesthesia | Nervous system disorders | 875 (3.71%) |
| Pruritus | Skin and subcutaneous tissue disorders | 813 (3.45%) |
| Rash | Skin and subcutaneous tissue disorders | 784 (3.33%) |
| Tachycardia | Cardiac disorders | 713 (3.03%) |
| Cough | Respiratory, thoracic and mediastinal disorders | 676 (2.87%) |
| Erythema | Skin and subcutaneous tissue disorders | 642 (2.73%) |
| Oropharyngeal pain | Respiratory, thoracic and mediastinal disorders | 551 (2.34%) |
| Syncope | Nervous system disorders | 540 (2.29%) |
| Hypoaesthesia | Nervous system disorders | 531 (2.25%) |
| Hyperhidrosis | Skin and subcutaneous tissue disorders | 529 (2.25%) |
| Off label use | Injury, poisoning and procedural complications | 508 (2.16%) |
| Chest pain | General disorders and administration site conditions | 475 (2.02%) |
| Product use issue | Injury, poisoning and procedural complications | 474 (2.01%) |
| Back pain | Musculoskeletal and connective tissue disorders | 473 (2.01%) |
| Vaccination site erythema | General disorders and administration site conditions | 471 (2.00%) |
| Vaccination site swelling | General disorders and administration site conditions | 466 (1.98%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Hypertension | Vascular disorders | 447 (1.90%) |
| Tremor | Nervous system disorders | 444 (1.88%) |
| Urticaria | Skin and subcutaneous tissue disorders | 435 (1.85%) |
| Influenza like illness | General disorders and administration site conditions | 423 (1.80%) |
| Feeling hot | General disorders and administration site conditions | 417 (1.77%) |
| Decreased appetite | Metabolism and nutrition disorders | 401 (1.70%) |
| Feeling abnormal | General disorders and administration site conditions | 398 (1.69%) |
| Palpitations | Cardiac disorders | 383 (1.63%) |
| Hypersensitivity | Immune system disorders | 374 (1.59%) |
| Respiratory distress | Respiratory, thoracic and mediastinal disorders | 363 (1.54%) |
| Anaphylactic reaction | Immune system disorders | 361 (1.53%) |
| Abdominal pain | Gastrointestinal disorders | 348 (1.48%) |
| Peripheral swelling | General disorders and administration site conditions | 347 (1.47%) |
| Neck pain | Musculoskeletal and connective tissue disorders | 341 (1.45%) |
| Chest discomfort | General disorders and administration site conditions | 335 (1.42%) |
| Feeling cold | General disorders and administration site conditions | 334 (1.42%) |
| Vertigo | Ear and labyrinth disorders | 329 (1.40%) |
| Insomnia | Psychiatric disorders | 328 (1.39%) |
| Abdominal pain upper | Gastrointestinal disorders | 327 (1.39%) |
| Migraine | Nervous system disorders | 311 (1.32%) |
| Somnolence | Nervous system disorders | 307 (1.30%) |
| Facial paralysis | Nervous system disorders | 304 (1.29%) |
| Paraesthesia oral | Gastrointestinal disorders | 301 (1.28%) |
| Poor quality product administered | Injury, poisoning and procedural complications | 297 (1.26%) |
| Heart rate increased | Investigations | 295 (1.25%) |
| Blood pressure increased | Investigations | 284 (1.21%) |
| Rhinorrhoea | Respiratory, thoracic and mediastinal disorders | 279 (1.18%) |
| Lethargy | Nervous system disorders | 278 (1.18%) |
| Loss of consciousness | Nervous system disorders | 270 (1.15%) |
| Hypotension | Vascular disorders | 259 (1.10%) |
| Illness | General disorders and administration site conditions | 256 (1.09%) |
| Muscular weakness | Musculoskeletal and connective tissue disorders | 245 (1.04%) |
| Presyncope | Nervous system disorders | 245 (1.04%) |
| Death | General disorders and administration site conditions | 241 (1.02%) |
| Swelling | General disorders and administration site conditions | 241 (1.02%) |
| Musculoskeletal stiffness | Musculoskeletal and connective tissue disorders | 240 (1.02%) |
| Body temperature increased | Investigations | 233 (0.99%) |
| Swelling face | General disorders and administration site conditions | 231 (0.98%) |
| Confusional state | Psychiatric disorders | 228 (0.97%) |
| Dysgeusia | Nervous system disorders | 226 (0.96%) |
| Lymph node pain | Blood and lymphatic system disorders | 207 (0.88%) |
| Vaccination site warmth | General disorders and administration site conditions | 207 (0.88%) |
| Flushing | Vascular disorders | 203 (0.86%) |
| Inappropriate schedule of product administration | Injury, poisoning and procedural complications | 200 (0.85%) |
| Influenza | Infections and infestations | 198 (0.84%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Oxygen saturation decreased | Investigations | 198 (0.84%) |
| Limb discomfort | Musculoskeletal and connective tissue disorders | 185 (0.79%) |
| Axillary pain | General disorders and administration site conditions | 184 (0.78%) |
| Dysphagia | Gastrointestinal disorders | 180 (0.76%) |
| Herpes zoster | Infections and infestations | 179 (0.76%) |
| Rash erythematous | Skin and subcutaneous tissue disorders | 172 (0.73%) |
| Gait disturbance | General disorders and administration site conditions | 169 (0.72%) |
| Eye pain | Eye disorders | 168 (0.71%) |
| Muscle spasms | Musculoskeletal and connective tissue disorders | 166 (0.70%) |
| Vaccination site pruritus | General disorders and administration site conditions | 166 (0.70%) |
| Anxiety | Psychiatric disorders | 165 (0.70%) |
| Product temperature excursion issue | Product issues | 165 (0.70%) |
| Hyperpyrexia | General disorders and administration site conditions | 163 (0.69%) |
| Sensitive skin | Skin and subcutaneous tissue disorders | 163 (0.69%) |
| Vision blurred | Eye disorders | 162 (0.69%) |
| Hot flush | Vascular disorders | 159 (0.67%) |
| Seizure | Nervous system disorders | 159 (0.67%) |
| Lip swelling | Gastrointestinal disorders | 155 (0.66%) |
| Rash pruritic | Skin and subcutaneous tissue disorders | 154 (0.65%) |
| Angioedema | Skin and subcutaneous tissue disorders | 153 (0.65%) |
| Nasopharyngitis | Infections and infestations | 151 (0.64%) |
| Hypoaesthesia oral | Gastrointestinal disorders | 145 (0.62%) |
| Throat irritation | Respiratory, thoracic and mediastinal disorders | 144 (0.61%) |
| Fall | Injury, poisoning and procedural complications | 142 (0.60%) |
| Suspected COVID-19 | Infections and infestations | 142 (0.60%) |
| Swollen tongue | Gastrointestinal disorders | 142 (0.60%) |
| Tinnitus | Ear and labyrinth disorders | 140 (0.59%) |
| Condition aggravated | General disorders and administration site conditions | 138 (0.59%) |
| Discomfort | General disorders and administration site conditions | 138 (0.59%) |
| Bone pain | Musculoskeletal and connective tissue disorders | 132 (0.56%) |
| Dry mouth | Gastrointestinal disorders | 131 (0.56%) |
| Throat tightness | Respiratory, thoracic and mediastinal disorders | 129 (0.55%) |
| Burning sensation | Nervous system disorders | 129 (0.55%) |
| Throat tightness | Respiratory, thoracic and mediastinal disorders | 129 (0.55%) |
| Cold sweat | Skin and subcutaneous tissue disorders | 126 (0.53%) |
| Abdominal discomfort | Gastrointestinal disorders | 123 (0.52%) |
| Disease recurrence | General disorders and administration site conditions | 121 (0.51%) |
| Ear pain | Ear and labyrinth disorders | 120 (0.51%) |
| Pallor | Vascular disorders | 117 (0.50%) |
| Pharyngeal swelling | Respiratory, thoracic and mediastinal disorders | 117 (0.50%) |
| General physical health deterioration | General disorders and administration site conditions | 115 (0.49%) |
| Ageusia | Nervous system disorders | 114 (0.48%) |
| Product preparation error | Injury, poisoning and procedural complications | 114 (0.48%) |
| SARS-CoV-2 test positive | Investigations | 114 (0.48%) |
| Disturbance in attention | Nervous system disorders | 113 (0.48%) |
| Cerebrovascular accident | Nervous system disorders | 111 (0.47%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Nasal congestion | Respiratory, thoracic and mediastinal disorders | 111 (0.47%) |
| Balance disorder | Nervous system disorders | 110 (0.47%) |
| Hypertensive crisis | Vascular disorders | 108 (0.46%) |
| Pneumonia | Infections and infestations | 108 (0.46%) |
| Wheezing | Respiratory, thoracic and mediastinal disorders | 107 (0.45%) |
| Dysentery | Infections and infestations | 102 (0.43%) |
| Oedema | General disorders and administration site conditions | 102 (0.43%) |
| Night sweats | Skin and subcutaneous tissue disorders | 101 (0.43%) |
| Incorrect route of product administration | Injury, poisoning and procedural complications | 99 (0.42%) |
| Vaccination site reaction | General disorders and administration site conditions | 97 (0.41%) |
| Mobility decreased | Musculoskeletal and connective tissue disorders | 96 (0.41%) |
| Inflammation | General disorders and administration site conditions | 93 (0.39%) |
| Atrial fibrillation | Cardiac disorders | 92 (0.39%) |
| Anosmia | Nervous system disorders | 91 (0.39%) |
| Blood pressure decreased | Investigations | 90 (0.38%) |
| Vaccination site oedema | General disorders and administration site conditions | 90 (0.38%) |
| Eye swelling | Eye disorders | 89 (0.38%) |
| Asthma | Respiratory, thoracic and mediastinal disorders | 88 (0.37%) |
| Peripheral coldness | Vascular disorders | 88 (0.37%) |
| Dysphonia | Respiratory, thoracic and mediastinal disorders | 87 (0.37%) |
| Depressed level of consciousness | Nervous system disorders | 86 (0.37%) |
| Vaccination site mass | General disorders and administration site conditions | 85 (0.36%) |
| Visual impairment | Eye disorders | 85 (0.36%) |
| Arrhythmia | Cardiac disorders | 83 (0.35%) |
| Bronchospasm | Respiratory, thoracic and mediastinal disorders | 80 (0.34%) |
| Joint swelling | Musculoskeletal and connective tissue disorders | 79 (0.34%) |
| Musculoskeletal pain | Musculoskeletal and connective tissue disorders | 79 (0.34%) |
| Neuralgia | Nervous system disorders | 77 (0.33%) |
| Disorientation | Psychiatric disorders | 76 (0.32%) |
| Epistaxis | Respiratory, thoracic and mediastinal disorders | 75 (0.32%) |
| Underdose | Injury, poisoning and procedural complications | 75 (0.32%) |
| Feeling of body temperature change | General disorders and administration site conditions | 74 (0.31%) |
| Head discomfort | Nervous system disorders | 74 (0.31%) |
| Maternal exposure during pregnancy | Injury, poisoning and procedural complications | 74 (0.31%) |
| Epilepsy | Nervous system disorders | 73 (0.31%) |
| Sudden death | General disorders and administration site conditions | 73 (0.31%) |
| Anaphylactic shock | Immune system disorders | 72 (0.31%) |
| C-reactive protein increased | Investigations | 72 (0.31%) |
| Contusion | Injury, poisoning and procedural complications | 71 (0.30%) |
| Sleep disorder | Psychiatric disorders | 71 (0.30%) |
| Face oedema | General disorders and administration site conditions | 70 (0.30%) |
| Nervousness | Psychiatric disorders | 70 (0.30%) |
| Dizziness postural | Nervous system disorders | 69 (0.29%) |
| Overdose | Injury, poisoning and procedural complications | 67 (0.28%) |
| SARS-CoV-2 antibody test negative | Investigations | 67 (0.28%) |
| Hypersomnia | Nervous system disorders | 65 (0.28%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Urinary tract infection | Infections and infestations | 64 (0.27%) |
| Vaccination site induration | General disorders and administration site conditions | 64 (0.27%) |
| Rash macular | Skin and subcutaneous tissue disorders | 62 (0.26%) |
| Speech disorder | Nervous system disorders | 62 (0.26%) |
| Taste disorder | Nervous system disorders | 62 (0.26%) |
| Cardiac failure | Cardiac disorders | 61 (0.26%) |
| Vaccination site movement impairment | General disorders and administration site conditions | 61 (0.26%) |
| Laryngeal oedema | Respiratory, thoracic and mediastinal disorders | 60 (0.25%) |
| Photophobia | Eye disorders | 60 (0.25%) |
| Vaccination site inflammation | General disorders and administration site conditions | 60 (0.25%) |
| Vaccination site rash | General disorders and administration site conditions | 60 (0.25%) |
| Dysarthria | Nervous system disorders | 59 (0.25%) |
| Cellulitis | Infections and infestations | 58 (0.25%) |
| Joint range of motion decreased | Musculoskeletal and connective tissue disorders | 58 (0.25%) |
| Odynophagia | Gastrointestinal disorders | 58 (0.25%) |
| Pain in jaw | Musculoskeletal and connective tissue disorders | 57 (0.24%) |
| Bradycardia | Cardiac disorders | 56 (0.24%) |
| Loss of personal independence in daily activities | Social circumstances | 56 (0.24%) |
| Nodule | General disorders and administration site conditions | 56 (0.24%) |
| Facial paresis | Nervous system disorders | 55 (0.23%) |
| Myocardial infarction | Cardiac disorders | 55 (0.23%) |
| Pain of skin | Skin and subcutaneous tissue disorders | 55 (0.23%) |
| Sneezing | Respiratory, thoracic and mediastinal disorders | 55 (0.23%) |
| Allergy to vaccine | Immune system disorders | 54 (0.23%) |
| Hallucination | Psychiatric disorders | 54 (0.23%) |
| Lymphadenitis | Blood and lymphatic system disorders | 54 (0.23%) |
| Sensation of foreign body | General disorders and administration site conditions | 54 (0.23%) |
| Dehydration | Metabolism and nutrition disorders | 53 (0.22%) |
| Eye pruritus | Eye disorders | 53 (0.22%) |
| Oedema peripheral | General disorders and administration site conditions | 53 (0.22%) |
| Facial pain | General disorders and administration site conditions | 52 (0.22%) |
| Gait inability | General disorders and administration site conditions | 52 (0.22%) |
| Lip oedema | Gastrointestinal disorders | 51 (0.22%) |
| Movement disorder | Nervous system disorders | 51 (0.22%) |
| Oropharyngeal discomfort | Respiratory, thoracic and mediastinal disorders | 51 (0.22%) |
| Lacrimation increased | Eye disorders | 50 (0.21%) |
| Muscle fatigue | Musculoskeletal and connective tissue disorders | 50 (0.21%) |
| Ocular hyperaemia | Eye disorders | 50 (0.21%) |
| Oral herpes | Infections and infestations | 50 (0.21%) |
| Productive cough | Respiratory, thoracic and mediastinal disorders | 50 (0.21%) |
| Restlessness | Psychiatric disorders | 50 (0.21%) |
| Tongue oedema | Gastrointestinal disorders | 50 (0.21%) |
| Vaccination site paraesthesia | General disorders and administration site conditions | 50 (0.21%) |
| Thirst | General disorders and administration site conditions | 49 (0.21%) |
| Ear discomfort | Ear and labyrinth disorders | 48 (0.20%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Pulmonary embolism | Respiratory, thoracic and mediastinal disorders | 48 (0.20%) |
| Muscle twitching | Musculoskeletal and connective tissue disorders | 47 (0.20%) |
| Breast pain | Reproductive system and breast disorders | 46 (0.20%) |
| Dyspepsia | Gastrointestinal disorders | 46 (0.20%) |
| Dyspnoea exertional | Respiratory, thoracic and mediastinal disorders | 46 (0.20%) |
| Vaccination site bruising | General disorders and administration site conditions | 46 (0.20%) |
| Circulatory collapse | Vascular disorders | 45 (0.19%) |
| Induration | General disorders and administration site conditions | 45 (0.19%) |
| Tension headache | Nervous system disorders | 45 (0.19%) |
| Cardiac arrest | Cardiac disorders | 44 (0.19%) |
| Irritability | Psychiatric disorders | 44 (0.19%) |
| Tachypnoea | Respiratory, thoracic and mediastinal disorders | 44 (0.19%) |
| Local reaction | General disorders and administration site conditions | 43 (0.18%) |
| Blister | Skin and subcutaneous tissue disorders | 42 (0.18%) |
| Poor quality sleep | Nervous system disorders | 42 (0.18%) |
| Agitation | Psychiatric disorders | 41 (0.17%) |
| Dysstasia | Nervous system disorders | 41 (0.17%) |
| Flatulence | Gastrointestinal disorders | 41 (0.17%) |
| Transient ischaemic attack | Nervous system disorders | 41 (0.17%) |
| Angina pectoris | Cardiac disorders | 40 (0.17%) |
| Arthritis | Musculoskeletal and connective tissue disorders | 40 (0.17%) |
| Deafness | Ear and labyrinth disorders | 40 (0.17%) |
| Retching | Gastrointestinal disorders | 40 (0.17%) |
| Vaccination site hypersensitivity | General disorders and administration site conditions | 40 (0.17%) |
| Hyperventilation | Respiratory, thoracic and mediastinal disorders | 39 (0.17%) |
| Aphasia | Nervous system disorders | 38 (0.16%) |
| COVID-19 pneumonia | Infections and infestations | 38 (0.16%) |
| Joint stiffness | Musculoskeletal and connective tissue disorders | 38 (0.16%) |
| Mouth ulceration | Gastrointestinal disorders | 38 (0.16%) |
| Parosmia | Nervous system disorders | 38 (0.16%) |
| Product administered to patient of inappropriate age | Injury, poisoning and procedural complications | 38 (0.16%) |
| SARS-CoV-2 antibody test positive | Investigations | 38 (0.16%) |
| Eyelid oedema | Eye disorders | 37 (0.16%) |
| Hemiparesis | Nervous system disorders | 37 (0.16%) |
| Hyperthermia | General disorders and administration site conditions | 37 (0.16%) |
| Hypothermia | General disorders and administration site conditions | 37 (0.16%) |
| Musculoskeletal chest pain | Musculoskeletal and connective tissue disorders | 37 (0.16%) |
| Paralysis | Nervous system disorders | 37 (0.16%) |
| Periorbital swelling | Eye disorders | 37 (0.16%) |
| Product preparation issue | Injury, poisoning and procedural complications | 37 (0.16%) |
| Tenderness | General disorders and administration site conditions | 37 (0.16%) |
| Delirium | Psychiatric disorders | 36 (0.15%) |
| Glossodynia | Gastrointestinal disorders | 36 (0.15%) |
| Abdominal distension | Gastrointestinal disorders | 35 (0.15%) |
| Hypoxia | Respiratory, thoracic and mediastinal disorders | 35 (0.15%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Neuropathy peripheral | Nervous system disorders | 35 (0.15%) |
| Respiratory failure | Respiratory, thoracic and mediastinal disorders | 35 (0.15%) |
| Haemorrhage | Vascular disorders | 34 (0.14%) |
| Hypoacusis | Ear and labyrinth disorders | 34 (0.14%) |
| Infection | Infections and infestations | 34 (0.14%) |
| Memory impairment | Nervous system disorders | 34 (0.14%) |
| Oral pain | Gastrointestinal disorders | 34 (0.14%) |
| Rash papular | Skin and subcutaneous tissue disorders | 34 (0.14%) |
| Eye irritation | Eye disorders | 33 (0.14%) |
| Heart rate decreased | Investigations | 33 (0.14%) |
| Hypoglycaemia | Metabolism and nutrition disorders | 33 (0.14%) |
| Muscle tightness | Musculoskeletal and connective tissue disorders | 33 (0.14%) |
| Petechiae | Skin and subcutaneous tissue disorders | 33 (0.14%) |
| Cardiovascular disorder | Cardiac disorders | 32 (0.14%) |
| Dry throat | Respiratory, thoracic and mediastinal disorders | 32 (0.14%) |
| Eczema | Skin and subcutaneous tissue disorders | 32 (0.14%) |
| Pharyngeal paraesthesia | Respiratory, thoracic and mediastinal disorders | 32 (0.14%) |
| Renal pain | Renal and urinary disorders | 32 (0.14%) |
| Sinus tachycardia | Cardiac disorders | 32 (0.14%) |
| Skin burning sensation | Skin and subcutaneous tissue disorders | 32 (0.14%) |
| Circumstance or information capable of leading to medication error | Injury, poisoning and procedural complications | 31 (0.13%) |
| Crying | General disorders and administration site conditions | 31 (0.13%) |
| Depressed mood | Psychiatric disorders | 31 (0.13%) |
| Diplopia | Eye disorders | 31 (0.13%) |
| Exposure via breast milk | Injury, poisoning and procedural complications | 31 (0.13%) |
| Feeding disorder | Metabolism and nutrition disorders | 31 (0.13%) |
| Musculoskeletal discomfort | Musculoskeletal and connective tissue disorders | 31 (0.13%) |
| No adverse event | General disorders and administration site conditions | 31 (0.13%) |
| Oral discomfort | Gastrointestinal disorders | 31 (0.13%) |
| Sensory disturbance | Nervous system disorders | 31 (0.13%) |
| Skin discolouration | Skin and subcutaneous tissue disorders | 31 (0.13%) |
| Unresponsive to stimuli | Nervous system disorders | 31 (0.13%) |
| Vaccination complication | Injury, poisoning and procedural complications | 31 (0.13%) |
| Vaccination site haemorrhage | General disorders and administration site conditions | 31 (0.13%) |
| Asthenopia | Eye disorders | 30 (0.13%) |
| Hemiparaesthesia | Nervous system disorders | 30 (0.13%) |
| Ischaemic stroke | Nervous system disorders | 30 (0.13%) |
| Sinus headache | Nervous system disorders | 30 (0.13%) |
| Vaccination site discomfort | General disorders and administration site conditions | 30 (0.13%) |
| Blood glucose increased | Investigations | 29 (0.12%) |
| Cyanosis | Vascular disorders | 29 (0.12%) |
| Hyperaesthesia | Nervous system disorders | 29 (0.12%) |
| Middle insomnia | Psychiatric disorders | 29 (0.12%) |
| Respiratory rate increased | Investigations | 29 (0.12%) |
| Spinal pain | Musculoskeletal and connective tissue disorders | 29 (0.12%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Body temperature decreased | Investigations | 28 (0.12%) |
| Exposure during pregnancy | Injury, poisoning and procedural complications | 28 (0.12%) |
| Localised oedema | General disorders and administration site conditions | 28 (0.12%) |
| Rash maculo-papular | Skin and subcutaneous tissue disorders | 28 (0.12%) |
| Skin warm | Skin and subcutaneous tissue disorders | 28 (0.12%) |
| Thrombosis | Vascular disorders | 28 (0.12%) |
| Constipation | Gastrointestinal disorders | 27 (0.11%) |
| Injection site pain | General disorders and administration site conditions | 27 (0.11%) |
| Nightmare | Psychiatric disorders | 27 (0.11%) |
| Oral pruritus | Gastrointestinal disorders | 27 (0.11%) |
| Type I hypersensitivity | Immune system disorders | 27 (0.11%) |
| Blindness | Eye disorders | 26 (0.11%) |
| Dermatitis allergic | Skin and subcutaneous tissue disorders | 26 (0.11%) |
| Drug hypersensitivity | Immune system disorders | 26 (0.11%) |
| Extensive swelling of vaccinated limb | General disorders and administration site conditions | 26 (0.11%) |
| Generalised tonic-clonic seizure | Nervous system disorders | 26 (0.11%) |
| Haematochezia | Gastrointestinal disorders | 26 (0.11%) |
| Heart rate irregular | Investigations | 26 (0.11%) |
| Mouth swelling | Gastrointestinal disorders | 26 (0.11%) |
| Pulmonary pain | Respiratory, thoracic and mediastinal disorders | 26 (0.11%) |
| Respiratory disorder | Respiratory, thoracic and mediastinal disorders | 26 (0.11%) |
| Rhinitis | Infections and infestations | 26 (0.11%) |
| Therapeutic response unexpected | General disorders and administration site conditions | 26 (0.11%) |
| Vaccination site haematoma | General disorders and administration site conditions | 26 (0.11%) |
| Vaccination site lymphadenopathy | General disorders and administration site conditions | 26 (0.11%) |
| Weight decreased | Investigations | 26 (0.11%) |
| Conjunctivitis | Infections and infestations | 25 (0.11%) |
| Extrasystoles | Cardiac disorders | 25 (0.11%) |
| Migraine with aura | Nervous system disorders | 25 (0.11%) |
| Sensory loss | Nervous system disorders | 25 (0.11%) |
| Acute kidney injury | Renal and urinary disorders | 24 (0.10%) |
| Altered state of consciousness | Nervous system disorders | 24 (0.10%) |
| Amnesia | Nervous system disorders | 24 (0.10%) |
| Conjunctival haemorrhage | Eye disorders | 24 (0.10%) |
| Gastrointestinal pain | Gastrointestinal disorders | 24 (0.10%) |
| Lower respiratory tract infection | Infections and infestations | 24 (0.10%) |
| Photopsia | Eye disorders | 24 (0.10%) |
| Thrombocytopenia | Blood and lymphatic system disorders | 24 (0.10%) |
| Chronic obstructive pulmonary disease | Respiratory, thoracic and mediastinal disorders | 23 (0.10%) |
| Deep vein thrombosis | Vascular disorders | 23 (0.10%) |
| Dry skin | Skin and subcutaneous tissue disorders | 23 (0.10%) |
| Feeling drunk | General disorders and administration site conditions | 23 (0.10%) |
| Gastrointestinal disorder | Gastrointestinal disorders | 23 (0.10%) |
| Gastrooesophageal reflux disease | Gastrointestinal disorders | 23 (0.10%) |
| Head injury | Injury, poisoning and procedural complications | 23 (0.10%) |
| Mental impairment | Nervous system disorders | 23 (0.10%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Pericarditis | Cardiac disorders | 23 (0.10%) |
| Product administered at inappropriate site | Injury, poisoning and procedural complications | 23 (0.10%) |
| Sepsis | Infections and infestations | 23 (0.10%) |
| Sweating fever | Infections and infestations | 23 (0.10%) |
| Abdominal pain lower | Gastrointestinal disorders | 22 (0.09%) |
| Asymptomatic COVID-19 | Infections and infestations | 22 (0.09%) |
| Cognitive disorder | Nervous system disorders | 22 (0.09%) |
| Dysaesthesia | Nervous system disorders | 22 (0.09%) |
| Impaired work ability | Social circumstances | 22 (0.09%) |
| Injected limb mobility decreased | General disorders and administration site conditions | 22 (0.09%) |
| Monoplegia | Nervous system disorders | 22 (0.09%) |
| Painful respiration | Respiratory, thoracic and mediastinal disorders | 22 (0.09%) |
| Toothache | Gastrointestinal disorders | 22 (0.09%) |
| Vaccination site hypoaesthesia | General disorders and administration site conditions | 22 (0.09%) |
| Wrong technique in product usage process | Injury, poisoning and procedural complications | 22 (0.09%) |
| Cardiac flutter | Cardiac disorders | 21 (0.09%) |
| Hemiplegia | Nervous system disorders | 21 (0.09%) |
| Mental fatigue | Psychiatric disorders | 21 (0.09%) |
| Nervous system disorder | Nervous system disorders | 21 (0.09%) |
| Pneumonia aspiration | Respiratory, thoracic and mediastinal disorders | 21 (0.09%) |
| Renal failure | Renal and urinary disorders | 21 (0.09%) |
| Swelling of eyelid | Eye disorders | 21 (0.09%) |
| White blood cell count increased | Investigations | 21 (0.09%) |
| Aphonia | Respiratory, thoracic and mediastinal disorders | 20 (0.08%) |
| Blood pressure systolic increased | Investigations | 20 (0.08%) |
| Body temperature abnormal | Investigations | 20 (0.08%) |
| Dry eye | Eye disorders | 20 (0.08%) |
| Guillain-Barre syndrome | Nervous system disorders | 20 (0.08%) |
| Haematoma | Vascular disorders | 20 (0.08%) |
| Myocarditis | Cardiac disorders | 20 (0.08%) |
| Pulmonary oedema | Respiratory, thoracic and mediastinal disorders | 20 (0.08%) |
| Rheumatoid arthritis | Musculoskeletal and connective tissue disorders | 20 (0.08%) |
| Sinusitis | Infections and infestations | 20 (0.08%) |
| Skin disorder | Skin and subcutaneous tissue disorders | 20 (0.08%) |
| Stress | Psychiatric disorders | 20 (0.08%) |
| Tongue discomfort | Gastrointestinal disorders | 20 (0.08%) |
| Ventricular extrasystoles | Cardiac disorders | 20 (0.08%) |
| Acute myocardial infarction | Cardiac disorders | 19 (0.08%) |
| Antibody test abnormal | Investigations | 19 (0.08%) |
| Cerebral haemorrhage | Nervous system disorders | 19 (0.08%) |
| Coordination abnormal | Nervous system disorders | 19 (0.08%) |
| Dyskinesia | Nervous system disorders | 19 (0.08%) |
| Groin pain | Musculoskeletal and connective tissue disorders | 19 (0.08%) |
| Hypokinesia | Nervous system disorders | 19 (0.08%) |
| Menorrhagia | Reproductive system and breast disorders | 19 (0.08%) |
| Ocular discomfort | Eye disorders | 19 (0.08%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|------------------------------|--|-----------------|
| Rash vesicular | Skin and subcutaneous tissue disorders | 19 (0.08%) |
| Skin lesion | Skin and subcutaneous tissue disorders | 19 (0.08%) |
| Skin reaction | Skin and subcutaneous tissue disorders | 19 (0.08%) |
| Urinary incontinence | Renal and urinary disorders | 19 (0.08%) |
| Urinary retention | Renal and urinary disorders | 19 (0.08%) |
| Vaccination failure | Injury, poisoning and procedural complications | 19 (0.08%) |
| Vaccination site cellulitis | Infections and infestations | 19 (0.08%) |
| Depression | Psychiatric disorders | 18 (0.08%) |
| Exposure to SARS-CoV-2 | Injury, poisoning and procedural complications | 18 (0.08%) |
| Hyperglycaemia | Metabolism and nutrition disorders | 18 (0.08%) |
| Hypopnoea | Respiratory, thoracic and mediastinal disorders | 18 (0.08%) |
| Lip pruritus | Gastrointestinal disorders | 18 (0.08%) |
| Palatal oedema | Gastrointestinal disorders | 18 (0.08%) |
| Panic attack | Psychiatric disorders | 18 (0.08%) |
| Pharyngeal oedema | Respiratory, thoracic and mediastinal disorders | 18 (0.08%) |
| Rectal haemorrhage | Gastrointestinal disorders | 18 (0.08%) |
| Respiration abnormal | Respiratory, thoracic and mediastinal disorders | 18 (0.08%) |
| Supraventricular tachycardia | Cardiac disorders | 18 (0.08%) |
| Vaccination site urticaria | General disorders and administration site conditions | 18 (0.08%) |
| Abortion spontaneous | Pregnancy, puerperium and perinatal conditions | 17 (0.07%) |
| Dysuria | Renal and urinary disorders | 17 (0.07%) |
| Eructation | Gastrointestinal disorders | 17 (0.07%) |
| Immune thrombocytopenia | Blood and lymphatic system disorders | 17 (0.07%) |
| Laryngospasm | Respiratory, thoracic and mediastinal disorders | 17 (0.07%) |
| Musculoskeletal disorder | Musculoskeletal and connective tissue disorders | 17 (0.07%) |
| Photosensitivity reaction | Skin and subcutaneous tissue disorders | 17 (0.07%) |
| Skin irritation | Skin and subcutaneous tissue disorders | 17 (0.07%) |
| Tongue disorder | Gastrointestinal disorders | 17 (0.07%) |
| Vaginal haemorrhage | Reproductive system and breast disorders | 17 (0.07%) |
| Apathy | Psychiatric disorders | 16 (0.07%) |
| Eating disorder | Psychiatric disorders | 16 (0.07%) |
| Encephalitis | Infections and infestations | 16 (0.07%) |
| Eye disorder | Eye disorders | 16 (0.07%) |
| Gout | Metabolism and nutrition disorders | 16 (0.07%) |
| Hypotonia | Nervous system disorders | 16 (0.07%) |
| Panic reaction | Psychiatric disorders | 16 (0.07%) |
| Peripheral vascular disorder | Vascular disorders | 16 (0.07%) |
| Platelet count decreased | Investigations | 16 (0.07%) |
| Shock | Vascular disorders | 16 (0.07%) |
| Tongue pruritus | Gastrointestinal disorders | 16 (0.07%) |
| Abnormal dreams | Psychiatric disorders | 15 (0.06%) |
| Acute respiratory failure | Respiratory, thoracic and mediastinal disorders | 15 (0.06%) |
| Arthropathy | Musculoskeletal and connective tissue disorders | 15 (0.06%) |
| Blood pressure fluctuation | Vascular disorders | 15 (0.06%) |
| Ear infection | Infections and infestations | 15 (0.06%) |
| Haematemesis | Gastrointestinal disorders | 15 (0.06%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Haemoptysis | Respiratory, thoracic and mediastinal disorders | 15 (0.06%) |
| Hypokalaemia | Metabolism and nutrition disorders | 15 (0.06%) |
| Livedo reticularis | Skin and subcutaneous tissue disorders | 15 (0.06%) |
| Lung disorder | Respiratory, thoracic and mediastinal disorders | 15 (0.06%) |
| Lymphoedema | Vascular disorders | 15 (0.06%) |
| Menstrual disorder | Reproductive system and breast disorders | 15 (0.06%) |
| Neutropenia | Blood and lymphatic system disorders | 15 (0.06%) |
| Pollakiuria | Renal and urinary disorders | 15 (0.06%) |
| Respiratory arrest | Respiratory, thoracic and mediastinal disorders | 15 (0.06%) |
| Salivary hypersecretion | Gastrointestinal disorders | 15 (0.06%) |
| Stridor | Respiratory, thoracic and mediastinal disorders | 15 (0.06%) |
| Vaccination site joint movement impairment | General disorders and administration site conditions | 15 (0.06%) |
| Accidental exposure to product | Injury, poisoning and procedural complications | 14 (0.06%) |
| Anaphylactoid reaction | Immune system disorders | 14 (0.06%) |
| Cardio-respiratory arrest | Cardiac disorders | 14 (0.06%) |
| Cluster headache | Nervous system disorders | 14 (0.06%) |
| Cystitis | Infections and infestations | 14 (0.06%) |
| Eye haemorrhage | Eye disorders | 14 (0.06%) |
| Febrile convulsion | Nervous system disorders | 14 (0.06%) |
| Formication | Nervous system disorders | 14 (0.06%) |
| Gastric disorder | Gastrointestinal disorders | 14 (0.06%) |
| Hemianaesthesia | Nervous system disorders | 14 (0.06%) |
| Nasal discomfort | Respiratory, thoracic and mediastinal disorders | 14 (0.06%) |
| Pulse abnormal | Investigations | 14 (0.06%) |
| Respiratory tract infection | Infections and infestations | 14 (0.06%) |
| Sinus congestion | Respiratory, thoracic and mediastinal disorders | 14 (0.06%) |
| Sinus disorder | Respiratory, thoracic and mediastinal disorders | 14 (0.06%) |
| Sinus pain | Respiratory, thoracic and mediastinal disorders | 14 (0.06%) |
| Skin exfoliation | Skin and subcutaneous tissue disorders | 14 (0.06%) |
| Thinking abnormal | Psychiatric disorders | 14 (0.06%) |
| Trigeminal neuralgia | Nervous system disorders | 14 (0.06%) |
| Vaccination site discolouration | General disorders and administration site conditions | 14 (0.06%) |
| Aphthous ulcer | Gastrointestinal disorders | 13 (0.06%) |
| Bursitis | Musculoskeletal and connective tissue disorders | 13 (0.06%) |
| Deafness unilateral | Ear and labyrinth disorders | 13 (0.06%) |
| Dementia | Nervous system disorders | 13 (0.06%) |
| Diarrhoea haemorrhagic | Gastrointestinal disorders | 13 (0.06%) |
| Exposure via skin contact | Injury, poisoning and procedural complications | 13 (0.06%) |
| Eyelid ptosis | Eye disorders | 13 (0.06%) |
| Flank pain | Musculoskeletal and connective tissue disorders | 13 (0.06%) |
| Haematuria | Renal and urinary disorders | 13 (0.06%) |
| Incorrect dose administered | Injury, poisoning and procedural complications | 13 (0.06%) |
| Monoparesis | Nervous system disorders | 13 (0.06%) |
| Muscle contractions involuntary | Nervous system disorders | 13 (0.06%) |
| Periorbital oedema | Eye disorders | 13 (0.06%) |
| Sciatica | Nervous system disorders | 13 (0.06%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-------------------------------------|--|-----------------|
| Anaemia | Blood and lymphatic system disorders | 12 (0.05%) |
| Bedridden | Social circumstances | 12 (0.05%) |
| Breast swelling | Reproductive system and breast disorders | 12 (0.05%) |
| Cerebral infarction | Nervous system disorders | 12 (0.05%) |
| Dermatitis bullous | Skin and subcutaneous tissue disorders | 12 (0.05%) |
| Emotional distress | Psychiatric disorders | 12 (0.05%) |
| Eye injury | Injury, poisoning and procedural complications | 12 (0.05%) |
| Feeling jittery | General disorders and administration site conditions | 12 (0.05%) |
| Fibromyalgia | Musculoskeletal and connective tissue disorders | 12 (0.05%) |
| Gastroenteritis | Infections and infestations | 12 (0.05%) |
| Heart rate abnormal | Investigations | 12 (0.05%) |
| Menstruation delayed | Reproductive system and breast disorders | 12 (0.05%) |
| Multiple organ dysfunction syndrome | General disorders and administration site conditions | 12 (0.05%) |
| Muscle rigidity | Musculoskeletal and connective tissue disorders | 12 (0.05%) |
| Purpura | Skin and subcutaneous tissue disorders | 12 (0.05%) |
| Rales | Respiratory, thoracic and mediastinal disorders | 12 (0.05%) |
| Temperature regulation disorder | General disorders and administration site conditions | 12 (0.05%) |
| Tunnel vision | Nervous system disorders | 12 (0.05%) |
| Vaccination site nodule | General disorders and administration site conditions | 12 (0.05%) |
| Vasculitis | Vascular disorders | 12 (0.05%) |
| Alanine aminotransferase increased | Investigations | 11 (0.05%) |
| Asthmatic crisis | Respiratory, thoracic and mediastinal disorders | 11 (0.05%) |
| Blood glucose decreased | Investigations | 11 (0.05%) |
| Blood pressure abnormal | Investigations | 11 (0.05%) |
| Bradypnea | Psychiatric disorders | 11 (0.05%) |
| Bronchitis | Infections and infestations | 11 (0.05%) |
| Choking sensation | Respiratory, thoracic and mediastinal disorders | 11 (0.05%) |
| Coma | Nervous system disorders | 11 (0.05%) |
| Dermatitis | Skin and subcutaneous tissue disorders | 11 (0.05%) |
| Erythema multiforme | Skin and subcutaneous tissue disorders | 11 (0.05%) |
| Faeces discoloured | Gastrointestinal disorders | 11 (0.05%) |
| Haemoglobin decreased | Investigations | 11 (0.05%) |
| Hyperacusis | Ear and labyrinth disorders | 11 (0.05%) |
| Impaired driving ability | Social circumstances | 11 (0.05%) |
| Incomplete course of vaccination | Injury, poisoning and procedural complications | 11 (0.05%) |
| Limb mass | Musculoskeletal and connective tissue disorders | 11 (0.05%) |
| Lymphopenia | Blood and lymphatic system disorders | 11 (0.05%) |
| Motor dysfunction | Nervous system disorders | 11 (0.05%) |
| Muscle contracture | Musculoskeletal and connective tissue disorders | 11 (0.05%) |
| Myoclonus | Nervous system disorders | 11 (0.05%) |
| Nasal oedema | Respiratory, thoracic and mediastinal disorders | 11 (0.05%) |
| Neurological symptom | Nervous system disorders | 11 (0.05%) |
| Pneumonitis | Respiratory, thoracic and mediastinal disorders | 11 (0.05%) |
| Psoriasis | Skin and subcutaneous tissue disorders | 11 (0.05%) |
| Skin swelling | Skin and subcutaneous tissue disorders | 11 (0.05%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Sleep disorder due to general medical condition, insomnia type | Psychiatric disorders | 11 (0.05%) |
| Status epilepticus | Nervous system disorders | 11 (0.05%) |
| Tonsillar hypertrophy | Respiratory, thoracic and mediastinal disorders | 11 (0.05%) |
| Viral infection | Infections and infestations | 11 (0.05%) |
| Vomiting projectile | Gastrointestinal disorders | 11 (0.05%) |
| Accidental overdose | Injury, poisoning and procedural complications | 10 (0.04%) |
| Anal incontinence | Gastrointestinal disorders | 10 (0.04%) |
| Axillary mass | Musculoskeletal and connective tissue disorders | 10 (0.04%) |
| Blood urine present | Investigations | 10 (0.04%) |
| Cardiac disorder | Cardiac disorders | 10 (0.04%) |
| Cardiac failure acute | Cardiac disorders | 10 (0.04%) |
| Coronavirus infection | Infections and infestations | 10 (0.04%) |
| Ear disorder | Ear and labyrinth disorders | 10 (0.04%) |
| Ear pruritus | Ear and labyrinth disorders | 10 (0.04%) |
| Ear swelling | Ear and labyrinth disorders | 10 (0.04%) |
| Erectile dysfunction | Reproductive system and breast disorders | 10 (0.04%) |
| Fibrin D dimer increased | Investigations | 10 (0.04%) |
| Hypotonic-hyporesponsive episode | Nervous system disorders | 10 (0.04%) |
| International normalised ratio increased | Investigations | 10 (0.04%) |
| Limb injury | Injury, poisoning and procedural complications | 10 (0.04%) |
| Mass | General disorders and administration site conditions | 10 (0.04%) |
| Nuchal rigidity | Musculoskeletal and connective tissue disorders | 10 (0.04%) |
| Obstructive airways disorder | Respiratory, thoracic and mediastinal disorders | 10 (0.04%) |
| Ophthalmic herpes zoster | Infections and infestations | 10 (0.04%) |
| Paranasal sinus discomfort | Respiratory, thoracic and mediastinal disorders | 10 (0.04%) |
| Q fever | Infections and infestations | 10 (0.04%) |
| Rhinalgia | Respiratory, thoracic and mediastinal disorders | 10 (0.04%) |
| Stomatitis | Gastrointestinal disorders | 10 (0.04%) |
| Sudden hearing loss | Ear and labyrinth disorders | 10 (0.04%) |
| Suffocation feeling | Respiratory, thoracic and mediastinal disorders | 10 (0.04%) |
| Tachyarrhythmia | Cardiac disorders | 10 (0.04%) |
| Vertigo positional | Ear and labyrinth disorders | 10 (0.04%) |
| Vitreous floaters | Eye disorders | 10 (0.04%) |
| Acute coronary syndrome | Cardiac disorders | 9 (0.04%) |
| Acute pulmonary oedema | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Blindness transient | Eye disorders | 9 (0.04%) |
| Choking | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Chromaturia | Renal and urinary disorders | 9 (0.04%) |
| Crohn's disease | Gastrointestinal disorders | 9 (0.04%) |
| Diabetes mellitus | Metabolism and nutrition disorders | 9 (0.04%) |
| Diverticulitis | Infections and infestations | 9 (0.04%) |
| Dysmenorrhoea | Reproductive system and breast disorders | 9 (0.04%) |
| Dyspnoea at rest | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Fluid retention | Metabolism and nutrition disorders | 9 (0.04%) |
| Frequent bowel movements | Gastrointestinal disorders | 9 (0.04%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-------------------------------------|--|-----------------|
| Gingival pain | Gastrointestinal disorders | 9 (0.04%) |
| Initial insomnia | Psychiatric disorders | 9 (0.04%) |
| Joint effusion | Musculoskeletal and connective tissue disorders | 9 (0.04%) |
| Lymphangitis | Infections and infestations | 9 (0.04%) |
| Mental disorder | Psychiatric disorders | 9 (0.04%) |
| Metrorrhagia | Reproductive system and breast disorders | 9 (0.04%) |
| Myelitis transverse | Nervous system disorders | 9 (0.04%) |
| Neurogenic shock | Vascular disorders | 9 (0.04%) |
| Oedema mouth | Gastrointestinal disorders | 9 (0.04%) |
| Oral disorder | Gastrointestinal disorders | 9 (0.04%) |
| Paresis | Nervous system disorders | 9 (0.04%) |
| Pelvic pain | Reproductive system and breast disorders | 9 (0.04%) |
| Pharyngeal erythema | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Pharyngeal hypoaesthesia | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Pharyngitis | Infections and infestations | 9 (0.04%) |
| Pulmonary thrombosis | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Sluggishness | General disorders and administration site conditions | 9 (0.04%) |
| Tension | Psychiatric disorders | 9 (0.04%) |
| Tonic convulsion | Nervous system disorders | 9 (0.04%) |
| Upper-airway cough syndrome | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Upper respiratory tract congestion | Respiratory, thoracic and mediastinal disorders | 9 (0.04%) |
| Visual field defect | Nervous system disorders | 9 (0.04%) |
| White blood cell count decreased | Investigations | 9 (0.04%) |
| Abnormal faeces | Gastrointestinal disorders | 8 (0.03%) |
| Acne | Skin and subcutaneous tissue disorders | 8 (0.03%) |
| Aggression | Psychiatric disorders | 8 (0.03%) |
| Alopecia | Skin and subcutaneous tissue disorders | 8 (0.03%) |
| Appendicitis | Infections and infestations | 8 (0.03%) |
| Atrial flutter | Cardiac disorders | 8 (0.03%) |
| Blepharospasm | Eye disorders | 8 (0.03%) |
| Body height decreased | Investigations | 8 (0.03%) |
| Body temperature fluctuation | Investigations | 8 (0.03%) |
| Breast tenderness | Reproductive system and breast disorders | 8 (0.03%) |
| Communication disorder | Psychiatric disorders | 8 (0.03%) |
| Dizziness exertional | Nervous system disorders | 8 (0.03%) |
| Erysipelas | Infections and infestations | 8 (0.03%) |
| Eye discharge | Eye disorders | 8 (0.03%) |
| Eye oedema | Eye disorders | 8 (0.03%) |
| Facial neuralgia | Nervous system disorders | 8 (0.03%) |
| Gastrointestinal haemorrhage | Gastrointestinal disorders | 8 (0.03%) |
| General physical condition abnormal | Investigations | 8 (0.03%) |
| Gingival swelling | Gastrointestinal disorders | 8 (0.03%) |
| Hangover | General disorders and administration site conditions | 8 (0.03%) |
| Herpes simplex | Infections and infestations | 8 (0.03%) |
| Hypernatraemia | Metabolism and nutrition disorders | 8 (0.03%) |
| Immune system disorder | Immune system disorders | 8 (0.03%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-------------------------------------|--|-----------------|
| Incontinence | Renal and urinary disorders | 8 (0.03%) |
| Increased upper airway secretion | Respiratory, thoracic and mediastinal disorders | 8 (0.03%) |
| Irritable bowel syndrome | Gastrointestinal disorders | 8 (0.03%) |
| Labyrinthitis | Infections and infestations | 8 (0.03%) |
| Leukocytosis | Blood and lymphatic system disorders | 8 (0.03%) |
| Mechanical urticaria | Skin and subcutaneous tissue disorders | 8 (0.03%) |
| Melaena | Gastrointestinal disorders | 8 (0.03%) |
| Mood altered | Psychiatric disorders | 8 (0.03%) |
| Myelitis | Infections and infestations | 8 (0.03%) |
| Nystagmus | Nervous system disorders | 8 (0.03%) |
| Optic neuritis | Nervous system disorders | 8 (0.03%) |
| Palatal swelling | Gastrointestinal disorders | 8 (0.03%) |
| Personality change | Psychiatric disorders | 8 (0.03%) |
| Pharyngeal inflammation | Respiratory, thoracic and mediastinal disorders | 8 (0.03%) |
| Pleural effusion | Respiratory, thoracic and mediastinal disorders | 8 (0.03%) |
| Raynaud's phenomenon | Vascular disorders | 8 (0.03%) |
| Restless legs syndrome | Nervous system disorders | 8 (0.03%) |
| Skin mass | Skin and subcutaneous tissue disorders | 8 (0.03%) |
| Skin tightness | Skin and subcutaneous tissue disorders | 8 (0.03%) |
| Synovial cyst | Musculoskeletal and connective tissue disorders | 8 (0.03%) |
| Temperature intolerance | General disorders and administration site conditions | 8 (0.03%) |
| Transaminases increased | Investigations | 8 (0.03%) |
| Upper respiratory tract infection | Infections and infestations | 8 (0.03%) |
| Uveitis | Eye disorders | 8 (0.03%) |
| Wrong product administered | Injury, poisoning and procedural complications | 8 (0.03%) |
| Acute respiratory distress syndrome | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Anaesthesia oral | Gastrointestinal disorders | 7 (0.03%) |
| Arthritis reactive | Musculoskeletal and connective tissue disorders | 7 (0.03%) |
| Aspiration | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Ataxia | Nervous system disorders | 7 (0.03%) |
| Autoimmune disorder | Immune system disorders | 7 (0.03%) |
| Cardiac failure congestive | Cardiac disorders | 7 (0.03%) |
| Cheilitis | Gastrointestinal disorders | 7 (0.03%) |
| Deafness neurosensory | Ear and labyrinth disorders | 7 (0.03%) |
| Drooling | Nervous system disorders | 7 (0.03%) |
| Electrocardiogram abnormal | Investigations | 7 (0.03%) |
| Erythema of eyelid | Eye disorders | 7 (0.03%) |
| Eye movement disorder | Eye disorders | 7 (0.03%) |
| Faeces soft | Gastrointestinal disorders | 7 (0.03%) |
| Fear | Psychiatric disorders | 7 (0.03%) |
| Haemorrhagic stroke | Nervous system disorders | 7 (0.03%) |
| Hallucination, visual | Psychiatric disorders | 7 (0.03%) |
| Hepatic pain | Hepatobiliary disorders | 7 (0.03%) |
| Herpes virus infection | Infections and infestations | 7 (0.03%) |
| Hypophagia | Metabolism and nutrition disorders | 7 (0.03%) |
| Kidney infection | Infections and infestations | 7 (0.03%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Mouth haemorrhage | Gastrointestinal disorders | 7 (0.03%) |
| Muscle strain | Injury, poisoning and procedural complications | 7 (0.03%) |
| Oropharyngeal oedema | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Orthostatic hypotension | Vascular disorders | 7 (0.03%) |
| Oxygen saturation abnormal | Investigations | 7 (0.03%) |
| Pleurisy | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Pleuritic pain | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Polydipsia | Metabolism and nutrition disorders | 7 (0.03%) |
| Polymyalgia rheumatica | Musculoskeletal and connective tissue disorders | 7 (0.03%) |
| Psychomotor hyperactivity | Nervous system disorders | 7 (0.03%) |
| Pulmonary congestion | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Pustule | Infections and infestations | 7 (0.03%) |
| Rash morbilliform | Skin and subcutaneous tissue disorders | 7 (0.03%) |
| Red blood cell sedimentation rate increased | Investigations | 7 (0.03%) |
| Respiratory tract oedema | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Throat clearing | Respiratory, thoracic and mediastinal disorders | 7 (0.03%) |
| Troponin increased | Investigations | 7 (0.03%) |
| Type IV hypersensitivity reaction | Immune system disorders | 7 (0.03%) |
| Vaccination site hyperaesthesia | General disorders and administration site conditions | 7 (0.03%) |
| Vaccination site irritation | General disorders and administration site conditions | 7 (0.03%) |
| Vaccination site joint erythema | General disorders and administration site conditions | 7 (0.03%) |
| Vaccination site vesicles | General disorders and administration site conditions | 7 (0.03%) |
| Ventricular tachycardia | Cardiac disorders | 7 (0.03%) |
| Wound | Injury, poisoning and procedural complications | 7 (0.03%) |
| Asphyxia | Respiratory, thoracic and mediastinal disorders | 6 (0.03%) |
| Atelectasis | Respiratory, thoracic and mediastinal disorders | 6 (0.03%) |
| Atrioventricular block complete | Cardiac disorders | 6 (0.03%) |
| Bundle branch block right | Cardiac disorders | 6 (0.03%) |
| Cardiogenic shock | Cardiac disorders | 6 (0.03%) |
| Clonus | Nervous system disorders | 6 (0.03%) |
| Costochondritis | Musculoskeletal and connective tissue disorders | 6 (0.03%) |
| Diabetes mellitus inadequate control | Metabolism and nutrition disorders | 6 (0.03%) |
| Dissociation | Psychiatric disorders | 6 (0.03%) |
| Drug interaction | General disorders and administration site conditions | 6 (0.03%) |
| Encephalopathy | Nervous system disorders | 6 (0.03%) |
| Foreign body sensation in eyes | Eye disorders | 6 (0.03%) |
| Gastritis | Gastrointestinal disorders | 6 (0.03%) |
| Hallucination, auditory | Psychiatric disorders | 6 (0.03%) |
| Herpes ophthalmic | Infections and infestations | 6 (0.03%) |
| Hyperkalaemia | Metabolism and nutrition disorders | 6 (0.03%) |
| Hyponatraemia | Metabolism and nutrition disorders | 6 (0.03%) |
| Hyposmia | Nervous system disorders | 6 (0.03%) |
| Immunisation anxiety related reaction | Psychiatric disorders | 6 (0.03%) |
| Injection related reaction | Injury, poisoning and procedural complications | 6 (0.03%) |
| Irregular breathing | Respiratory, thoracic and mediastinal disorders | 6 (0.03%) |
| Jaundice | Hepatobiliary disorders | 6 (0.03%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Lip pain | Gastrointestinal disorders | 6 (0.03%) |
| Liver function test increased | Investigations | 6 (0.03%) |
| Lung infiltration | Respiratory, thoracic and mediastinal disorders | 6 (0.03%) |
| Mastitis | Infections and infestations | 6 (0.03%) |
| Micturition urgency | Renal and urinary disorders | 6 (0.03%) |
| Mood swings | Psychiatric disorders | 6 (0.03%) |
| Neck mass | Musculoskeletal and connective tissue disorders | 6 (0.03%) |
| Nerve compression | Nervous system disorders | 6 (0.03%) |
| Nerve injury | Injury, poisoning and procedural complications | 6 (0.03%) |
| Neuralgic amyotrophy | Nervous system disorders | 6 (0.03%) |
| Neutrophil count increased | Investigations | 6 (0.03%) |
| Oral candidiasis | Infections and infestations | 6 (0.03%) |
| Oral mucosal blistering | Gastrointestinal disorders | 6 (0.03%) |
| Pancreatitis acute | Gastrointestinal disorders | 6 (0.03%) |
| Periarthritis | Musculoskeletal and connective tissue disorders | 6 (0.03%) |
| Petit mal epilepsy | Nervous system disorders | 6 (0.03%) |
| Piloerection | Skin and subcutaneous tissue disorders | 6 (0.03%) |
| Postural orthostatic tachycardia syndrome | Cardiac disorders | 6 (0.03%) |
| Product administration error | Injury, poisoning and procedural complications | 6 (0.03%) |
| Renal disorder | Renal and urinary disorders | 6 (0.03%) |
| Renal impairment | Renal and urinary disorders | 6 (0.03%) |
| Respiratory fatigue | Respiratory, thoracic and mediastinal disorders | 6 (0.03%) |
| Seasonal allergy | Immune system disorders | 6 (0.03%) |
| Sedation | Nervous system disorders | 6 (0.03%) |
| Septic shock | Infections and infestations | 6 (0.03%) |
| Tendonitis | Musculoskeletal and connective tissue disorders | 6 (0.03%) |
| Tendon pain | Musculoskeletal and connective tissue disorders | 6 (0.03%) |
| Thrombophlebitis superficial | Vascular disorders | 6 (0.03%) |
| Tonic clonic movements | Nervous system disorders | 6 (0.03%) |
| Trigeminal nerve disorder | Nervous system disorders | 6 (0.03%) |
| Trismus | Musculoskeletal and connective tissue disorders | 6 (0.03%) |
| Urinary tract infection bacterial | Infections and infestations | 6 (0.03%) |
| Vaccination site infection | Infections and infestations | 6 (0.03%) |
| Vaccination site joint pain | General disorders and administration site conditions | 6 (0.03%) |
| Vlth nerve paralysis | Nervous system disorders | 6 (0.03%) |
| | | 6 (0.03%) |
| Abdominal rigidity | Gastrointestinal disorders | 5 (0.02%) |
| Abnormal behaviour | Psychiatric disorders | 5 (0.02%) |
| Adnexa uteri pain | Reproductive system and breast disorders | 5 (0.02%) |
| Anaesthesia | Nervous system disorders | 5 (0.02%) |
| Ankylosing spondylitis | Musculoskeletal and connective tissue disorders | 5 (0.02%) |
| Apnoea | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |
| Aspartate aminotransferase increased | Investigations | 5 (0.02%) |
| Autoimmune thyroiditis | Endocrine disorders | 5 (0.02%) |
| Back disorder | Musculoskeletal and connective tissue disorders | 5 (0.02%) |
| Bladder disorder | Renal and urinary disorders | 5 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-------------------------------------|---|-----------------|
| Blood creatinine increased | Investigations | 5 (0.02%) |
| Breast mass | Reproductive system and breast disorders | 5 (0.02%) |
| Breath sounds abnormal | Investigations | 5 (0.02%) |
| Catarrh | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |
| Colitis | Gastrointestinal disorders | 5 (0.02%) |
| Diabetic ketoacidosis | Metabolism and nutrition disorders | 5 (0.02%) |
| Dysphemia | Psychiatric disorders | 5 (0.02%) |
| Dystonia | Nervous system disorders | 5 (0.02%) |
| Euphoric mood | Psychiatric disorders | 5 (0.02%) |
| Eyelid pain | Eye disorders | 5 (0.02%) |
| Facial discomfort | General disorders and administration site conditions | 5 (0.02%) |
| Food refusal | Metabolism and nutrition disorders | 5 (0.02%) |
| Gamma-glutamyltransferase increased | Investigations | 5 (0.02%) |
| Generalised oedema | General disorders and administration site conditions | 5 (0.02%) |
| Hallucinations, mixed | Psychiatric disorders | 5 (0.02%) |
| Hepatitis acute | Hepatobiliary disorders | 5 (0.02%) |
| Herpes zoster reactivation | Infections and infestations | 5 (0.02%) |
| Hyperaemia | Vascular disorders | 5 (0.02%) |
| Hyperleukocytosis | Blood and lymphatic system disorders | 5 (0.02%) |
| Hypogeusia | Nervous system disorders | 5 (0.02%) |
| Incorrect dosage administered | Injury, poisoning and procedural complications | 5 (0.02%) |
| Increased bronchial secretion | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |
| Injection site erythema | General disorders and administration site conditions | 5 (0.02%) |
| Injection site warmth | General disorders and administration site conditions | 5 (0.02%) |
| Laryngitis | Infections and infestations | 5 (0.02%) |
| Lip blister | Gastrointestinal disorders | 5 (0.02%) |
| Lip dry | Gastrointestinal disorders | 5 (0.02%) |
| Liquid product physical issue | Product issues | 5 (0.02%) |
| Listless | Psychiatric disorders | 5 (0.02%) |
| Liver function test abnormal | Investigations | 5 (0.02%) |
| Lividity | Skin and subcutaneous tissue disorders | 5 (0.02%) |
| Localised infection | Infections and infestations | 5 (0.02%) |
| Loss of control of legs | General disorders and administration site conditions | 5 (0.02%) |
| Lymphoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 (0.02%) |
| Macroglossia | Congenital, familial and genetic disorders | 5 (0.02%) |
| Metastases to lymph nodes | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 (0.02%) |
| Miliaria | Skin and subcutaneous tissue disorders | 5 (0.02%) |
| Miosis | Eye disorders | 5 (0.02%) |
| Motion sickness | Ear and labyrinth disorders | 5 (0.02%) |
| Multiple sclerosis relapse | Nervous system disorders | 5 (0.02%) |
| Muscle discomfort | Musculoskeletal and connective tissue disorders | 5 (0.02%) |
| Mydriasis | Eye disorders | 5 (0.02%) |
| Myositis | Musculoskeletal and connective tissue disorders | 5 (0.02%) |
| Nasal pruritus | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|------------------------------------|--|-----------------|
| Nipple pain | Reproductive system and breast disorders | 5 (0.02%) |
| Oesophageal pain | Gastrointestinal disorders | 5 (0.02%) |
| Oropharyngeal blistering | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |
| Osteoarthritis | Musculoskeletal and connective tissue disorders | 5 (0.02%) |
| Papule | Skin and subcutaneous tissue disorders | 5 (0.02%) |
| Pemphigoid | Skin and subcutaneous tissue disorders | 5 (0.02%) |
| Peripheral sensory neuropathy | Nervous system disorders | 5 (0.02%) |
| Polyarthritis | Musculoskeletal and connective tissue disorders | 5 (0.02%) |
| Polyuria | Renal and urinary disorders | 5 (0.02%) |
| Rash pustular | Infections and infestations | 5 (0.02%) |
| Reaction to excipient | Immune system disorders | 5 (0.02%) |
| Respiratory depression | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |
| Respiratory rate decreased | Investigations | 5 (0.02%) |
| Respiratory tract congestion | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |
| Rhinitis allergic | Respiratory, thoracic and mediastinal disorders | 5 (0.02%) |
| Scratch | Injury, poisoning and procedural complications | 5 (0.02%) |
| Secretion discharge | General disorders and administration site conditions | 5 (0.02%) |
| Sialoadenitis | Infections and infestations | 5 (0.02%) |
| Skin abrasion | Injury, poisoning and procedural complications | 5 (0.02%) |
| Skin laceration | Injury, poisoning and procedural complications | 5 (0.02%) |
| Sleep paralysis | Nervous system disorders | 5 (0.02%) |
| Slow speech | Nervous system disorders | 5 (0.02%) |
| Stevens-Johnson syndrome | Skin and subcutaneous tissue disorders | 5 (0.02%) |
| Stupor | Nervous system disorders | 5 (0.02%) |
| Suicidal ideation | Psychiatric disorders | 5 (0.02%) |
| Temporomandibular joint syndrome | Musculoskeletal and connective tissue disorders | 5 (0.02%) |
| Tonsillitis | Infections and infestations | 5 (0.02%) |
| Urosepsis | Infections and infestations | 5 (0.02%) |
| Vaccination site abscess | Infections and infestations | 5 (0.02%) |
| Vaccination site coldness | General disorders and administration site conditions | 5 (0.02%) |
| Ventricular fibrillation | Cardiac disorders | 5 (0.02%) |
| Vestibular neuronitis | Infections and infestations | 5 (0.02%) |
| Visual acuity reduced | Eye disorders | 5 (0.02%) |
| Vitreous detachment | Eye disorders | 5 (0.02%) |
| Abnormal sensation in eye | Eye disorders | 4 (0.02%) |
| Adverse drug reaction | General disorders and administration site conditions | 4 (0.02%) |
| Adverse event | General disorders and administration site conditions | 4 (0.02%) |
| Anal haemorrhage | Gastrointestinal disorders | 4 (0.02%) |
| Atrial tachycardia | Cardiac disorders | 4 (0.02%) |
| Auricular swelling | Ear and labyrinth disorders | 4 (0.02%) |
| Autoimmune haemolytic anaemia | Blood and lymphatic system disorders | 4 (0.02%) |
| Autonomic nervous system imbalance | Nervous system disorders | 4 (0.02%) |
| Behaviour disorder | Psychiatric disorders | 4 (0.02%) |
| Blepharitis | Eye disorders | 4 (0.02%) |
| Blindness unilateral | Eye disorders | 4 (0.02%) |
| Blood pressure diastolic increased | Investigations | 4 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------------|--|-----------------|
| Bowel movement irregularity | Gastrointestinal disorders | 4 (0.02%) |
| Bradykinesia | Nervous system disorders | 4 (0.02%) |
| Brain oedema | Nervous system disorders | 4 (0.02%) |
| Breast discharge | Reproductive system and breast disorders | 4 (0.02%) |
| Butterfly rash | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Cachexia | Metabolism and nutrition disorders | 4 (0.02%) |
| Cardiopulmonary failure | Cardiac disorders | 4 (0.02%) |
| Cerebral haematoma | Nervous system disorders | 4 (0.02%) |
| Chapped lips | Gastrointestinal disorders | 4 (0.02%) |
| Chillblains | Injury, poisoning and procedural complications | 4 (0.02%) |
| Coronavirus test positive | Investigations | 4 (0.02%) |
| Cranial nerve disorder | Nervous system disorders | 4 (0.02%) |
| Cutaneous vasculitis | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Cystitis haemorrhagic | Renal and urinary disorders | 4 (0.02%) |
| Dermatitis atopic | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Disease progression | General disorders and administration site conditions | 4 (0.02%) |
| Disorganised speech | Psychiatric disorders | 4 (0.02%) |
| Drug eruption | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Emotional disorder | Psychiatric disorders | 4 (0.02%) |
| Enlarged uvula | Gastrointestinal disorders | 4 (0.02%) |
| Eosinophil count increased | Investigations | 4 (0.02%) |
| Epigastric discomfort | Gastrointestinal disorders | 4 (0.02%) |
| Erythema nodosum | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Eye haematoma | Eye disorders | 4 (0.02%) |
| Eye infection | Infections and infestations | 4 (0.02%) |
| Eyelid function disorder | Eye disorders | 4 (0.02%) |
| Face injury | Injury, poisoning and procedural complications | 4 (0.02%) |
| Facial nerve disorder | Nervous system disorders | 4 (0.02%) |
| Facial spasm | Nervous system disorders | 4 (0.02%) |
| Foaming at mouth | General disorders and administration site conditions | 4 (0.02%) |
| Furuncle | Infections and infestations | 4 (0.02%) |
| Gastrointestinal sounds abnormal | Gastrointestinal disorders | 4 (0.02%) |
| Gaze palsy | Eye disorders | 4 (0.02%) |
| Glomerular filtration rate decreased | Investigations | 4 (0.02%) |
| Grip strength decreased | Investigations | 4 (0.02%) |
| Haemorrhoids | Gastrointestinal disorders | 4 (0.02%) |
| Hemidysaesthesia | Nervous system disorders | 4 (0.02%) |
| Hepatic enzyme increased | Investigations | 4 (0.02%) |
| Hepatitis | Hepatobiliary disorders | 4 (0.02%) |
| Hiccups | Respiratory, thoracic and mediastinal disorders | 4 (0.02%) |
| Hypoaesthesia eye | Eye disorders | 4 (0.02%) |
| Hypoaesthesia teeth | Gastrointestinal disorders | 4 (0.02%) |
| Hypoperfusion | Vascular disorders | 4 (0.02%) |
| Illrd nerve paralysis | Nervous system disorders | 4 (0.02%) |
| Immobile | Social circumstances | 4 (0.02%) |
| Increased tendency to bruise | Blood and lymphatic system disorders | 4 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Inflammatory marker increased | Investigations | 4 (0.02%) |
| Injection site rash | General disorders and administration site conditions | 4 (0.02%) |
| International normalised ratio decreased | Investigations | 4 (0.02%) |
| Interstitial lung disease | Respiratory, thoracic and mediastinal disorders | 4 (0.02%) |
| Intestinal obstruction | Gastrointestinal disorders | 4 (0.02%) |
| Intranasal paraesthesia | Respiratory, thoracic and mediastinal disorders | 4 (0.02%) |
| Joint injury | Injury, poisoning and procedural complications | 4 (0.02%) |
| Joint warmth | Musculoskeletal and connective tissue disorders | 4 (0.02%) |
| Language disorder | Nervous system disorders | 4 (0.02%) |
| Laryngeal dyspnoea | Respiratory, thoracic and mediastinal disorders | 4 (0.02%) |
| Left ventricular failure | Cardiac disorders | 4 (0.02%) |
| Meniere's disease | Ear and labyrinth disorders | 4 (0.02%) |
| Menstruation irregular | Reproductive system and breast disorders | 4 (0.02%) |
| Mucous stools | Gastrointestinal disorders | 4 (0.02%) |
| Muscle swelling | Musculoskeletal and connective tissue disorders | 4 (0.02%) |
| Myocardial ischaemia | Cardiac disorders | 4 (0.02%) |
| Near death experience | Psychiatric disorders | 4 (0.02%) |
| Non-cardiac chest pain | General disorders and administration site conditions | 4 (0.02%) |
| Noninfective gingivitis | Gastrointestinal disorders | 4 (0.02%) |
| Occipital neuralgia | Nervous system disorders | 4 (0.02%) |
| Occupational exposure to product | Injury, poisoning and procedural complications | 4 (0.02%) |
| Oedema mucosal | General disorders and administration site conditions | 4 (0.02%) |
| Pancreatitis | Gastrointestinal disorders | 4 (0.02%) |
| Pancytopenia | Blood and lymphatic system disorders | 4 (0.02%) |
| Paraparesis | Nervous system disorders | 4 (0.02%) |
| Parotitis | Infections and infestations | 4 (0.02%) |
| Pericardial effusion | Cardiac disorders | 4 (0.02%) |
| Peroneal nerve palsy | Nervous system disorders | 4 (0.02%) |
| Pharyngeal disorder | Respiratory, thoracic and mediastinal disorders | 4 (0.02%) |
| Pharyngeal ulceration | Respiratory, thoracic and mediastinal disorders | 4 (0.02%) |
| Product dose omission issue | Injury, poisoning and procedural complications | 4 (0.02%) |
| Product quality issue | Product issues | 4 (0.02%) |
| Product storage error | Injury, poisoning and procedural complications | 4 (0.02%) |
| Psychotic disorder | Psychiatric disorders | 4 (0.02%) |
| Rhabdomyolysis | Musculoskeletal and connective tissue disorders | 4 (0.02%) |
| Sensation of blood flow | General disorders and administration site conditions | 4 (0.02%) |
| Sense of oppression | General disorders and administration site conditions | 4 (0.02%) |
| Skin plaque | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Skin ulcer | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Sleep disorder due to a general medical condition | Psychiatric disorders | 4 (0.02%) |
| Splenomegaly | Blood and lymphatic system disorders | 4 (0.02%) |
| Staring | Psychiatric disorders | 4 (0.02%) |
| Subarachnoid haemorrhage | Nervous system disorders | 4 (0.02%) |
| Subcutaneous abscess | Infections and infestations | 4 (0.02%) |
| Synovitis | Musculoskeletal and connective tissue disorders | 4 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Systemic lupus erythematosus | Musculoskeletal and connective tissue disorders | 4 (0.02%) |
| Terminal insomnia | Psychiatric disorders | 4 (0.02%) |
| Tongue discolouration | Gastrointestinal disorders | 4 (0.02%) |
| Tongue dry | Gastrointestinal disorders | 4 (0.02%) |
| Upper airway obstruction | Respiratory, thoracic and mediastinal disorders | 4 (0.02%) |
| Upper gastrointestinal haemorrhage | Gastrointestinal disorders | 4 (0.02%) |
| Vaccination site papule | General disorders and administration site conditions | 4 (0.02%) |
| Vasoconstriction | Vascular disorders | 4 (0.02%) |
| Vasodilatation | Vascular disorders | 4 (0.02%) |
| Venous thrombosis limb | Vascular disorders | 4 (0.02%) |
| Yellow skin | Skin and subcutaneous tissue disorders | 4 (0.02%) |
| Abnormal weight gain | Metabolism and nutrition disorders | 3 (0.01%) |
| Acute abdomen | Gastrointestinal disorders | 3 (0.01%) |
| Acute vestibular syndrome | Ear and labyrinth disorders | 3 (0.01%) |
| Adrenocortical insufficiency acute | Endocrine disorders | 3 (0.01%) |
| Allergic reaction to excipient | Immune system disorders | 3 (0.01%) |
| Allodynia | Nervous system disorders | 3 (0.01%) |
| Anal sphincter atony | Gastrointestinal disorders | 3 (0.01%) |
| Anger | Psychiatric disorders | 3 (0.01%) |
| Anuria | Renal and urinary disorders | 3 (0.01%) |
| Arrhythmia supraventricular | Cardiac disorders | 3 (0.01%) |
| Atrioventricular block | Cardiac disorders | 3 (0.01%) |
| Aura | Nervous system disorders | 3 (0.01%) |
| Blood alkaline phosphatase increased | Investigations | 3 (0.01%) |
| Blood bilirubin increased | Investigations | 3 (0.01%) |
| Blood cholesterol increased | Investigations | 3 (0.01%) |
| Blood creatine phosphokinase increased | Investigations | 3 (0.01%) |
| Blood glucose abnormal | Investigations | 3 (0.01%) |
| Blood iron decreased | Investigations | 3 (0.01%) |
| Blood lactate dehydrogenase increased | Investigations | 3 (0.01%) |
| Blood lactic acid increased | Investigations | 3 (0.01%) |
| Blood potassium decreased | Investigations | 3 (0.01%) |
| Blood sodium decreased | Investigations | 3 (0.01%) |
| Breath odour | Gastrointestinal disorders | 3 (0.01%) |
| Bronchiectasis | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Bundle branch block left | Cardiac disorders | 3 (0.01%) |
| Cardiac fibrillation | Cardiac disorders | 3 (0.01%) |
| Central nervous system lesion | Nervous system disorders | 3 (0.01%) |
| Cerebellar syndrome | Nervous system disorders | 3 (0.01%) |
| Cerebral disorder | Nervous system disorders | 3 (0.01%) |
| Cerebral thrombosis | Nervous system disorders | 3 (0.01%) |
| Cervicobrachial syndrome | Nervous system disorders | 3 (0.01%) |
| Chest X-ray abnormal | Investigations | 3 (0.01%) |
| Cholinergic syndrome | Nervous system disorders | 3 (0.01%) |
| Chronic fatigue syndrome | General disorders and administration site conditions | 3 (0.01%) |
| Coagulopathy | Blood and lymphatic system disorders | 3 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------|--|-----------------|
| Colitis ulcerative | Gastrointestinal disorders | 3 (0.01%) |
| Complex regional pain syndrome | Nervous system disorders | 3 (0.01%) |
| Conjunctival hyperaemia | Eye disorders | 3 (0.01%) |
| Conjunctival irritation | Eye disorders | 3 (0.01%) |
| Consciousness fluctuating | Nervous system disorders | 3 (0.01%) |
| Coronary artery disease | Cardiac disorders | 3 (0.01%) |
| Defaecation urgency | Gastrointestinal disorders | 3 (0.01%) |
| Derealisation | Psychiatric disorders | 3 (0.01%) |
| Diet refusal | Metabolism and nutrition disorders | 3 (0.01%) |
| Diplegia | Nervous system disorders | 3 (0.01%) |
| Extensor plantar response | Nervous system disorders | 3 (0.01%) |
| Extrapyramidal disorder | Nervous system disorders | 3 (0.01%) |
| Eye contusion | Injury, poisoning and procedural complications | 3 (0.01%) |
| Eye inflammation | Eye disorders | 3 (0.01%) |
| Eyelid irritation | Eye disorders | 3 (0.01%) |
| Feeling of despair | Psychiatric disorders | 3 (0.01%) |
| Food aversion | Metabolism and nutrition disorders | 3 (0.01%) |
| Fungal infection | Infections and infestations | 3 (0.01%) |
| Gastric haemorrhage | Gastrointestinal disorders | 3 (0.01%) |
| Gastrointestinal hypermotility | Gastrointestinal disorders | 3 (0.01%) |
| Genital ulceration | Reproductive system and breast disorders | 3 (0.01%) |
| Gingivitis | Infections and infestations | 3 (0.01%) |
| Glaucoma | Eye disorders | 3 (0.01%) |
| Goitre | Endocrine disorders | 3 (0.01%) |
| Haemorrhage urinary tract | Renal and urinary disorders | 3 (0.01%) |
| Hepatocellular injury | Hepatobiliary disorders | 3 (0.01%) |
| Herpes zoster oticus | Infections and infestations | 3 (0.01%) |
| Hormone level abnormal | Investigations | 3 (0.01%) |
| Hunger | General disorders and administration site conditions | 3 (0.01%) |
| Hyperaesthesia teeth | Gastrointestinal disorders | 3 (0.01%) |
| Hyperchlorhydria | Gastrointestinal disorders | 3 (0.01%) |
| Hyperreflexia | Nervous system disorders | 3 (0.01%) |
| Hypertensive emergency | Vascular disorders | 3 (0.01%) |
| Hypertransaminasaemia | Hepatobiliary disorders | 3 (0.01%) |
| Hyporeflexia | Nervous system disorders | 3 (0.01%) |
| Hypotensive crisis | Vascular disorders | 3 (0.01%) |
| Hypothyroidism | Endocrine disorders | 3 (0.01%) |
| Hypovolaemic shock | Vascular disorders | 3 (0.01%) |
| Immunodeficiency | Immune system disorders | 3 (0.01%) |
| Incoherent | Nervous system disorders | 3 (0.01%) |
| Injection site urticaria | General disorders and administration site conditions | 3 (0.01%) |
| Intestinal ischaemia | Gastrointestinal disorders | 3 (0.01%) |
| Iridocyclitis | Eye disorders | 3 (0.01%) |
| Ischaemic cerebral infarction | Nervous system disorders | 3 (0.01%) |
| Jaw disorder | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Joint dislocation | Injury, poisoning and procedural complications | 3 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------------|---|-----------------|
| Laryngeal discomfort | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Laryngeal obstruction | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Laryngeal pain | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Leukopenia | Blood and lymphatic system disorders | 3 (0.01%) |
| Limb immobilisation | Surgical and medical procedures | 3 (0.01%) |
| Lipase increased | Investigations | 3 (0.01%) |
| Lip disorder | Gastrointestinal disorders | 3 (0.01%) |
| Logorrhoea | Psychiatric disorders | 3 (0.01%) |
| Macule | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Malignant hypertension | Vascular disorders | 3 (0.01%) |
| Mastication disorder | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Medication error | Injury, poisoning and procedural complications | 3 (0.01%) |
| Metamorphopsia | Eye disorders | 3 (0.01%) |
| Micturition disorder | Renal and urinary disorders | 3 (0.01%) |
| Muscle disorder | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Muscle spasticity | Nervous system disorders | 3 (0.01%) |
| Myalgia intercostal | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Myasthenia gravis | Nervous system disorders | 3 (0.01%) |
| Myelosuppression | Blood and lymphatic system disorders | 3 (0.01%) |
| Myocardial necrosis marker increased | Investigations | 3 (0.01%) |
| Myofascial pain syndrome | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Myosclerosis | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Narcolepsy | Nervous system disorders | 3 (0.01%) |
| Nasal dryness | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Neurodermatitis | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Neutrophil count decreased | Investigations | 3 (0.01%) |
| Noninfective encephalitis | Nervous system disorders | 3 (0.01%) |
| Occupational exposure to SARS-CoV-2 | Injury, poisoning and procedural complications | 3 (0.01%) |
| Ophthalmic herpes simplex | Infections and infestations | 3 (0.01%) |
| Optic neuropathy | Eye disorders | 3 (0.01%) |
| Oral dysaesthesia | Gastrointestinal disorders | 3 (0.01%) |
| Oral mucosal erythema | Gastrointestinal disorders | 3 (0.01%) |
| Oropharyngeal spasm | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Oversensing | Product issues | 3 (0.01%) |
| Paranasal sinus hypersecretion | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Parkinsonism | Nervous system disorders | 3 (0.01%) |
| Partial seizures | Nervous system disorders | 3 (0.01%) |
| Pharyngeal mass | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Phlebitis | Vascular disorders | 3 (0.01%) |
| Phonophobia | Psychiatric disorders | 3 (0.01%) |
| Platelet count increased | Investigations | 3 (0.01%) |
| Pneumonia bacterial | Infections and infestations | 3 (0.01%) |
| Postmenopausal haemorrhage | Reproductive system and breast disorders | 3 (0.01%) |
| Product supply issue | Product issues | 3 (0.01%) |
| Proteinuria | Renal and urinary disorders | 3 (0.01%) |
| Pulmonary infarction | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------|--|-----------------|
| Pyelonephritis | Infections and infestations | 3 (0.01%) |
| Quality of life decreased | Investigations | 3 (0.01%) |
| Reduced facial expression | Nervous system disorders | 3 (0.01%) |
| Respiratory symptom | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Retinal migraine | Nervous system disorders | 3 (0.01%) |
| Retinal tear | Eye disorders | 3 (0.01%) |
| Retrograde amnesia | Nervous system disorders | 3 (0.01%) |
| Rhonchi | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Road traffic accident | Injury, poisoning and procedural complications | 3 (0.01%) |
| Rosacea | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Scab | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Serum ferritin increased | Investigations | 3 (0.01%) |
| Shock symptom | Vascular disorders | 3 (0.01%) |
| Sinus bradycardia | Cardiac disorders | 3 (0.01%) |
| Sjogren's syndrome | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Skin erosion | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Skin haemorrhage | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Soft tissue infection | Infections and infestations | 3 (0.01%) |
| Sopor | Psychiatric disorders | 3 (0.01%) |
| Supraventricular extrasystoles | Cardiac disorders | 3 (0.01%) |
| Systolic hypertension | Vascular disorders | 3 (0.01%) |
| Testicular pain | Reproductive system and breast disorders | 3 (0.01%) |
| Thermal burn | Injury, poisoning and procedural complications | 3 (0.01%) |
| Thrombophlebitis | Vascular disorders | 3 (0.01%) |
| Tongue biting | Nervous system disorders | 3 (0.01%) |
| Tongue coated | Gastrointestinal disorders | 3 (0.01%) |
| Tongue erythema | Gastrointestinal disorders | 3 (0.01%) |
| Tongue movement disturbance | Gastrointestinal disorders | 3 (0.01%) |
| Tongue ulceration | Gastrointestinal disorders | 3 (0.01%) |
| Toxic epidermal necrolysis | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Tracheitis | Infections and infestations | 3 (0.01%) |
| Type 1 diabetes mellitus | Metabolism and nutrition disorders | 3 (0.01%) |
| Ulnar nerve injury | Injury, poisoning and procedural complications | 3 (0.01%) |
| Upper limb fracture | Injury, poisoning and procedural complications | 3 (0.01%) |
| Urine odour abnormal | Renal and urinary disorders | 3 (0.01%) |
| Urticaria papular | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Vaccination site extravasation | General disorders and administration site conditions | 3 (0.01%) |
| Vaccination site necrosis | General disorders and administration site conditions | 3 (0.01%) |
| Vascular dementia | Nervous system disorders | 3 (0.01%) |
| Vasculitic rash | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Vein disorder | Vascular disorders | 3 (0.01%) |
| Venous thrombosis | Vascular disorders | 3 (0.01%) |
| Viral pharyngitis | Infections and infestations | 3 (0.01%) |
| Viral rash | Infections and infestations | 3 (0.01%) |
| Vocal cord disorder | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Volvulus | Gastrointestinal disorders | 3 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Vulvovaginal candidiasis | Infections and infestations | 3 (0.01%) |
| Walking disability | Social circumstances | 3 (0.01%) |
| Yawning | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Abdominal wall haemorrhage | Gastrointestinal disorders | 2 (0.01%) |
| Abortion | Pregnancy, puerperium and perinatal conditions | 2 (0.01%) |
| Abscess | Infections and infestations | 2 (0.01%) |
| Abscess oral | Infections and infestations | 2 (0.01%) |
| Accommodation disorder | Eye disorders | 2 (0.01%) |
| Acute febrile neutrophilic dermatosis | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Acute leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.01%) |
| Acute myeloid leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.01%) |
| Administration site movement impairment | General disorders and administration site conditions | 2 (0.01%) |
| Adverse reaction | General disorders and administration site conditions | 2 (0.01%) |
| Affect lability | Psychiatric disorders | 2 (0.01%) |
| Amaurosis fugax | Eye disorders | 2 (0.01%) |
| Amylase increased | Investigations | 2 (0.01%) |
| Anaphylactoid shock | Immune system disorders | 2 (0.01%) |
| Angiopathy | Vascular disorders | 2 (0.01%) |
| Anterograde amnesia | Nervous system disorders | 2 (0.01%) |
| Aortic aneurysm | Vascular disorders | 2 (0.01%) |
| Appetite disorder | Metabolism and nutrition disorders | 2 (0.01%) |
| Application site coldness | General disorders and administration site conditions | 2 (0.01%) |
| Areflexia | Nervous system disorders | 2 (0.01%) |
| Arterial occlusive disease | Vascular disorders | 2 (0.01%) |
| Ascites | Gastrointestinal disorders | 2 (0.01%) |
| Atrioventricular block first degree | Cardiac disorders | 2 (0.01%) |
| Autoscopy | Psychiatric disorders | 2 (0.01%) |
| Bacille Calmette-Guerin scar reactivation | Immune system disorders | 2 (0.01%) |
| Back injury | Injury, poisoning and procedural complications | 2 (0.01%) |
| Bacterial infection | Infections and infestations | 2 (0.01%) |
| Band sensation | Nervous system disorders | 2 (0.01%) |
| Basal ganglia stroke | Nervous system disorders | 2 (0.01%) |
| Behcet's syndrome | Vascular disorders | 2 (0.01%) |
| Blood blister | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Blood chloride decreased | Investigations | 2 (0.01%) |
| Blood count abnormal | Investigations | 2 (0.01%) |
| Blood glucose fluctuation | Investigations | 2 (0.01%) |
| Blood ketone body increased | Investigations | 2 (0.01%) |
| Blood pressure diastolic decreased | Investigations | 2 (0.01%) |
| Blood pressure immeasurable | Investigations | 2 (0.01%) |
| Blood pressure systolic decreased | Investigations | 2 (0.01%) |
| Blood test abnormal | Investigations | 2 (0.01%) |
| Blue toe syndrome | Vascular disorders | 2 (0.01%) |
| Bone swelling | Musculoskeletal and connective tissue disorders | 2 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|----------------------------------|---|-----------------|
| Brachial plexus injury | Injury, poisoning and procedural complications | 2 (0.01%) |
| Brain injury | Nervous system disorders | 2 (0.01%) |
| Brain stem syndrome | Nervous system disorders | 2 (0.01%) |
| Breast cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.01%) |
| Breast cyst | Reproductive system and breast disorders | 2 (0.01%) |
| Breast discomfort | Reproductive system and breast disorders | 2 (0.01%) |
| Breast enlargement | Reproductive system and breast disorders | 2 (0.01%) |
| Breast inflammation | Reproductive system and breast disorders | 2 (0.01%) |
| Breath sounds | Investigations | 2 (0.01%) |
| Bronchial disorder | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Burning sensation mucosal | Nervous system disorders | 2 (0.01%) |
| Candida infection | Infections and infestations | 2 (0.01%) |
| Cardiovascular insufficiency | Cardiac disorders | 2 (0.01%) |
| Carotid bruit | Investigations | 2 (0.01%) |
| Carpal tunnel syndrome | Nervous system disorders | 2 (0.01%) |
| Cartilage injury | Injury, poisoning and procedural complications | 2 (0.01%) |
| Cataract | Eye disorders | 2 (0.01%) |
| Cerebral ischaemia | Nervous system disorders | 2 (0.01%) |
| Cerebral venous sinus thrombosis | Nervous system disorders | 2 (0.01%) |
| Cerebrovascular disorder | Nervous system disorders | 2 (0.01%) |
| Chest injury | Injury, poisoning and procedural complications | 2 (0.01%) |
| Chorea | Nervous system disorders | 2 (0.01%) |
| Choroidal neovascularisation | Eye disorders | 2 (0.01%) |
| Chronic respiratory failure | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Clonic convulsion | Nervous system disorders | 2 (0.01%) |
| Conjunctivitis allergic | Eye disorders | 2 (0.01%) |
| Conjunctivitis bacterial | Infections and infestations | 2 (0.01%) |
| Corneal reflex decreased | Investigations | 2 (0.01%) |
| Coronary artery occlusion | Cardiac disorders | 2 (0.01%) |
| Crepitations | General disorders and administration site conditions | 2 (0.01%) |
| Deafness bilateral | Ear and labyrinth disorders | 2 (0.01%) |
| Deafness transitory | Ear and labyrinth disorders | 2 (0.01%) |
| Decreased activity | General disorders and administration site conditions | 2 (0.01%) |
| Decreased immune responsiveness | Immune system disorders | 2 (0.01%) |
| Decreased interest | Psychiatric disorders | 2 (0.01%) |
| Delusion | Psychiatric disorders | 2 (0.01%) |
| Dermatitis exfoliative | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Dermatosis | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Dermo-hypodermatitis | Infections and infestations | 2 (0.01%) |
| Diaphragmatic spasm | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Discharge | General disorders and administration site conditions | 2 (0.01%) |
| Drowning | General disorders and administration site conditions | 2 (0.01%) |
| Duodenogastric reflux | Gastrointestinal disorders | 2 (0.01%) |
| Dyschromatopsia | Eye disorders | 2 (0.01%) |
| Dysgraphia | Nervous system disorders | 2 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Ear canal erythema | Ear and labyrinth disorders | 2 (0.01%) |
| Ear haemorrhage | Ear and labyrinth disorders | 2 (0.01%) |
| Eating disorder symptom | Metabolism and nutrition disorders | 2 (0.01%) |
| Ecchymosis | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Ejection fraction decreased | Investigations | 2 (0.01%) |
| Electrocardiogram QT prolonged | Investigations | 2 (0.01%) |
| Electrocardiogram repolarisation abnormality | Investigations | 2 (0.01%) |
| Electrolyte imbalance | Metabolism and nutrition disorders | 2 (0.01%) |
| Enanthema | General disorders and administration site conditions | 2 (0.01%) |
| Eosinophil count decreased | Investigations | 2 (0.01%) |
| Epicondylitis | Injury, poisoning and procedural complications | 2 (0.01%) |
| Epiglottic oedema | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Episcleritis | Eye disorders | 2 (0.01%) |
| Epstein-Barr virus infection | Infections and infestations | 2 (0.01%) |
| Escherichia infection | Infections and infestations | 2 (0.01%) |
| Essential tremor | Nervous system disorders | 2 (0.01%) |
| Eustachian tube disorder | Ear and labyrinth disorders | 2 (0.01%) |
| Excessive cerumen production | Ear and labyrinth disorders | 2 (0.01%) |
| Exercise tolerance decreased | General disorders and administration site conditions | 2 (0.01%) |
| Exfoliative rash | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Expired product administered | Injury, poisoning and procedural complications | 2 (0.01%) |
| External ear pain | Ear and labyrinth disorders | 2 (0.01%) |
| Extraocular muscle paresis | Eye disorders | 2 (0.01%) |
| Eyelid rash | Eye disorders | 2 (0.01%) |
| Eyelids pruritus | Eye disorders | 2 (0.01%) |
| Facial bones fracture | Injury, poisoning and procedural complications | 2 (0.01%) |
| Faecal vomiting | Gastrointestinal disorders | 2 (0.01%) |
| Faeces pale | Gastrointestinal disorders | 2 (0.01%) |
| Fasciitis | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Femur fracture | Injury, poisoning and procedural complications | 2 (0.01%) |
| Foetal growth restriction | Pregnancy, puerperium and perinatal conditions | 2 (0.01%) |
| Folliculitis | Infections and infestations | 2 (0.01%) |
| Food allergy | Immune system disorders | 2 (0.01%) |
| Foot deformity | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Foreign body in throat | Injury, poisoning and procedural complications | 2 (0.01%) |
| Fracture | Injury, poisoning and procedural complications | 2 (0.01%) |
| Frostbite | Injury, poisoning and procedural complications | 2 (0.01%) |
| Frustration tolerance decreased | Psychiatric disorders | 2 (0.01%) |
| Gastroenteritis viral | Infections and infestations | 2 (0.01%) |
| Gastrointestinal motility disorder | Gastrointestinal disorders | 2 (0.01%) |
| General symptom | General disorders and administration site conditions | 2 (0.01%) |
| Genital pain | Reproductive system and breast disorders | 2 (0.01%) |
| Giant cell arteritis | Vascular disorders | 2 (0.01%) |
| Gingival bleeding | Gastrointestinal disorders | 2 (0.01%) |
| Gingival discomfort | Gastrointestinal disorders | 2 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Gingival erythema | Gastrointestinal disorders | 2 (0.01%) |
| Gonorrhoea | Infections and infestations | 2 (0.01%) |
| Granulomatous lymphadenitis | Blood and lymphatic system disorders | 2 (0.01%) |
| Haematocrit decreased | Investigations | 2 (0.01%) |
| Haemorrhage subcutaneous | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Head titubation | Nervous system disorders | 2 (0.01%) |
| Hemianopia homonymous | Nervous system disorders | 2 (0.01%) |
| Hemiplegic migraine | Nervous system disorders | 2 (0.01%) |
| Hepatic failure | Hepatobiliary disorders | 2 (0.01%) |
| Hepatitis cholestatic | Hepatobiliary disorders | 2 (0.01%) |
| Herpes simplex reactivation | Infections and infestations | 2 (0.01%) |
| Herpes zoster cutaneous disseminated | Infections and infestations | 2 (0.01%) |
| Herpes zoster infection neurological | Infections and infestations | 2 (0.01%) |
| Hip fracture | Injury, poisoning and procedural complications | 2 (0.01%) |
| Histamine intolerance | Metabolism and nutrition disorders | 2 (0.01%) |
| Hordeolum | Infections and infestations | 2 (0.01%) |
| Hypercapnia | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Hypersensitivity vasculitis | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Hypertensive urgency | Vascular disorders | 2 (0.01%) |
| Hypertonia | Nervous system disorders | 2 (0.01%) |
| Hypocalcaemia | Metabolism and nutrition disorders | 2 (0.01%) |
| Hyporesponsive to stimuli | Nervous system disorders | 2 (0.01%) |
| Hypoventilation | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Ileus paralytic | Gastrointestinal disorders | 2 (0.01%) |
| Immunisation reaction | Immune system disorders | 2 (0.01%) |
| Increased viscosity of upper respiratory secretion | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Infarction | Vascular disorders | 2 (0.01%) |
| Infective exacerbation of chronic obstructive airways disease | Infections and infestations | 2 (0.01%) |
| Infertility | Reproductive system and breast disorders | 2 (0.01%) |
| Inflammatory pain | General disorders and administration site conditions | 2 (0.01%) |
| Infusion related reaction | Injury, poisoning and procedural complications | 2 (0.01%) |
| Injection site pruritus | General disorders and administration site conditions | 2 (0.01%) |
| Injection site swelling | General disorders and administration site conditions | 2 (0.01%) |
| Inner ear disorder | Ear and labyrinth disorders | 2 (0.01%) |
| Inspiratory capacity decreased | Investigations | 2 (0.01%) |
| Insulin resistance | Metabolism and nutrition disorders | 2 (0.01%) |
| Intercostal neuralgia | Nervous system disorders | 2 (0.01%) |
| Internal haemorrhage | Vascular disorders | 2 (0.01%) |
| Intestinal perforation | Gastrointestinal disorders | 2 (0.01%) |
| Intestinal pseudo-obstruction | Gastrointestinal disorders | 2 (0.01%) |
| Intraocular pressure increased | Investigations | 2 (0.01%) |
| Intussusception | Gastrointestinal disorders | 2 (0.01%) |
| Irritability postvaccinal | General disorders and administration site conditions | 2 (0.01%) |
| IVth nerve paralysis | Nervous system disorders | 2 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------------|---|-----------------|
| Ketoacidosis | Metabolism and nutrition disorders | 2 (0.01%) |
| Labile blood pressure | Vascular disorders | 2 (0.01%) |
| Lack of spontaneous speech | Psychiatric disorders | 2 (0.01%) |
| Lacrimation decreased | Eye disorders | 2 (0.01%) |
| Lactic acidosis | Metabolism and nutrition disorders | 2 (0.01%) |
| Laryngeal stenosis | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Leukoencephalopathy | Nervous system disorders | 2 (0.01%) |
| Lichen planus | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Ligament sprain | Injury, poisoning and procedural complications | 2 (0.01%) |
| Lip discolouration | Gastrointestinal disorders | 2 (0.01%) |
| Lip erythema | Gastrointestinal disorders | 2 (0.01%) |
| Lip exfoliation | Gastrointestinal disorders | 2 (0.01%) |
| Liver injury | Hepatobiliary disorders | 2 (0.01%) |
| Lower respiratory tract congestion | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Lymphocyte count decreased | Investigations | 2 (0.01%) |
| Lymphocytosis | Blood and lymphatic system disorders | 2 (0.01%) |
| Malnutrition | Metabolism and nutrition disorders | 2 (0.01%) |
| Maternal exposure timing unspecified | Injury, poisoning and procedural complications | 2 (0.01%) |
| Meningeal disorder | Nervous system disorders | 2 (0.01%) |
| Meningism | Nervous system disorders | 2 (0.01%) |
| Meningitis | Infections and infestations | 2 (0.01%) |
| Meningitis aseptic | Infections and infestations | 2 (0.01%) |
| Meningitis viral | Infections and infestations | 2 (0.01%) |
| Metabolic acidosis | Metabolism and nutrition disorders | 2 (0.01%) |
| Metastases to peritoneum | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.01%) |
| Microembolism | Vascular disorders | 2 (0.01%) |
| Monocyte count decreased | Investigations | 2 (0.01%) |
| Monocytosis | Blood and lymphatic system disorders | 2 (0.01%) |
| Mononeuropathy | Nervous system disorders | 2 (0.01%) |
| Morning sickness | Pregnancy, puerperium and perinatal conditions | 2 (0.01%) |
| Mouth breathing | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Mouth injury | Injury, poisoning and procedural complications | 2 (0.01%) |
| Mucosal disorder | General disorders and administration site conditions | 2 (0.01%) |
| Mucosal dryness | General disorders and administration site conditions | 2 (0.01%) |
| Muscle rupture | Injury, poisoning and procedural complications | 2 (0.01%) |
| Mutism | Psychiatric disorders | 2 (0.01%) |
| Myokymia | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Nail discolouration | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Nasal disorder | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Necrosis | General disorders and administration site conditions | 2 (0.01%) |
| Needle issue | Product issues | 2 (0.01%) |
| Neoplasm malignant | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.01%) |
| Nephrolithiasis | Renal and urinary disorders | 2 (0.01%) |
| Nephropathy | Renal and urinary disorders | 2 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|------------------------------------|---|-----------------|
| Nephrotic syndrome | Renal and urinary disorders | 2 (0.01%) |
| Neuritis | Nervous system disorders | 2 (0.01%) |
| Neurologic neglect syndrome | Nervous system disorders | 2 (0.01%) |
| Neurotoxicity | Nervous system disorders | 2 (0.01%) |
| Oesophageal stenosis | Gastrointestinal disorders | 2 (0.01%) |
| Oral mucosal exfoliation | Gastrointestinal disorders | 2 (0.01%) |
| Orchitis | Infections and infestations | 2 (0.01%) |
| Orthopnoea | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Otitis externa | Infections and infestations | 2 (0.01%) |
| Panniculitis | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Papilloedema | Eye disorders | 2 (0.01%) |
| Parkinson's disease | Nervous system disorders | 2 (0.01%) |
| Pemphigus | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Periorbital cellulitis | Infections and infestations | 2 (0.01%) |
| Periorbital pain | Eye disorders | 2 (0.01%) |
| Peripheral nerve injury | Injury, poisoning and procedural complications | 2 (0.01%) |
| Persistent depressive disorder | Psychiatric disorders | 2 (0.01%) |
| Pertussis | Infections and infestations | 2 (0.01%) |
| Pharyngitis streptococcal | Infections and infestations | 2 (0.01%) |
| Pityriasis | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Polymerase chain reaction positive | Investigations | 2 (0.01%) |
| Polymyositis | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Polyneuropathy | Nervous system disorders | 2 (0.01%) |
| Post herpetic neuralgia | Nervous system disorders | 2 (0.01%) |
| Postictal state | Nervous system disorders | 2 (0.01%) |
| Post procedural complication | Injury, poisoning and procedural complications | 2 (0.01%) |
| Premature baby | Pregnancy, puerperium and perinatal conditions | 2 (0.01%) |
| Premenstrual syndrome | Reproductive system and breast disorders | 2 (0.01%) |
| Procedural nausea | Injury, poisoning and procedural complications | 2 (0.01%) |
| Proctalgia | Gastrointestinal disorders | 2 (0.01%) |
| Product colour issue | Product issues | 2 (0.01%) |
| Product complaint | Product issues | 2 (0.01%) |
| Product container issue | Product issues | 2 (0.01%) |
| Product leakage | Product issues | 2 (0.01%) |
| Product prescribing error | Injury, poisoning and procedural complications | 2 (0.01%) |
| Prothrombin time prolonged | Investigations | 2 (0.01%) |
| Psychiatric symptom | Psychiatric disorders | 2 (0.01%) |
| Psychogenic seizure | Nervous system disorders | 2 (0.01%) |
| Psychomotor skills impaired | Nervous system disorders | 2 (0.01%) |
| Psychotic symptom | Psychiatric disorders | 2 (0.01%) |
| Pulmonary arterial hypertension | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Pulmonary artery thrombosis | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Pulpitis dental | Infections and infestations | 2 (0.01%) |
| Pulseless electrical activity | Cardiac disorders | 2 (0.01%) |
| Pupillary disorder | Eye disorders | 2 (0.01%) |
| Quadripareisis | Nervous system disorders | 2 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Reaction to preservatives | Immune system disorders | 2 (0.01%) |
| Rectal discharge | Gastrointestinal disorders | 2 (0.01%) |
| Renal colic | Renal and urinary disorders | 2 (0.01%) |
| Respiratory acidosis | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Respiratory alkalosis | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Respiratory tract irritation | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Retinal detachment | Eye disorders | 2 (0.01%) |
| Retinal haemorrhage | Eye disorders | 2 (0.01%) |
| Retinal vein occlusion | Eye disorders | 2 (0.01%) |
| Rheumatoid factor positive | Investigations | 2 (0.01%) |
| Rotator cuff syndrome | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Sarcoidosis | Immune system disorders | 2 (0.01%) |
| SARS-CoV-2 antibody test | Investigations | 2 (0.01%) |
| SARS-CoV-2 test negative | Investigations | 2 (0.01%) |
| Scar | Injury, poisoning and procedural complications | 2 (0.01%) |
| Scleral discolouration | Eye disorders | 2 (0.01%) |
| Screaming | General disorders and administration site conditions | 2 (0.01%) |
| Scrotal pain | Reproductive system and breast disorders | 2 (0.01%) |
| Seizure like phenomena | Nervous system disorders | 2 (0.01%) |
| Sense of a foreshortened future | Psychiatric disorders | 2 (0.01%) |
| Sensitisation | Immune system disorders | 2 (0.01%) |
| Sensitivity to weather change | General disorders and administration site conditions | 2 (0.01%) |
| Serum sickness | Immune system disorders | 2 (0.01%) |
| Skin fissures | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Skin laxity | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Skin necrosis | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Skin oedema | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Skin temperature | Investigations | 2 (0.01%) |
| Sleep apnoea syndrome | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Sleep terror | Psychiatric disorders | 2 (0.01%) |
| Small intestinal haemorrhage | Gastrointestinal disorders | 2 (0.01%) |
| Somatic symptom disorder | Psychiatric disorders | 2 (0.01%) |
| Spinal cord disorder | Nervous system disorders | 2 (0.01%) |
| Sputum abnormal | Investigations | 2 (0.01%) |
| Stiff tongue | Gastrointestinal disorders | 2 (0.01%) |
| Subileus | Gastrointestinal disorders | 2 (0.01%) |
| Sudden cardiac death | General disorders and administration site conditions | 2 (0.01%) |
| Sudden visual loss | Eye disorders | 2 (0.01%) |
| Suicide attempt | Psychiatric disorders | 2 (0.01%) |
| Syringe issue | Product issues | 2 (0.01%) |
| Systemic inflammatory response syndrome | General disorders and administration site conditions | 2 (0.01%) |
| Tachycardia paroxysmal | Cardiac disorders | 2 (0.01%) |
| Tachyphrenia | Psychiatric disorders | 2 (0.01%) |
| Tearfulness | Psychiatric disorders | 2 (0.01%) |
| Tenosynovitis | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Terminal state | General disorders and administration site conditions | 2 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Thermal burns of eye | Injury, poisoning and procedural complications | 2 (0.01%) |
| Thrombocytopenic purpura | Blood and lymphatic system disorders | 2 (0.01%) |
| Thrombotic stroke | Nervous system disorders | 2 (0.01%) |
| Thyroid disorder | Endocrine disorders | 2 (0.01%) |
| Thyroid pain | Endocrine disorders | 2 (0.01%) |
| Tongue spasm | Gastrointestinal disorders | 2 (0.01%) |
| Tonsillar disorder | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Tooth disorder | Gastrointestinal disorders | 2 (0.01%) |
| Tooth infection | Infections and infestations | 2 (0.01%) |
| Torticollis | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Tracheal oedema | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Tracheal pain | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Transient global amnesia | Nervous system disorders | 2 (0.01%) |
| Traumatic lung injury | Injury, poisoning and procedural complications | 2 (0.01%) |
| Trichoglossia | Gastrointestinal disorders | 2 (0.01%) |
| Type 2 diabetes mellitus | Metabolism and nutrition disorders | 2 (0.01%) |
| Ulcer | General disorders and administration site conditions | 2 (0.01%) |
| Ulcerative keratitis | Eye disorders | 2 (0.01%) |
| Urine abnormality | Renal and urinary disorders | 2 (0.01%) |
| Urine flow decreased | Renal and urinary disorders | 2 (0.01%) |
| Urine output decreased | Investigations | 2 (0.01%) |
| Urine output increased | Investigations | 2 (0.01%) |
| Use of accessory respiratory muscles | Respiratory, thoracic and mediastinal disorders | 2 (0.01%) |
| Uterine haemorrhage | Reproductive system and breast disorders | 2 (0.01%) |
| Vaccination site dysaesthesia | General disorders and administration site conditions | 2 (0.01%) |
| Vaccination site joint inflammation | General disorders and administration site conditions | 2 (0.01%) |
| Vaccination site scab | General disorders and administration site conditions | 2 (0.01%) |
| Vaccination site thrombosis | General disorders and administration site conditions | 2 (0.01%) |
| Vaginal discharge | Reproductive system and breast disorders | 2 (0.01%) |
| Vascular headache | Nervous system disorders | 2 (0.01%) |
| Vascular purpura | Skin and subcutaneous tissue disorders | 2 (0.01%) |
| Vein discolouration | Vascular disorders | 2 (0.01%) |
| Ventricular arrhythmia | Cardiac disorders | 2 (0.01%) |
| Vertigo labyrinthine | Ear and labyrinth disorders | 2 (0.01%) |
| Vestibular disorder | Ear and labyrinth disorders | 2 (0.01%) |
| Vitreous disorder | Eye disorders | 2 (0.01%) |
| Vulvovaginal burning sensation | Reproductive system and breast disorders | 2 (0.01%) |
| Weight bearing difficulty | Musculoskeletal and connective tissue disorders | 2 (0.01%) |
| Weight fluctuation | Metabolism and nutrition disorders | 2 (0.01%) |
| Weight increased | Investigations | 2 (0.01%) |
| Wound complication | Injury, poisoning and procedural complications | 2 (0.01%) |
| Wrong technique in device usage process | Injury, poisoning and procedural complications | 2 (0.01%) |
| Xanthopsia | Eye disorders | 2 (0.01%) |
| Abdominal symptom | Gastrointestinal disorders | 1 (0.00%) |
| Abdominal tenderness | Gastrointestinal disorders | 1 (0.00%) |
| Abdominal wall haematoma | Gastrointestinal disorders | 1 (0.00%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Abnormal withdrawal bleeding | Reproductive system and breast disorders | 1 (0.00%) |
| Abortion missed | Pregnancy, puerperium and perinatal conditions | 1 (0.00%) |
| Acarodermatitis | Infections and infestations | 1 (0.00%) |
| Accident | Injury, poisoning and procedural complications | 1 (0.00%) |
| Accidental underdose | Injury, poisoning and procedural complications | 1 (0.00%) |
| Acidosis | Metabolism and nutrition disorders | 1 (0.00%) |
| Acquired macroglossia | Gastrointestinal disorders | 1 (0.00%) |
| Acrochordon | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Activated partial thromboplastin time prolonged | Investigations | 1 (0.00%) |
| Acute cardiac event | Cardiac disorders | 1 (0.00%) |
| Acute left ventricular failure | Cardiac disorders | 1 (0.00%) |
| Administration site joint movement impairment | General disorders and administration site conditions | 1 (0.00%) |
| Administration site pain | General disorders and administration site conditions | 1 (0.00%) |
| Administration site warmth | General disorders and administration site conditions | 1 (0.00%) |
| Adrenal disorder | Endocrine disorders | 1 (0.00%) |
| Adult failure to thrive | Metabolism and nutrition disorders | 1 (0.00%) |
| Aerococcus urinae infection | Infections and infestations | 1 (0.00%) |
| Agranulocytosis | Blood and lymphatic system disorders | 1 (0.00%) |
| Airway burns | Injury, poisoning and procedural complications | 1 (0.00%) |
| Alcohol interaction | General disorders and administration site conditions | 1 (0.00%) |
| Alcohol intolerance | Metabolism and nutrition disorders | 1 (0.00%) |
| Alexia | Nervous system disorders | 1 (0.00%) |
| Allergic cough | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Allergic oedema | Immune system disorders | 1 (0.00%) |
| Allergic sinusitis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Allergy to arthropod sting | Immune system disorders | 1 (0.00%) |
| Amyloidosis | Immune system disorders | 1 (0.00%) |
| Anal skin tags | Gastrointestinal disorders | 1 (0.00%) |
| Aneurysm | Vascular disorders | 1 (0.00%) |
| Aneurysm ruptured | Vascular disorders | 1 (0.00%) |
| Angiomyolipoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Angle closure glaucoma | Eye disorders | 1 (0.00%) |
| Anion gap abnormal | Investigations | 1 (0.00%) |
| Anisocytosis | Blood and lymphatic system disorders | 1 (0.00%) |
| Anorectal discomfort | Gastrointestinal disorders | 1 (0.00%) |
| Anovulatory cycle | Endocrine disorders | 1 (0.00%) |
| Anterior chamber cell | Eye disorders | 1 (0.00%) |
| Antibody test negative | Investigations | 1 (0.00%) |
| Antinuclear antibody positive | Investigations | 1 (0.00%) |
| Antiphospholipid syndrome | Blood and lymphatic system disorders | 1 (0.00%) |
| Anti-thyroid antibody positive | Investigations | 1 (0.00%) |
| Anxiety disorder | Psychiatric disorders | 1 (0.00%) |
| Aortic aneurysm rupture | Vascular disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Aortic dissection | Vascular disorders | 1 (0.00%) |
| Aortic stenosis | Vascular disorders | 1 (0.00%) |
| Apallic syndrome | Nervous system disorders | 1 (0.00%) |
| Apparent death | General disorders and administration site conditions | 1 (0.00%) |
| Application site pain | General disorders and administration site conditions | 1 (0.00%) |
| Application site pruritus | General disorders and administration site conditions | 1 (0.00%) |
| Application site vesicles | General disorders and administration site conditions | 1 (0.00%) |
| Aptyalism | Gastrointestinal disorders | 1 (0.00%) |
| Arterial rupture | Vascular disorders | 1 (0.00%) |
| Arteriosclerosis | Vascular disorders | 1 (0.00%) |
| Arteritis | Vascular disorders | 1 (0.00%) |
| Arthritis bacterial | Infections and infestations | 1 (0.00%) |
| Arthritis enteropathic | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Arthropod bite | Injury, poisoning and procedural complications | 1 (0.00%) |
| Arthropod sting | Injury, poisoning and procedural complications | 1 (0.00%) |
| Asthma exercise induced | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Atrophic glossitis | Gastrointestinal disorders | 1 (0.00%) |
| Atypical femur fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Atypical pneumonia | Infections and infestations | 1 (0.00%) |
| Auditory disorder | Ear and labyrinth disorders | 1 (0.00%) |
| Autoantibody negative | Investigations | 1 (0.00%) |
| Autoimmune demyelinating disease | Nervous system disorders | 1 (0.00%) |
| Autoimmune uveitis | Eye disorders | 1 (0.00%) |
| Automatism | Psychiatric disorders | 1 (0.00%) |
| Autophony | Ear and labyrinth disorders | 1 (0.00%) |
| Axillary vein thrombosis | Vascular disorders | 1 (0.00%) |
| Axonal neuropathy | Nervous system disorders | 1 (0.00%) |
| Azotaemia | Renal and urinary disorders | 1 (0.00%) |
| Bacterial diarrhoea | Infections and infestations | 1 (0.00%) |
| Bacterial rhinitis | Infections and infestations | 1 (0.00%) |
| Bacterial sepsis | Infections and infestations | 1 (0.00%) |
| Bacterial test positive | Investigations | 1 (0.00%) |
| Barotrauma | Injury, poisoning and procedural complications | 1 (0.00%) |
| Basal ganglia infarction | Nervous system disorders | 1 (0.00%) |
| Basedow's disease | Endocrine disorders | 1 (0.00%) |
| Basilar artery thrombosis | Nervous system disorders | 1 (0.00%) |
| B-cell lymphoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| B-cell type acute leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Belligerence | Psychiatric disorders | 1 (0.00%) |
| Benign breast neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Beta haemolytic streptococcal infection | Infections and infestations | 1 (0.00%) |
| Binocular eye movement disorder | Eye disorders | 1 (0.00%) |
| Bipolar disorder | Psychiatric disorders | 1 (0.00%) |
| Bladder irritation | Renal and urinary disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Bladder pain | Renal and urinary disorders | 1 (0.00%) |
| Bleeding time abnormal | Investigations | 1 (0.00%) |
| Blood albumin decreased | Investigations | 1 (0.00%) |
| Blood chloride increased | Investigations | 1 (0.00%) |
| Blood creatine phosphokinase MB increased | Investigations | 1 (0.00%) |
| Blood fibrinogen increased | Investigations | 1 (0.00%) |
| Blood glucose | Investigations | 1 (0.00%) |
| Blood immunoglobulin G decreased | Investigations | 1 (0.00%) |
| Blood lactate dehydrogenase abnormal | Investigations | 1 (0.00%) |
| Blood magnesium decreased | Investigations | 1 (0.00%) |
| Blood pH increased | Investigations | 1 (0.00%) |
| Blood potassium increased | Investigations | 1 (0.00%) |
| Blood pressure inadequately controlled | Vascular disorders | 1 (0.00%) |
| Blood testosterone increased | Investigations | 1 (0.00%) |
| Blood thyroid stimulating hormone increased | Investigations | 1 (0.00%) |
| Blood urea increased | Investigations | 1 (0.00%) |
| Blood viscosity increased | Investigations | 1 (0.00%) |
| Body dysmorphic disorder | Psychiatric disorders | 1 (0.00%) |
| Body temperature | Investigations | 1 (0.00%) |
| Bone contusion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Bone disorder | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Brain natriuretic peptide increased | Investigations | 1 (0.00%) |
| Brain neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Brain stem haemorrhage | Nervous system disorders | 1 (0.00%) |
| Brain stem stroke | Nervous system disorders | 1 (0.00%) |
| Breast abscess | Infections and infestations | 1 (0.00%) |
| Breast oedema | Reproductive system and breast disorders | 1 (0.00%) |
| Bronchial hyperreactivity | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bronchial oedema | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bronchiolitis | Infections and infestations | 1 (0.00%) |
| Bronchopneumopathy | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bronchopulmonary aspergillosis | Infections and infestations | 1 (0.00%) |
| Bronchostenosis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bruxism | Psychiatric disorders | 1 (0.00%) |
| Bundle branch block | Cardiac disorders | 1 (0.00%) |
| Burn oesophageal | Injury, poisoning and procedural complications | 1 (0.00%) |
| Burns second degree | Injury, poisoning and procedural complications | 1 (0.00%) |
| Bursal fluid accumulation | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Calcium ionised increased | Investigations | 1 (0.00%) |
| Capillary disorder | Vascular disorders | 1 (0.00%) |
| Capillary nail refill test abnormal | Investigations | 1 (0.00%) |
| Cardiac aneurysm | Cardiac disorders | 1 (0.00%) |
| Cardiac death | General disorders and administration site conditions | 1 (0.00%) |
| Cardiac discomfort | Cardiac disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Cardiac failure chronic | Cardiac disorders | 1 (0.00%) |
| Cardiac murmur | Investigations | 1 (0.00%) |
| Cardiomegaly | Cardiac disorders | 1 (0.00%) |
| Cardiomyopathy | Cardiac disorders | 1 (0.00%) |
| Carotid artery dissection | Nervous system disorders | 1 (0.00%) |
| Catonia | Psychiatric disorders | 1 (0.00%) |
| Central cord syndrome | Injury, poisoning and procedural complications | 1 (0.00%) |
| Central nervous system stimulation | Surgical and medical procedures | 1 (0.00%) |
| Cerebellar ataxia | Nervous system disorders | 1 (0.00%) |
| Cerebral artery stenosis | Nervous system disorders | 1 (0.00%) |
| Cerebral atrophy | Nervous system disorders | 1 (0.00%) |
| Cerebral hyperperfusion syndrome | Injury, poisoning and procedural complications | 1 (0.00%) |
| Cervical neuritis | Nervous system disorders | 1 (0.00%) |
| Cervical radiculopathy | Nervous system disorders | 1 (0.00%) |
| Chalazion | Eye disorders | 1 (0.00%) |
| Chest crushing | Injury, poisoning and procedural complications | 1 (0.00%) |
| Chest expansion decreased | Investigations | 1 (0.00%) |
| Cheyne-Stokes respiration | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Cholecystitis | Hepatobiliary disorders | 1 (0.00%) |
| Cholestasis | Hepatobiliary disorders | 1 (0.00%) |
| Cholestatic liver injury | Hepatobiliary disorders | 1 (0.00%) |
| Choluria | Renal and urinary disorders | 1 (0.00%) |
| Chondritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Chorioretinitis | Infections and infestations | 1 (0.00%) |
| Choroiditis | Eye disorders | 1 (0.00%) |
| Chronic inflammatory demyelinating polyradiculoneuropathy | Nervous system disorders | 1 (0.00%) |
| Chronic kidney disease | Renal and urinary disorders | 1 (0.00%) |
| Chronic myeloid leukaemia recurrent | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Chronic spontaneous urticaria | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Ciliary muscle spasm | Eye disorders | 1 (0.00%) |
| Circumoral oedema | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Circumoral swelling | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Citrobacter infection | Infections and infestations | 1 (0.00%) |
| Clostridium difficile infection | Infections and infestations | 1 (0.00%) |
| Clumsiness | Nervous system disorders | 1 (0.00%) |
| Coagulation time prolonged | Investigations | 1 (0.00%) |
| Coccidioidomycosis | Infections and infestations | 1 (0.00%) |
| Coccydynia | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Cold burn | Injury, poisoning and procedural complications | 1 (0.00%) |
| Colitis microscopic | Gastrointestinal disorders | 1 (0.00%) |
| Colon cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Complement factor C3 decreased | Investigations | 1 (0.00%) |
| Complication associated with device | General disorders and administration site conditions | 1 (0.00%) |
| Computerised tomogram normal | Investigations | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Concomitant disease aggravated | General disorders and administration site conditions | 1 (0.00%) |
| Concussion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Congestive cardiomyopathy | Cardiac disorders | 1 (0.00%) |
| Conjunctival oedema | Eye disorders | 1 (0.00%) |
| Contraindicated product administered | Injury, poisoning and procedural complications | 1 (0.00%) |
| Contraindication to vaccination | Social circumstances | 1 (0.00%) |
| Contrast media reaction | Immune system disorders | 1 (0.00%) |
| Corneal abrasion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Corneal disorder | Eye disorders | 1 (0.00%) |
| Corneal graft rejection | Immune system disorders | 1 (0.00%) |
| Corneal infiltrates | Eye disorders | 1 (0.00%) |
| Coronary artery stenosis | Cardiac disorders | 1 (0.00%) |
| Cor pulmonale | Cardiac disorders | 1 (0.00%) |
| Costovertebral angle tenderness | Renal and urinary disorders | 1 (0.00%) |
| Cranial nerve paralysis | Nervous system disorders | 1 (0.00%) |
| Craniofacial fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| C-reactive protein decreased | Investigations | 1 (0.00%) |
| Creatinine renal clearance decreased | Investigations | 1 (0.00%) |
| Creutzfeldt-Jakob disease | Infections and infestations | 1 (0.00%) |
| Crystal arthropathy | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| CSF protein increased | Investigations | 1 (0.00%) |
| CT hypotension complex | Vascular disorders | 1 (0.00%) |
| Cutaneous symptom | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Cyst | General disorders and administration site conditions | 1 (0.00%) |
| Cystitis klebsiella | Infections and infestations | 1 (0.00%) |
| Cytomegalovirus infection | Infections and infestations | 1 (0.00%) |
| Daydreaming | Psychiatric disorders | 1 (0.00%) |
| Death neonatal | General disorders and administration site conditions | 1 (0.00%) |
| Decreased nasolabial fold | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Deficiency of bile secretion | Hepatobiliary disorders | 1 (0.00%) |
| Delusional disorder, unspecified type | Psychiatric disorders | 1 (0.00%) |
| Dementia Alzheimer's type | Nervous system disorders | 1 (0.00%) |
| Dementia with Lewy bodies | Nervous system disorders | 1 (0.00%) |
| Demyelinating polyneuropathy | Nervous system disorders | 1 (0.00%) |
| Demyelination | Nervous system disorders | 1 (0.00%) |
| Dental discomfort | Gastrointestinal disorders | 1 (0.00%) |
| Dermatitis acneiform | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Dermatitis diaper | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Dermatitis exfoliative generalised | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Diabetic complication | Metabolism and nutrition disorders | 1 (0.00%) |
| Diabetic diet | Surgical and medical procedures | 1 (0.00%) |
| Diabetic foot infection | Infections and infestations | 1 (0.00%) |
| Diabetic ketosis | Metabolism and nutrition disorders | 1 (0.00%) |
| Diabetic metabolic decompensation | Metabolism and nutrition disorders | 1 (0.00%) |
| Diabetic wound | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Diaphragmalgia | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Diaphragmatic paralysis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Diastolic hypotension | Vascular disorders | 1 (0.00%) |
| Disinhibition | Psychiatric disorders | 1 (0.00%) |
| Disseminated Bacillus Calmette-Guerin infection | Infections and infestations | 1 (0.00%) |
| Disseminated varicella zoster virus infection | Infections and infestations | 1 (0.00%) |
| Dissociative disorder | Psychiatric disorders | 1 (0.00%) |
| Diverticulum intestinal | Gastrointestinal disorders | 1 (0.00%) |
| Dreamy state | Nervous system disorders | 1 (0.00%) |
| Drug intolerance | General disorders and administration site conditions | 1 (0.00%) |
| Drug withdrawal syndrome | General disorders and administration site conditions | 1 (0.00%) |
| Dysaesthesia pharynx | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Dyschezia | Gastrointestinal disorders | 1 (0.00%) |
| Dyshidrotic eczema | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Dyslexia | Nervous system disorders | 1 (0.00%) |
| Dyslipidaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Dysmetria | Nervous system disorders | 1 (0.00%) |
| Dysmorphism | Congenital, familial and genetic disorders | 1 (0.00%) |
| Ear congestion | Ear and labyrinth disorders | 1 (0.00%) |
| Ear infection bacterial | Infections and infestations | 1 (0.00%) |
| Eczema herpeticum | Infections and infestations | 1 (0.00%) |
| Eczema nummular | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Eczema weeping | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Electric shock | Injury, poisoning and procedural complications | 1 (0.00%) |
| Electrocardiogram QRS complex prolonged | Investigations | 1 (0.00%) |
| Electrocardiogram ST segment abnormal | Investigations | 1 (0.00%) |
| Electrocardiogram ST segment depression | Investigations | 1 (0.00%) |
| Electrocardiogram ST-T change | Investigations | 1 (0.00%) |
| Electrocardiogram T wave inversion | Investigations | 1 (0.00%) |
| Electrocardiogram T wave peaked | Investigations | 1 (0.00%) |
| Electroencephalogram abnormal | Investigations | 1 (0.00%) |
| Embolism | Vascular disorders | 1 (0.00%) |
| Embolism arterial | Vascular disorders | 1 (0.00%) |
| Encephalitis post immunisation | Nervous system disorders | 1 (0.00%) |
| Endocarditis | Infections and infestations | 1 (0.00%) |
| Endodontic procedure | Surgical and medical procedures | 1 (0.00%) |
| Endolymphatic hydrops | Ear and labyrinth disorders | 1 (0.00%) |
| Endometriosis | Reproductive system and breast disorders | 1 (0.00%) |
| Energy increased | General disorders and administration site conditions | 1 (0.00%) |
| Enteritis | Gastrointestinal disorders | 1 (0.00%) |
| Enterocolitis | Gastrointestinal disorders | 1 (0.00%) |
| Eosinophilia | Blood and lymphatic system disorders | 1 (0.00%) |
| Epidermal necrosis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Epididymitis | Infections and infestations | 1 (0.00%) |
| Epiglottitis | Infections and infestations | 1 (0.00%) |
| Epiphyses premature fusion | Musculoskeletal and connective tissue disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Epstein-Barr virus test positive | Investigations | 1 (0.00%) |
| Erythema annulare | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Escherichia sepsis | Infections and infestations | 1 (0.00%) |
| Escherichia urinary tract infection | Infections and infestations | 1 (0.00%) |
| Excessive granulation tissue | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Exertional headache | Nervous system disorders | 1 (0.00%) |
| External ear cellulitis | Infections and infestations | 1 (0.00%) |
| External ear inflammation | Ear and labyrinth disorders | 1 (0.00%) |
| Extradural haematoma | Injury, poisoning and procedural complications | 1 (0.00%) |
| Eye abscess | Infections and infestations | 1 (0.00%) |
| Eye allergy | Eye disorders | 1 (0.00%) |
| Eye colour change | Eye disorders | 1 (0.00%) |
| Eye complication associated with device | General disorders and administration site conditions | 1 (0.00%) |
| Eyelid disorder | Eye disorders | 1 (0.00%) |
| Eyelid haematoma | Eye disorders | 1 (0.00%) |
| Eyelid myoclonus | Eye disorders | 1 (0.00%) |
| Eyelid myokymia | Eye disorders | 1 (0.00%) |
| Eyelid retraction | Eye disorders | 1 (0.00%) |
| Eyelid sensory disorder | Eye disorders | 1 (0.00%) |
| Eye opacity | Eye disorders | 1 (0.00%) |
| Facial asymmetry | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Familial hemiplegic migraine | Congenital, familial and genetic disorders | 1 (0.00%) |
| Fat tissue increased | General disorders and administration site conditions | 1 (0.00%) |
| Fear of falling | Psychiatric disorders | 1 (0.00%) |
| Fear of injection | Psychiatric disorders | 1 (0.00%) |
| Femoral artery embolism | Vascular disorders | 1 (0.00%) |
| Femoral neck fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Fine motor skill dysfunction | Nervous system disorders | 1 (0.00%) |
| Flashback | Psychiatric disorders | 1 (0.00%) |
| Fluid intake reduced | Metabolism and nutrition disorders | 1 (0.00%) |
| Fluid overload | Metabolism and nutrition disorders | 1 (0.00%) |
| Foetal death | Pregnancy, puerperium and perinatal conditions | 1 (0.00%) |
| Food craving | Metabolism and nutrition disorders | 1 (0.00%) |
| Food poisoning | Gastrointestinal disorders | 1 (0.00%) |
| Forced expiratory volume increased | Investigations | 1 (0.00%) |
| Fracture blisters | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Full blood count abnormal | Investigations | 1 (0.00%) |
| Functional gastrointestinal disorder | Gastrointestinal disorders | 1 (0.00%) |
| Fungal skin infection | Infections and infestations | 1 (0.00%) |
| Gallbladder disorder | Hepatobiliary disorders | 1 (0.00%) |
| Gastric antral vascular ectasia | Gastrointestinal disorders | 1 (0.00%) |
| Gastric ulcer | Gastrointestinal disorders | 1 (0.00%) |
| Gastric varices haemorrhage | Gastrointestinal disorders | 1 (0.00%) |
| Gastric volvulus | Gastrointestinal disorders | 1 (0.00%) |
| Gastritis bacterial | Infections and infestations | 1 (0.00%) |
| Gastrointestinal hypomotility | Gastrointestinal disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Gastrointestinal infection | Infections and infestations | 1 (0.00%) |
| Gastrointestinal inflammation | Gastrointestinal disorders | 1 (0.00%) |
| Gastrointestinal necrosis | Gastrointestinal disorders | 1 (0.00%) |
| Gastrointestinal stoma complication | Injury, poisoning and procedural complications | 1 (0.00%) |
| Genital herpes | Infections and infestations | 1 (0.00%) |
| Genital lesion | Reproductive system and breast disorders | 1 (0.00%) |
| Genitourinary symptom | Renal and urinary disorders | 1 (0.00%) |
| Gingival blister | Gastrointestinal disorders | 1 (0.00%) |
| Gingivitis ulcerative | Gastrointestinal disorders | 1 (0.00%) |
| Glassy eyes | General disorders and administration site conditions | 1 (0.00%) |
| Gliosis | Nervous system disorders | 1 (0.00%) |
| Glomerulonephritis | Renal and urinary disorders | 1 (0.00%) |
| Glomerulonephritis minimal lesion | Renal and urinary disorders | 1 (0.00%) |
| Glucose tolerance impaired | Metabolism and nutrition disorders | 1 (0.00%) |
| Glycosylated haemoglobin increased | Investigations | 1 (0.00%) |
| Good syndrome | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Grip strength | Investigations | 1 (0.00%) |
| Grunting | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Haemarthrosis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Haematocrit increased | Investigations | 1 (0.00%) |
| Haemodynamic instability | Vascular disorders | 1 (0.00%) |
| Haemoglobin increased | Investigations | 1 (0.00%) |
| Haemolytic anaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Haemophagocytic lymphohistiocytosis | Immune system disorders | 1 (0.00%) |
| Haemorrhage intracranial | Nervous system disorders | 1 (0.00%) |
| Haemorrhagic diathesis | Blood and lymphatic system disorders | 1 (0.00%) |
| Haemorrhagic varicella syndrome | Infections and infestations | 1 (0.00%) |
| Haemothorax | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Hair colour changes | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Hallucination, olfactory | Psychiatric disorders | 1 (0.00%) |
| Halo vision | Eye disorders | 1 (0.00%) |
| Hand dermatitis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Haptoglobin increased | Investigations | 1 (0.00%) |
| Head banging | Psychiatric disorders | 1 (0.00%) |
| Heart rate | Investigations | 1 (0.00%) |
| Heart sounds abnormal | Investigations | 1 (0.00%) |
| Heat oedema | Injury, poisoning and procedural complications | 1 (0.00%) |
| Helicobacter infection | Infections and infestations | 1 (0.00%) |
| Hemianopia heteronymous | Nervous system disorders | 1 (0.00%) |
| Hemihyperaesthesia | Nervous system disorders | 1 (0.00%) |
| Hepatic cirrhosis | Hepatobiliary disorders | 1 (0.00%) |
| Hepatic function abnormal | Hepatobiliary disorders | 1 (0.00%) |
| Hepatitis infectious mononucleosis | Infections and infestations | 1 (0.00%) |
| Hepatomegaly | Hepatobiliary disorders | 1 (0.00%) |
| Hereditary haemorrhagic telangiectasia | Congenital, familial and genetic disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Herpes dermatitis | Infections and infestations | 1 (0.00%) |
| Herpes zoster meningitis | Infections and infestations | 1 (0.00%) |
| High-pitched crying | General disorders and administration site conditions | 1 (0.00%) |
| Hoffmann's sign | Nervous system disorders | 1 (0.00%) |
| Horner's syndrome | Nervous system disorders | 1 (0.00%) |
| Hospitalisation | Surgical and medical procedures | 1 (0.00%) |
| Hydronephrosis | Renal and urinary disorders | 1 (0.00%) |
| Hyperbilirubinaemia | Hepatobiliary disorders | 1 (0.00%) |
| Hypercalcaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hyperdynamic left ventricle | Cardiac disorders | 1 (0.00%) |
| Hyperfibrinogenaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Hypergeusia | Nervous system disorders | 1 (0.00%) |
| Hyperglycinaemia | Congenital, familial and genetic disorders | 1 (0.00%) |
| Hyperkinesia | Nervous system disorders | 1 (0.00%) |
| Hyperlipidaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hyperphagia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hypersexuality | Psychiatric disorders | 1 (0.00%) |
| Hyperthyroidism | Endocrine disorders | 1 (0.00%) |
| Hypertonic bladder | Renal and urinary disorders | 1 (0.00%) |
| Hypertrophy of tongue papillae | Gastrointestinal disorders | 1 (0.00%) |
| Hypervitaminosis B12 | Metabolism and nutrition disorders | 1 (0.00%) |
| Hypoglossal nerve disorder | Nervous system disorders | 1 (0.00%) |
| Hypokalaemic syndrome | Metabolism and nutrition disorders | 1 (0.00%) |
| Hypomenorrhoea | Reproductive system and breast disorders | 1 (0.00%) |
| Hypophosphataemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hyposomnia | Psychiatric disorders | 1 (0.00%) |
| Idiopathic intracranial hypertension | Nervous system disorders | 1 (0.00%) |
| Idiosyncratic drug reaction | General disorders and administration site conditions | 1 (0.00%) |
| Ill-defined disorder | General disorders and administration site conditions | 1 (0.00%) |
| Illusion | Psychiatric disorders | 1 (0.00%) |
| Immune-mediated adverse reaction | Immune system disorders | 1 (0.00%) |
| Immunosuppression | Immune system disorders | 1 (0.00%) |
| Impaired gastric emptying | Gastrointestinal disorders | 1 (0.00%) |
| Impaired healing | General disorders and administration site conditions | 1 (0.00%) |
| Impetigo | Infections and infestations | 1 (0.00%) |
| Increased appetite | Metabolism and nutrition disorders | 1 (0.00%) |
| Increased insulin requirement | Metabolism and nutrition disorders | 1 (0.00%) |
| Increased viscosity of bronchial secretion | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Indifference | Psychiatric disorders | 1 (0.00%) |
| Infantile vomiting | Gastrointestinal disorders | 1 (0.00%) |
| Infected dermal cyst | Infections and infestations | 1 (0.00%) |
| Infected skin ulcer | Infections and infestations | 1 (0.00%) |
| Infectious mononucleosis | Infections and infestations | 1 (0.00%) |
| Inflammatory bowel disease | Gastrointestinal disorders | 1 (0.00%) |
| Infrequent bowel movements | Gastrointestinal disorders | 1 (0.00%) |
| Infusion site bruising | General disorders and administration site conditions | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Injection site discomfort | General disorders and administration site conditions | 1 (0.00%) |
| Injection site extravasation | General disorders and administration site conditions | 1 (0.00%) |
| Injection site hypersensitivity | General disorders and administration site conditions | 1 (0.00%) |
| Injection site indentation | General disorders and administration site conditions | 1 (0.00%) |
| Injection site inflammation | General disorders and administration site conditions | 1 (0.00%) |
| Injection site irritation | General disorders and administration site conditions | 1 (0.00%) |
| Injection site joint movement impairment | General disorders and administration site conditions | 1 (0.00%) |
| Injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Insulin-requiring type 2 diabetes mellitus | Metabolism and nutrition disorders | 1 (0.00%) |
| Intentional overdose | Injury, poisoning and procedural complications | 1 (0.00%) |
| Intercepted medication error | Injury, poisoning and procedural complications | 1 (0.00%) |
| Intercepted product preparation error | Injury, poisoning and procedural complications | 1 (0.00%) |
| Interleukin level increased | Investigations | 1 (0.00%) |
| International normalised ratio abnormal | Investigations | 1 (0.00%) |
| Intervertebral discitis | Infections and infestations | 1 (0.00%) |
| Intervertebral disc protrusion | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Intracardiac thrombus | Cardiac disorders | 1 (0.00%) |
| Intracranial aneurysm | Nervous system disorders | 1 (0.00%) |
| Intracranial haematoma | Nervous system disorders | 1 (0.00%) |
| Intracranial pressure increased | Nervous system disorders | 1 (0.00%) |
| Intranasal hypoaesthesia | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Iritis | Eye disorders | 1 (0.00%) |
| Iron deficiency | Metabolism and nutrition disorders | 1 (0.00%) |
| Iron deficiency anaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Irregular sleep wake rhythm disorder | Nervous system disorders | 1 (0.00%) |
| Ischaemic cardiomyopathy | Cardiac disorders | 1 (0.00%) |
| IVth nerve paresis | Nervous system disorders | 1 (0.00%) |
| Jaw fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Joint instability | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Joint lock | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Joint noise | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Jugular vein distension | Vascular disorders | 1 (0.00%) |
| Jugular vein thrombosis | Vascular disorders | 1 (0.00%) |
| Keratic precipitates | Eye disorders | 1 (0.00%) |
| Laboratory test normal | Investigations | 1 (0.00%) |
| Lack of vaccination site rotation | Injury, poisoning and procedural complications | 1 (0.00%) |
| Lacunar infarction | Nervous system disorders | 1 (0.00%) |
| Laryngeal disorder | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Laryngeal erythema | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Larynx irritation | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Lateropulsion | Nervous system disorders | 1 (0.00%) |
| Laziness | Psychiatric disorders | 1 (0.00%) |
| Left ventricular dysfunction | Cardiac disorders | 1 (0.00%) |
| Left ventricular hypertrophy | Cardiac disorders | 1 (0.00%) |
| Leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Leukaemoid reaction | Blood and lymphatic system disorders | 1 (0.00%) |
| Leukocyturia | Renal and urinary disorders | 1 (0.00%) |
| Libido decreased | Psychiatric disorders | 1 (0.00%) |
| Lip haemorrhage | Gastrointestinal disorders | 1 (0.00%) |
| Lipodystrophy acquired | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Lip scab | Gastrointestinal disorders | 1 (0.00%) |
| Lip ulceration | Gastrointestinal disorders | 1 (0.00%) |
| Listeriosis | Infections and infestations | 1 (0.00%) |
| Liver disorder | Hepatobiliary disorders | 1 (0.00%) |
| Liver tenderness | Hepatobiliary disorders | 1 (0.00%) |
| Long thoracic nerve palsy | Nervous system disorders | 1 (0.00%) |
| Loss of bladder sensation | Renal and urinary disorders | 1 (0.00%) |
| Loss of libido | Psychiatric disorders | 1 (0.00%) |
| Low density lipoprotein increased | Investigations | 1 (0.00%) |
| Lower limb fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Lumbar puncture abnormal | Investigations | 1 (0.00%) |
| Lung abscess | Infections and infestations | 1 (0.00%) |
| Lung carcinoma cell type unspecified stage I | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Lymph gland infection | Infections and infestations | 1 (0.00%) |
| Lymph node palpable | Investigations | 1 (0.00%) |
| Lymph nodes scan abnormal | Investigations | 1 (0.00%) |
| Lymphocyte count abnormal | Investigations | 1 (0.00%) |
| Lymphocyte count increased | Investigations | 1 (0.00%) |
| Lymphocyte percentage decreased | Investigations | 1 (0.00%) |
| Macular rupture | Eye disorders | 1 (0.00%) |
| Madarosis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Major depression | Psychiatric disorders | 1 (0.00%) |
| Malignant lymphoid neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Mallory-Weiss syndrome | Gastrointestinal disorders | 1 (0.00%) |
| Mania | Psychiatric disorders | 1 (0.00%) |
| Marasmus | Metabolism and nutrition disorders | 1 (0.00%) |
| Mast cell activation syndrome | Blood and lymphatic system disorders | 1 (0.00%) |
| Mastoid disorder | Ear and labyrinth disorders | 1 (0.00%) |
| Maternal exposure during breast feeding | Injury, poisoning and procedural complications | 1 (0.00%) |
| May-Thurner syndrome | Vascular disorders | 1 (0.00%) |
| Mean cell volume decreased | Investigations | 1 (0.00%) |
| Mean cell volume increased | Investigations | 1 (0.00%) |
| Medial tibial stress syndrome | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Melanocytic naevus | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Meningioma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Meningitis bacterial | Infections and infestations | 1 (0.00%) |
| Meningitis herpes | Infections and infestations | 1 (0.00%) |
| Meningitis noninfective | Nervous system disorders | 1 (0.00%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Menopausal symptoms | Reproductive system and breast disorders | 1 (0.00%) |
| Mental status changes | Psychiatric disorders | 1 (0.00%) |
| Microcytic anaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Mitral valve disease | Cardiac disorders | 1 (0.00%) |
| Moaning | General disorders and administration site conditions | 1 (0.00%) |
| Monocyte count increased | Investigations | 1 (0.00%) |
| Mononucleosis syndrome | Infections and infestations | 1 (0.00%) |
| Mood disorder due to a general medical condition | Psychiatric disorders | 1 (0.00%) |
| Mucosal hyperaemia | General disorders and administration site conditions | 1 (0.00%) |
| Mucosal pain | General disorders and administration site conditions | 1 (0.00%) |
| Mucosa vesicle | General disorders and administration site conditions | 1 (0.00%) |
| Multi-organ disorder | General disorders and administration site conditions | 1 (0.00%) |
| Multiple allergies | Immune system disorders | 1 (0.00%) |
| Multiple injuries | Injury, poisoning and procedural complications | 1 (0.00%) |
| Multiple sclerosis | Nervous system disorders | 1 (0.00%) |
| Muscle atrophy | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Muscle oedema | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Muscle tone disorder | Nervous system disorders | 1 (0.00%) |
| Myasthenia gravis crisis | Nervous system disorders | 1 (0.00%) |
| Myocardial hypoxia | Cardiac disorders | 1 (0.00%) |
| Myocardial necrosis | Cardiac disorders | 1 (0.00%) |
| Myocarditis infectious | Infections and infestations | 1 (0.00%) |
| Myoclonic dystonia | Congenital, familial and genetic disorders | 1 (0.00%) |
| Nasal crusting | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Nasal obstruction | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Nasal odour | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Necrotising fasciitis | Infections and infestations | 1 (0.00%) |
| Neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Neoplasm progression | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Neoplasm skin | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Nephritis | Renal and urinary disorders | 1 (0.00%) |
| Nerve degeneration | Nervous system disorders | 1 (0.00%) |
| Neurogenic bladder | Renal and urinary disorders | 1 (0.00%) |
| Neurological examination normal | Investigations | 1 (0.00%) |
| Neuromuscular pain | Nervous system disorders | 1 (0.00%) |
| Neuromyopathy | Nervous system disorders | 1 (0.00%) |
| Neuropsychiatric symptoms | Psychiatric disorders | 1 (0.00%) |
| Neurosensory hypoacusis | Ear and labyrinth disorders | 1 (0.00%) |
| Neutrophil count abnormal | Investigations | 1 (0.00%) |
| Neutrophilia | Blood and lymphatic system disorders | 1 (0.00%) |
| Neutrophilic dermatosis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Neutrophil percentage increased | Investigations | 1 (0.00%) |
| Nitrite urine present | Investigations | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Nocturnal dyspnoea | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Noninfective chorioretinitis | Eye disorders | 1 (0.00%) |
| Normocytic anaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| N-terminal prohormone brain natriuretic peptide increased | Investigations | 1 (0.00%) |
| Numb chin syndrome | Nervous system disorders | 1 (0.00%) |
| Obliterative bronchiolitis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Obstruction | General disorders and administration site conditions | 1 (0.00%) |
| Obstruction gastric | Gastrointestinal disorders | 1 (0.00%) |
| Oculogyric crisis | Eye disorders | 1 (0.00%) |
| Oedematous pancreatitis | Gastrointestinal disorders | 1 (0.00%) |
| Oesophageal disorder | Gastrointestinal disorders | 1 (0.00%) |
| Oesophageal spasm | Gastrointestinal disorders | 1 (0.00%) |
| Oligoarthritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Oligomenorrhoea | Reproductive system and breast disorders | 1 (0.00%) |
| Oliguria | Renal and urinary disorders | 1 (0.00%) |
| Ophthalmoplegia | Eye disorders | 1 (0.00%) |
| Opisthotonus | Nervous system disorders | 1 (0.00%) |
| Optic ischaemic neuropathy | Eye disorders | 1 (0.00%) |
| Optic nerve disorder | Eye disorders | 1 (0.00%) |
| Oral blood blister | Gastrointestinal disorders | 1 (0.00%) |
| Oral fungal infection | Infections and infestations | 1 (0.00%) |
| Oral mucosal eruption | Gastrointestinal disorders | 1 (0.00%) |
| Orbital oedema | Eye disorders | 1 (0.00%) |
| Oropharyngeal swelling | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Orthostatic hypertension | Vascular disorders | 1 (0.00%) |
| Osteoporosis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Otitis media acute | Infections and infestations | 1 (0.00%) |
| Overweight | Metabolism and nutrition disorders | 1 (0.00%) |
| Ovulation pain | Reproductive system and breast disorders | 1 (0.00%) |
| Oxygen saturation | Investigations | 1 (0.00%) |
| Oxygen saturation immeasurable | Investigations | 1 (0.00%) |
| Palatal disorder | Gastrointestinal disorders | 1 (0.00%) |
| Palatal ulcer | Gastrointestinal disorders | 1 (0.00%) |
| Palmar erythema | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Palpable purpura | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pancreatitis necrotising | Gastrointestinal disorders | 1 (0.00%) |
| Pancreatitis relapsing | Gastrointestinal disorders | 1 (0.00%) |
| Panic disorder | Psychiatric disorders | 1 (0.00%) |
| Paraesthesia ear | Ear and labyrinth disorders | 1 (0.00%) |
| Paraganglion neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Paranoia | Psychiatric disorders | 1 (0.00%) |
| Paraplegia | Nervous system disorders | 1 (0.00%) |
| Peak expiratory flow rate decreased | Investigations | 1 (0.00%) |
| Peau d'orange | Skin and subcutaneous tissue disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Pelvic discomfort | Reproductive system and breast disorders | 1 (0.00%) |
| Performance status decreased | General disorders and administration site conditions | 1 (0.00%) |
| Perineal pain | Reproductive system and breast disorders | 1 (0.00%) |
| Periorbital discomfort | Eye disorders | 1 (0.00%) |
| Periorbital haematoma | Injury, poisoning and procedural complications | 1 (0.00%) |
| Peripheral artery thrombosis | Vascular disorders | 1 (0.00%) |
| Peripheral circulatory failure | Vascular disorders | 1 (0.00%) |
| Peripheral ischaemia | Vascular disorders | 1 (0.00%) |
| Peripheral nerve paresthesia | Nervous system disorders | 1 (0.00%) |
| Peripheral sensorimotor neuropathy | Nervous system disorders | 1 (0.00%) |
| Peripheral venous disease | Vascular disorders | 1 (0.00%) |
| Pernio-like erythema | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Persistent postural-perceptual dizziness | Nervous system disorders | 1 (0.00%) |
| Phaeochromocytoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Pharyngeal enanthema | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Pharyngeal haemorrhage | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Pharyngotonsillitis | Infections and infestations | 1 (0.00%) |
| Phrenic nerve injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| pH urine | Investigations | 1 (0.00%) |
| pH urine increased | Investigations | 1 (0.00%) |
| Physical deconditioning | General disorders and administration site conditions | 1 (0.00%) |
| Physical examination abnormal | Investigations | 1 (0.00%) |
| Pigmentation disorder | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pituitary apoplexy | Endocrine disorders | 1 (0.00%) |
| Plantar fasciitis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Plasma cell myeloma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Platelet anisocytosis | Blood and lymphatic system disorders | 1 (0.00%) |
| Platelet count abnormal | Investigations | 1 (0.00%) |
| Platelet disorder | Blood and lymphatic system disorders | 1 (0.00%) |
| Pleocytosis | Nervous system disorders | 1 (0.00%) |
| Plicated tongue | Gastrointestinal disorders | 1 (0.00%) |
| Pneumonia moraxella | Infections and infestations | 1 (0.00%) |
| Pneumonia pneumococcal | Infections and infestations | 1 (0.00%) |
| Pneumonia staphylococcal | Infections and infestations | 1 (0.00%) |
| Pneumonia streptococcal | Infections and infestations | 1 (0.00%) |
| Pneumoperitoneum | Gastrointestinal disorders | 1 (0.00%) |
| Polychondritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Polycythaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Polymenorrhoea | Reproductive system and breast disorders | 1 (0.00%) |
| Poor peripheral circulation | Vascular disorders | 1 (0.00%) |
| Post laminectomy syndrome | Injury, poisoning and procedural complications | 1 (0.00%) |
| Postoperative wound complication | Injury, poisoning and procedural complications | 1 (0.00%) |
| Postprandial hypoglycaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Post-traumatic neuralgia | Nervous system disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Post viral fatigue syndrome | Infections and infestations | 1 (0.00%) |
| Pressure of speech | Psychiatric disorders | 1 (0.00%) |
| Primary cough headache | Nervous system disorders | 1 (0.00%) |
| Procedural dizziness | Injury, poisoning and procedural complications | 1 (0.00%) |
| Procedural haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Procedural site reaction | Injury, poisoning and procedural complications | 1 (0.00%) |
| Product communication issue | Injury, poisoning and procedural complications | 1 (0.00%) |
| Product lot number issue | Product issues | 1 (0.00%) |
| Product packaging quantity issue | Product issues | 1 (0.00%) |
| Product taste abnormal | Product issues | 1 (0.00%) |
| Prophylaxis of nausea and vomiting | Surgical and medical procedures | 1 (0.00%) |
| Prostatitis | Reproductive system and breast disorders | 1 (0.00%) |
| Prostatomegaly | Reproductive system and breast disorders | 1 (0.00%) |
| Prurigo | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pruritus allergic | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pseudodementia | Psychiatric disorders | 1 (0.00%) |
| Psoriatic arthropathy | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Psychotic disorder due to a general medical condition | Psychiatric disorders | 1 (0.00%) |
| Pulmonary sepsis | Infections and infestations | 1 (0.00%) |
| Pulse absent | Investigations | 1 (0.00%) |
| Pulse pressure decreased | Investigations | 1 (0.00%) |
| Pulse waveform abnormal | Investigations | 1 (0.00%) |
| Puncture site bruise | General disorders and administration site conditions | 1 (0.00%) |
| Puncture site discharge | General disorders and administration site conditions | 1 (0.00%) |
| Pupils unequal | Eye disorders | 1 (0.00%) |
| Pustular psoriasis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pyramidal tract syndrome | Nervous system disorders | 1 (0.00%) |
| Quadrantanopia | Nervous system disorders | 1 (0.00%) |
| Radial pulse abnormal | Investigations | 1 (0.00%) |
| Radiculopathy | Nervous system disorders | 1 (0.00%) |
| Rash rubelliform | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Reaction to previous exposure to any vaccine | Injury, poisoning and procedural complications | 1 (0.00%) |
| Reading disorder | Psychiatric disorders | 1 (0.00%) |
| Rectal tenesmus | Gastrointestinal disorders | 1 (0.00%) |
| Red blood cell count decreased | Investigations | 1 (0.00%) |
| Red blood cell sedimentation rate abnormal | Investigations | 1 (0.00%) |
| Red cell distribution width increased | Investigations | 1 (0.00%) |
| Red ear syndrome | Ear and labyrinth disorders | 1 (0.00%) |
| Red man syndrome | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Regurgitation | Gastrointestinal disorders | 1 (0.00%) |
| Renal atrophy | Renal and urinary disorders | 1 (0.00%) |
| Renal haemorrhage | Renal and urinary disorders | 1 (0.00%) |
| Repetitive speech | Nervous system disorders | 1 (0.00%) |
| Respiratory tract infection bacterial | Infections and infestations | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Resting tremor | Nervous system disorders | 1 (0.00%) |
| Retinal artery occlusion | Eye disorders | 1 (0.00%) |
| Retinal degeneration | Eye disorders | 1 (0.00%) |
| Retinal disorder | Eye disorders | 1 (0.00%) |
| Retinal toxicity | Eye disorders | 1 (0.00%) |
| Retinal vascular thrombosis | Eye disorders | 1 (0.00%) |
| Retinitis | Infections and infestations | 1 (0.00%) |
| Retinopathy | Eye disorders | 1 (0.00%) |
| Reversible airways obstruction | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Reversible cerebral vasoconstriction syndrome | Nervous system disorders | 1 (0.00%) |
| Rheumatic disorder | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Rib fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Right ventricular failure | Cardiac disorders | 1 (0.00%) |
| Rinne tuning fork test abnormal | Investigations | 1 (0.00%) |
| Root canal infection | Infections and infestations | 1 (0.00%) |
| Ruptured cerebral aneurysm | Nervous system disorders | 1 (0.00%) |
| Sacroiliitis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Saliva discolouration | Gastrointestinal disorders | 1 (0.00%) |
| Salivary duct obstruction | Gastrointestinal disorders | 1 (0.00%) |
| Salt craving | Metabolism and nutrition disorders | 1 (0.00%) |
| Sarcoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| SARS-CoV-2 sepsis | Infections and infestations | 1 (0.00%) |
| SARS-CoV-2 test | Investigations | 1 (0.00%) |
| SARS-CoV-2 test false positive | Investigations | 1 (0.00%) |
| Scleroderma associated digital ulcer | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Scrotal disorder | Reproductive system and breast disorders | 1 (0.00%) |
| Scrotal erythema | Reproductive system and breast disorders | 1 (0.00%) |
| Scrotal inflammation | Reproductive system and breast disorders | 1 (0.00%) |
| Second primary malignancy | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Seizure cluster | Nervous system disorders | 1 (0.00%) |
| Self-injurious ideation | Psychiatric disorders | 1 (0.00%) |
| Sensorimotor disorder | Nervous system disorders | 1 (0.00%) |
| Serum sickness-like reaction | Immune system disorders | 1 (0.00%) |
| Severe acute respiratory syndrome | Infections and infestations | 1 (0.00%) |
| Shoulder injury related to vaccine administration | General disorders and administration site conditions | 1 (0.00%) |
| Sinus arrest | Cardiac disorders | 1 (0.00%) |
| Sinus node dysfunction | Cardiac disorders | 1 (0.00%) |
| Sinus rhythm | Investigations | 1 (0.00%) |
| Sitting disability | Social circumstances | 1 (0.00%) |
| Skeletal injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Skin depigmentation | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skin discomfort | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skin hypertrophy | Skin and subcutaneous tissue disorders | 1 (0.00%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Skin odour abnormal | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skull fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Sleep attacks | Psychiatric disorders | 1 (0.00%) |
| Sleep deficit | Nervous system disorders | 1 (0.00%) |
| Sleep disorder due to general medical condition, hypersomnia type | Psychiatric disorders | 1 (0.00%) |
| Sleep inertia | Psychiatric disorders | 1 (0.00%) |
| Sleep talking | Psychiatric disorders | 1 (0.00%) |
| Slow response to stimuli | Nervous system disorders | 1 (0.00%) |
| Small intestinal obstruction | Gastrointestinal disorders | 1 (0.00%) |
| Snoring | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Social avoidant behaviour | Psychiatric disorders | 1 (0.00%) |
| Social fear | Psychiatric disorders | 1 (0.00%) |
| Soft tissue injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Spinal cord injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Spinal disorder | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Spinal osteoarthritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Spinal stenosis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Spondylitis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Sputum increased | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Staphylococcal infection | Infections and infestations | 1 (0.00%) |
| Stereotypy | Psychiatric disorders | 1 (0.00%) |
| Stertor | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Stoma site haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Stoma site pain | Injury, poisoning and procedural complications | 1 (0.00%) |
| Stomatitis haemorrhagic | Gastrointestinal disorders | 1 (0.00%) |
| Strabismus | Eye disorders | 1 (0.00%) |
| Streptococcal bacteraemia | Infections and infestations | 1 (0.00%) |
| Streptococcal infection | Infections and infestations | 1 (0.00%) |
| Streptococcus test positive | Investigations | 1 (0.00%) |
| Subclavian artery thrombosis | Vascular disorders | 1 (0.00%) |
| Subclavian vein thrombosis | Vascular disorders | 1 (0.00%) |
| Subdural haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Sudden onset of sleep | Nervous system disorders | 1 (0.00%) |
| Sunburn | Injury, poisoning and procedural complications | 1 (0.00%) |
| Superinfection bacterial | Infections and infestations | 1 (0.00%) |
| Suprapubic pain | General disorders and administration site conditions | 1 (0.00%) |
| Swollen joint count increased | Investigations | 1 (0.00%) |
| Synovial fluid white blood cells positive | Investigations | 1 (0.00%) |
| Systemic immune activation | Immune system disorders | 1 (0.00%) |
| Takayasu's arteritis | Vascular disorders | 1 (0.00%) |
| Tardive dyskinesia | Nervous system disorders | 1 (0.00%) |
| Temporal lobe epilepsy | Nervous system disorders | 1 (0.00%) |
| Tendon disorder | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Tendon injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Terminal ileitis | Gastrointestinal disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------------|---|-----------------|
| Testicular torsion | Reproductive system and breast disorders | 1 (0.00%) |
| Tetany | Metabolism and nutrition disorders | 1 (0.00%) |
| Therapeutic product effect increased | General disorders and administration site conditions | 1 (0.00%) |
| Thermohypoaesthesia | Nervous system disorders | 1 (0.00%) |
| Thirst decreased | General disorders and administration site conditions | 1 (0.00%) |
| Thoracic outlet syndrome | Nervous system disorders | 1 (0.00%) |
| Thrombotic thrombocytopenic purpura | Blood and lymphatic system disorders | 1 (0.00%) |
| Thunderclap headache | Nervous system disorders | 1 (0.00%) |
| Thyroid cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Thyroid hormones increased | Investigations | 1 (0.00%) |
| Thyroiditis | Endocrine disorders | 1 (0.00%) |
| Thyroid mass | Endocrine disorders | 1 (0.00%) |
| Tic | Psychiatric disorders | 1 (0.00%) |
| Tongue blistering | Gastrointestinal disorders | 1 (0.00%) |
| Tongue eruption | Gastrointestinal disorders | 1 (0.00%) |
| Tongue injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Tonsillar erythema | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Tonsillar ulcer | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Tonsillitis bacterial | Infections and infestations | 1 (0.00%) |
| Tooth abscess | Infections and infestations | 1 (0.00%) |
| Torsade de pointes | Cardiac disorders | 1 (0.00%) |
| Toxicity to various agents | Injury, poisoning and procedural complications | 1 (0.00%) |
| Toxic skin eruption | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Transcription medication error | Injury, poisoning and procedural complications | 1 (0.00%) |
| Traumatic haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Treatment failure | General disorders and administration site conditions | 1 (0.00%) |
| Treatment noncompliance | General disorders and administration site conditions | 1 (0.00%) |
| Troponin I increased | Investigations | 1 (0.00%) |
| Troponin T increased | Investigations | 1 (0.00%) |
| Tryptase decreased | Investigations | 1 (0.00%) |
| Tuberculin test positive | Investigations | 1 (0.00%) |
| Tumour perforation | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Tympanic membrane disorder | Ear and labyrinth disorders | 1 (0.00%) |
| Tympanic membrane hyperaemia | Ear and labyrinth disorders | 1 (0.00%) |
| Type II hypersensitivity | Immune system disorders | 1 (0.00%) |
| Ulnar nerve palsy | Nervous system disorders | 1 (0.00%) |
| Upper respiratory tract inflammation | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Urethral disorder | Renal and urinary disorders | 1 (0.00%) |
| Urethral haemorrhage | Renal and urinary disorders | 1 (0.00%) |
| Urinary assistance device user | Social circumstances | 1 (0.00%) |
| Urinary sediment present | Investigations | 1 (0.00%) |
| Urinary tract candidiasis | Infections and infestations | 1 (0.00%) |
| Urinary tract disorder | Renal and urinary disorders | 1 (0.00%) |
| Urinary tract inflammation | Renal and urinary disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Urinary tract pain | Renal and urinary disorders | 1 (0.00%) |
| Urticaria chronic | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Urticarial vasculitis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Urticaria pressure | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Urticaria thermal | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Uterine inflammation | Reproductive system and breast disorders | 1 (0.00%) |
| Uterine pain | Reproductive system and breast disorders | 1 (0.00%) |
| Vaccination site atrophy | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site discharge | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site dryness | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site erosion | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site exfoliation | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site injury | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site ischaemia | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site macule | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site pustule | Infections and infestations | 1 (0.00%) |
| Vaccination site recall reaction | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site scar | General disorders and administration site conditions | 1 (0.00%) |
| Vaginal disorder | Reproductive system and breast disorders | 1 (0.00%) |
| Vaginal lesion | Reproductive system and breast disorders | 1 (0.00%) |
| Varicella | Infections and infestations | 1 (0.00%) |
| Varicella zoster virus infection | Infections and infestations | 1 (0.00%) |
| Varicose vein | Vascular disorders | 1 (0.00%) |
| Vascular encephalopathy | Nervous system disorders | 1 (0.00%) |
| Vascular pain | Vascular disorders | 1 (0.00%) |
| Vascular rupture | Vascular disorders | 1 (0.00%) |
| Vasospasm | Vascular disorders | 1 (0.00%) |
| Venous haemorrhage | Vascular disorders | 1 (0.00%) |
| Venous oxygen saturation decreased | Investigations | 1 (0.00%) |
| Vestibular migraine | Nervous system disorders | 1 (0.00%) |
| Viral labyrinthitis | Infections and infestations | 1 (0.00%) |
| Viral test | Investigations | 1 (0.00%) |
| Viral upper respiratory tract infection | Infections and infestations | 1 (0.00%) |
| Virologic failure | Infections and infestations | 1 (0.00%) |
| Vital capacity | Investigations | 1 (0.00%) |
| Vitamin B12 decreased | Investigations | 1 (0.00%) |
| Vitamin D decreased | Investigations | 1 (0.00%) |
| Vlth nerve paresis | Nervous system disorders | 1 (0.00%) |
| Vocal cord dysfunction | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Vulval abscess | Infections and infestations | 1 (0.00%) |
| Vulval disorder | Reproductive system and breast disorders | 1 (0.00%) |
| Vulvovaginal pain | Reproductive system and breast disorders | 1 (0.00%) |
| Vulvovaginal pruritus | Reproductive system and breast disorders | 1 (0.00%) |
| Vulvovaginal swelling | Reproductive system and breast disorders | 1 (0.00%) |
| Wandering pacemaker | Cardiac disorders | 1 (0.00%) |
| Weber tuning fork test abnormal | Investigations | 1 (0.00%) |



| Preferred Term | System Organ Class (SOC) | Number of Cases |
|----------------------------------|---|-----------------|
| White blood cells urine positive | Investigations | 1 (0.00%) |
| White coat hypertension | Vascular disorders | 1 (0.00%) |
| White matter lesion | Nervous system disorders | 1 (0.00%) |
| Winged scapula | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Withdrawal bleed | Reproductive system and breast disorders | 1 (0.00%) |
| Wound closure | Surgical and medical procedures | 1 (0.00%) |
| Wound haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Wound secretion | Injury, poisoning and procedural complications | 1 (0.00%) |

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

PF-07302048 - ALL

Reporting Period: Through 28-FEB-2021

Total Number of Cases: 42086 (100%) (ALL) / 42086 (OVERALL)

Total Number of Adverse Events (PT): 158893 (ALL)

NON CT

Total Number of Cases: 42086

Total Number of Adverse Events (PT): 158893

| | | Number of Cases | Percentage (%) |
|-------------------------------------|---|-----------------|----------------|
| Sex | | | |
| | FEMALE | 29914 | 71.1 % |
| | MALE | 9182 | 21.8 % |
| | NO DATA | 2990 | 7.1 % |
| Age Range | | | |
| Min = 0.01 Years | 0 to 27 days | 7 | 0.0 % |
| Max = 107.0 Years | 28 days to 23 months | 68 | 0.2 % |
| Mean = 50.9 | 2 to 11 years | 54 | 0.1 % |
| Median = 49.0 | 12 to 17 years | 46 | 0.1 % |
| Standard Deviation = 19.05 | 18 - 30 years | 4953 | 11.8 % |
| n = 34952 | 31 - 50 years | 13886 | 33.0 % |
| | 51 - 64 years | 7884 | 18.7 % |
| | 65 - 74 years | 3098 | 7.4 % |
| | Greater than or equal to 75 years | 5214 | 12.4 % |
| | Unknown | 6873 | 16.3 % |
| | N/A - age range only applies to post-birth patients | 3 | 0.0 % |
| Country Where Event Occurred | | | |
| | UNITED STATES | 13739 | 32.6 % |
| | UNITED KINGDOM | 13404 | 31.8 % |
| | ITALY | 2578 | 6.1 % |
| | GERMANY | 1913 | 4.5 % |
| | FRANCE | 1506 | 3.6 % |
| | PORTUGAL | 866 | 2.1 % |
| | SPAIN | 756 | 1.8 % |
| | MEXICO | 702 | 1.7 % |
| | SWEDEN | 648 | 1.5 % |
| | GREECE | 640 | 1.5 % |
| | DENMARK | 610 | 1.4 % |
| | ISRAEL | 569 | 1.4 % |
| | ROMANIA | 401 | 1.0 % |
| | POLAND | 388 | 0.9 % |
| | CZECH REPUBLIC | 306 | 0.7 % |
| | NORWAY | 294 | 0.7 % |
| | AUSTRIA | 288 | 0.7 % |
| | CANADA | 276 | 0.7 % |
| | FINLAND | 236 | 0.6 % |

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| | | Number of Cases | Percentage (%) |
|-----------------------------|--------------------------------------|-----------------|----------------|
| Country Where Event Occured | | | |
| | IRELAND | 235 | 0.6 % |
| | BELGIUM | 221 | 0.5 % |
| | HUNGARY | 191 | 0.5 % |
| | NETHERLANDS | 180 | 0.4 % |
| | CROATIA | 142 | 0.3 % |
| | LATVIA | 134 | 0.3 % |
| | ICELAND | 81 | 0.2 % |
| | ESTONIA | 77 | 0.2 % |
| | SLOVAKIA | 76 | 0.2 % |
| | BULGARIA | 71 | 0.2 % |
| | SLOVENIA | 68 | 0.2 % |
| | CYPRUS | 65 | 0.2 % |
| | PUERTO RICO | 56 | 0.1 % |
| | SERBIA | 56 | 0.1 % |
| | SWITZERLAND | 51 | 0.1 % |
| | CHILE | 43 | 0.1 % |
| | COSTA RICA | 40 | 0.1 % |
| | MALTA | 37 | 0.1 % |
| | UNITED ARAB EMIRATES | 29 | 0.1 % |
| | LITHUANIA | 27 | 0.1 % |
| | SAUDI ARABIA | 20 | 0.0 % |
| | LUXEMBOURG | 12 | 0.0 % |
| | SINGAPORE | 10 | 0.0 % |
| | QATAR | 7 | 0.0 % |
| | NORTHERN MARIANA ISLANDS | 4 | 0.0 % |
| | BAHRAIN | 3 | 0.0 % |
| | ECUADOR | 3 | 0.0 % |
| | JORDAN | 3 | 0.0 % |
| | KUWAIT | 3 | 0.0 % |
| | UNITED STATES MINOR OUTLYING ISLANDS | 3 | 0.0 % |
| | ANGOLA | 2 | 0.0 % |
| | HOLY SEE (VATICAN CITY STATE) | 2 | 0.0 % |
| | JAPAN | 2 | 0.0 % |
| | OMAN | 2 | 0.0 % |
| | AFGHANISTAN | 1 | 0.0 % |
| | ANDORRA | 1 | 0.0 % |
| | BERMUDA | 1 | 0.0 % |
| | COLOMBIA | 1 | 0.0 % |
| | FRENCH POLYNESIA | 1 | 0.0 % |
| | GIBRALTAR | 1 | 0.0 % |
| | INDIA | 1 | 0.0 % |
| | LEBANON | 1 | 0.0 % |
| | PANAMA | 1 | 0.0 % |

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| | | Number of Cases | Percentage (%) |
|------------------------------------|---|-----------------|----------------|
| Country Where Event Occured | | | |
| | TURKS AND CAICOS ISLANDS | 1 | 0.0 % |
| Source | | | |
| | Clinical Study | 224 | 0.5 % |
| | Literature - Non Study | 1 | 0.0 % |
| | Literature - Study | 14 | 0.0 % |
| | Solicited | 5 | 0.0 % |
| | Spontaneous | 41842 | 99.4 % |
| Case Seriousness | | | |
| | SERIOUS | 22299 | 53.0 % |
| | NONSERIOUS | 19787 | 47.0 % |
| HP/Medically Confirmed | | | |
| | Yes | 25379 | 60.3 % |
| | No | 16707 | 39.7 % |
| Special Populations | Pregnant/Breastfeeding Women | | |
| | Yes | 425 | 1.0 % |
| | Pediatric Non EIU | | |
| | Yes | 108 | 0.3 % |
| | Elderly | | |
| | Yes | 8312 | 19.8 % |
| | Race/Ethnicity | | |
| | ASIAN - HISPANIC OR LATINO | 12 | 0.0 % |
| | ASIAN - NO DATA | 357 | 0.8 % |
| | ASIAN - NOT HISPANIC OR LATINO | 382 | 0.9 % |
| | ASIAN - OTHER | 1 | 0.0 % |
| | BLACK - HISPANIC OR LATINO | 18 | 0.0 % |
| | BLACK - NO DATA | 314 | 0.7 % |
| | BLACK - NOT HISPANIC OR LATINO | 201 | 0.5 % |
| | BLACK - OTHER | 2 | 0.0 % |
| | CAUCASIAN - HISPANIC OR LATINO | 316 | 0.8 % |
| | CAUCASIAN - NO DATA | 3811 | 9.1 % |
| | CAUCASIAN - NOT HISPANIC OR LATINO | 3595 | 8.5 % |
| | CAUCASIAN - OTHER | 3 | 0.0 % |
| | NATIVE AMERICAN - HISPANIC OR LATINO | 12 | 0.0 % |
| | NATIVE AMERICAN - NO DATA | 54 | 0.1 % |
| | NATIVE AMERICAN - NOT HISPANIC OR LATINO | 25 | 0.1 % |
| | NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO | 2 | 0.0 % |
| | NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA | 12 | 0.0 % |
| | NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO | 24 | 0.1 % |
| | NO DATA - HISPANIC OR LATINO | 476 | 1.1 % |
| | NO DATA - NO DATA | 32301 | 76.7 % |
| | NO DATA - NOT HISPANIC OR LATINO | 116 | 0.3 % |
| | NO DATA - OTHER | 52 | 0.1 % |

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

PF-07302048 - ALL

Reporting Period: Through 28-FEB-2021
Total Number of Cases: 42086 (100%) (ALL) / 42086 (OVERALL)
Total Number of Adverse Events (PT): 158893 (ALL)

NON CT

Total Number of Cases: 42086
Total Number of Adverse Events (PT): 158893

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------|--|-----------------|
| Headache | Nervous system disorders | 10131 (24.07%) |
| Pyrexia | General disorders and administration site conditions | 7666 (18.22%) |
| Fatigue | General disorders and administration site conditions | 7338 (17.44%) |
| Chills | General disorders and administration site conditions | 5514 (13.10%) |
| Nausea | Gastrointestinal disorders | 5182 (12.31%) |
| Vaccination site pain | General disorders and administration site conditions | 5181 (12.31%) |
| Myalgia | Musculoskeletal and connective tissue disorders | 4915 (11.68%) |
| Pain in extremity | Musculoskeletal and connective tissue disorders | 3959 (9.41%) |
| Dizziness | Nervous system disorders | 3720 (8.84%) |
| Pain | General disorders and administration site conditions | 3691 (8.77%) |
| Arthralgia | Musculoskeletal and connective tissue disorders | 3525 (8.38%) |
| Malaise | General disorders and administration site conditions | 2897 (6.88%) |
| Asthenia | General disorders and administration site conditions | 2285 (5.43%) |
| Drug ineffective | General disorders and administration site conditions | 2201 (5.23%) |
| Dyspnoea | Respiratory, thoracic and mediastinal disorders | 2057 (4.89%) |
| Lymphadenopathy | Blood and lymphatic system disorders | 1972 (4.69%) |
| COVID-19 | Infections and infestations | 1927 (4.58%) |
| Diarrhoea | Gastrointestinal disorders | 1880 (4.47%) |
| Vomiting | Gastrointestinal disorders | 1698 (4.03%) |
| Paraesthesia | Nervous system disorders | 1500 (3.56%) |
| Pruritus | Skin and subcutaneous tissue disorders | 1447 (3.44%) |
| Rash | Skin and subcutaneous tissue disorders | 1404 (3.34%) |
| Cough | Respiratory, thoracic and mediastinal disorders | 1146 (2.72%) |
| Tachycardia | Cardiac disorders | 1098 (2.61%) |
| Erythema | Skin and subcutaneous tissue disorders | 1044 (2.48%) |
| Hypoesthesia | Nervous system disorders | 999 (2.37%) |
| Oropharyngeal pain | Respiratory, thoracic and mediastinal disorders | 948 (2.25%) |
| Vaccination site erythema | General disorders and administration site conditions | 930 (2.21%) |
| Vaccination site swelling | General disorders and administration site conditions | 913 (2.17%) |
| Hyperhidrosis | Skin and subcutaneous tissue disorders | 900 (2.14%) |
| Off label use | Injury, poisoning and procedural complications | 880 (2.09%) |
| Urticaria | Skin and subcutaneous tissue disorders | 862 (2.05%) |
| Influenza like illness | General disorders and administration site conditions | 835 (1.98%) |
| Product use issue | Injury, poisoning and procedural complications | 828 (1.97%) |
| Back pain | Musculoskeletal and connective tissue disorders | 809 (1.92%) |
| Feeling abnormal | General disorders and administration site conditions | 787 (1.87%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Feeling hot | General disorders and administration site conditions | 785 (1.87%) |
| Tremor | Nervous system disorders | 739 (1.76%) |
| Chest pain | General disorders and administration site conditions | 722 (1.72%) |
| Syncope | Nervous system disorders | 710 (1.69%) |
| Palpitations | Cardiac disorders | 698 (1.66%) |
| Neck pain | Musculoskeletal and connective tissue disorders | 669 (1.59%) |
| Peripheral swelling | General disorders and administration site conditions | 647 (1.54%) |
| Heart rate increased | Investigations | 644 (1.53%) |
| Hypertension | Vascular disorders | 641 (1.52%) |
| Decreased appetite | Metabolism and nutrition disorders | 637 (1.51%) |
| Chest discomfort | General disorders and administration site conditions | 612 (1.45%) |
| Hypersensitivity | Immune system disorders | 596 (1.42%) |
| Paraesthesia oral | Gastrointestinal disorders | 589 (1.40%) |
| Anaphylactic reaction | Immune system disorders | 588 (1.40%) |
| Feeling cold | General disorders and administration site conditions | 581 (1.38%) |
| Poor quality product administered | Injury, poisoning and procedural complications | 577 (1.37%) |
| Migraine | Nervous system disorders | 570 (1.35%) |
| Insomnia | Psychiatric disorders | 547 (1.30%) |
| Abdominal pain | Gastrointestinal disorders | 539 (1.28%) |
| Somnolence | Nervous system disorders | 533 (1.27%) |
| Inappropriate schedule of product administration | Injury, poisoning and procedural complications | 528 (1.25%) |
| Lethargy | Nervous system disorders | 516 (1.23%) |
| Abdominal pain upper | Gastrointestinal disorders | 510 (1.21%) |
| Vertigo | Ear and labyrinth disorders | 485 (1.15%) |
| Blood pressure increased | Investigations | 471 (1.12%) |
| Dysgeusia | Nervous system disorders | 462 (1.10%) |
| Swelling | General disorders and administration site conditions | 460 (1.09%) |
| Flushing | Vascular disorders | 458 (1.09%) |
| Rhinorrhoea | Respiratory, thoracic and mediastinal disorders | 452 (1.07%) |
| Facial paralysis | Nervous system disorders | 439 (1.04%) |
| Illness | General disorders and administration site conditions | 431 (1.02%) |
| SARS-CoV-2 test positive | Investigations | 415 (0.99%) |
| Vaccination site warmth | General disorders and administration site conditions | 410 (0.97%) |
| Musculoskeletal stiffness | Musculoskeletal and connective tissue disorders | 409 (0.97%) |
| Swelling face | General disorders and administration site conditions | 400 (0.95%) |
| Muscular weakness | Musculoskeletal and connective tissue disorders | 398 (0.95%) |
| Death | General disorders and administration site conditions | 395 (0.94%) |
| Respiratory distress | Respiratory, thoracic and mediastinal disorders | 393 (0.93%) |
| Lymph node pain | Blood and lymphatic system disorders | 390 (0.93%) |
| Presyncope | Nervous system disorders | 382 (0.91%) |
| Body temperature increased | Investigations | 381 (0.91%) |
| Limb discomfort | Musculoskeletal and connective tissue disorders | 373 (0.89%) |
| Hypotension | Vascular disorders | 359 (0.85%) |
| Loss of consciousness | Nervous system disorders | 357 (0.85%) |
| Axillary pain | General disorders and administration site conditions | 335 (0.80%) |



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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Vaccination site pruritus | General disorders and administration site conditions | 333 (0.79%) |
| Hypoaesthesia oral | Gastrointestinal disorders | 317 (0.75%) |
| Confusional state | Psychiatric disorders | 316 (0.75%) |
| Anxiety | Psychiatric disorders | 306 (0.73%) |
| Rash erythematous | Skin and subcutaneous tissue disorders | 305 (0.72%) |
| Vision blurred | Eye disorders | 299 (0.71%) |
| Muscle spasms | Musculoskeletal and connective tissue disorders | 291 (0.69%) |
| Influenza | Infections and infestations | 290 (0.69%) |
| Throat tightness | Respiratory, thoracic and mediastinal disorders | 288 (0.68%) |
| Hot flush | Vascular disorders | 287 (0.68%) |
| Eye pain | Eye disorders | 283 (0.67%) |
| Dysphagia | Gastrointestinal disorders | 281 (0.67%) |
| Product temperature excursion issue | Product issues | 280 (0.67%) |
| Lip swelling | Gastrointestinal disorders | 279 (0.66%) |
| Nasopharyngitis | Infections and infestations | 278 (0.66%) |
| Throat irritation | Respiratory, thoracic and mediastinal disorders | 278 (0.66%) |
| Rash pruritic | Skin and subcutaneous tissue disorders | 276 (0.66%) |
| Suspected COVID-19 | Infections and infestations | 270 (0.64%) |
| Nasal congestion | Respiratory, thoracic and mediastinal disorders | 268 (0.64%) |
| Swollen tongue | Gastrointestinal disorders | 268 (0.64%) |
| Herpes zoster | Infections and infestations | 259 (0.62%) |
| Gait disturbance | General disorders and administration site conditions | 256 (0.61%) |
| Oxygen saturation decreased | Investigations | 254 (0.60%) |
| Burning sensation | Nervous system disorders | 239 (0.57%) |
| Tinnitus | Ear and labyrinth disorders | 239 (0.57%) |
| Dry mouth | Gastrointestinal disorders | 238 (0.57%) |
| Condition aggravated | General disorders and administration site conditions | 231 (0.55%) |
| Underdose | Injury, poisoning and procedural complications | 229 (0.54%) |
| Ageusia | Nervous system disorders | 228 (0.54%) |
| Cold sweat | Skin and subcutaneous tissue disorders | 228 (0.54%) |
| Discomfort | General disorders and administration site conditions | 226 (0.54%) |
| Product preparation error | Injury, poisoning and procedural complications | 222 (0.53%) |
| Pharyngeal swelling | Respiratory, thoracic and mediastinal disorders | 221 (0.53%) |
| Ear pain | Ear and labyrinth disorders | 218 (0.52%) |
| Incorrect route of product administration | Injury, poisoning and procedural complications | 218 (0.52%) |
| Bone pain | Musculoskeletal and connective tissue disorders | 214 (0.51%) |
| Abdominal discomfort | Gastrointestinal disorders | 213 (0.51%) |
| Angioedema | Skin and subcutaneous tissue disorders | 209 (0.50%) |
| Fall | Injury, poisoning and procedural complications | 204 (0.48%) |
| Seizure | Nervous system disorders | 204 (0.48%) |
| Anosmia | Nervous system disorders | 194 (0.46%) |
| Maternal exposure during pregnancy | Injury, poisoning and procedural complications | 189 (0.45%) |
| Night sweats | Skin and subcutaneous tissue disorders | 188 (0.45%) |
| Pallor | Vascular disorders | 188 (0.45%) |
| Sensitive skin | Skin and subcutaneous tissue disorders | 178 (0.42%) |
| Eye swelling | Eye disorders | 175 (0.42%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Balance disorder | Nervous system disorders | 174 (0.41%) |
| Wheezing | Respiratory, thoracic and mediastinal disorders | 173 (0.41%) |
| Disease recurrence | General disorders and administration site conditions | 169 (0.40%) |
| Hyperpyrexia | General disorders and administration site conditions | 169 (0.40%) |
| Disturbance in attention | Nervous system disorders | 167 (0.40%) |
| Cerebrovascular accident | Nervous system disorders | 160 (0.38%) |
| Mobility decreased | Musculoskeletal and connective tissue disorders | 159 (0.38%) |
| Peripheral coldness | Vascular disorders | 159 (0.38%) |
| Rash macular | Skin and subcutaneous tissue disorders | 153 (0.36%) |
| Vaccination site mass | General disorders and administration site conditions | 151 (0.36%) |
| General physical health deterioration | General disorders and administration site conditions | 149 (0.35%) |
| Pneumonia | Infections and infestations | 147 (0.35%) |
| Circumstance or information capable of leading to medication error | Injury, poisoning and procedural complications | 144 (0.34%) |
| Dysphonia | Respiratory, thoracic and mediastinal disorders | 143 (0.34%) |
| Overdose | Injury, poisoning and procedural complications | 142 (0.34%) |
| Vaccination site reaction | General disorders and administration site conditions | 140 (0.33%) |
| Feeling of body temperature change | General disorders and administration site conditions | 137 (0.33%) |
| Product preparation issue | Injury, poisoning and procedural complications | 137 (0.33%) |
| Joint swelling | Musculoskeletal and connective tissue disorders | 136 (0.32%) |
| Sleep disorder | Psychiatric disorders | 136 (0.32%) |
| Exposure via breast milk | Injury, poisoning and procedural complications | 133 (0.32%) |
| Head discomfort | Nervous system disorders | 133 (0.32%) |
| Vaccination site movement impairment | General disorders and administration site conditions | 133 (0.32%) |
| Inflammation | General disorders and administration site conditions | 132 (0.31%) |
| Visual impairment | Eye disorders | 129 (0.31%) |
| Asthma | Respiratory, thoracic and mediastinal disorders | 128 (0.30%) |
| Epistaxis | Respiratory, thoracic and mediastinal disorders | 127 (0.30%) |
| Vaccination site rash | General disorders and administration site conditions | 126 (0.30%) |
| Allergy to vaccine | Immune system disorders | 125 (0.30%) |
| Atrial fibrillation | Cardiac disorders | 125 (0.30%) |
| Blood pressure decreased | Investigations | 125 (0.30%) |
| Dizziness postural | Nervous system disorders | 123 (0.29%) |
| Hypertensive crisis | Vascular disorders | 123 (0.29%) |
| Vaccination site induration | General disorders and administration site conditions | 122 (0.29%) |
| Oedema | General disorders and administration site conditions | 121 (0.29%) |
| Photophobia | Eye disorders | 117 (0.28%) |
| Nervousness | Psychiatric disorders | 116 (0.28%) |
| Neuralgia | Nervous system disorders | 115 (0.27%) |
| Sneezing | Respiratory, thoracic and mediastinal disorders | 114 (0.27%) |
| Taste disorder | Nervous system disorders | 114 (0.27%) |
| Vaccination site oedema | General disorders and administration site conditions | 114 (0.27%) |
| Contusion | Injury, poisoning and procedural complications | 112 (0.27%) |
| Hypersomnia | Nervous system disorders | 112 (0.27%) |
| Pain in jaw | Musculoskeletal and connective tissue disorders | 112 (0.27%) |
| Musculoskeletal pain | Musculoskeletal and connective tissue disorders | 111 (0.26%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Sudden death | General disorders and administration site conditions | 109 (0.26%) |
| Anaphylactic shock | Immune system disorders | 107 (0.25%) |
| Depressed level of consciousness | Nervous system disorders | 106 (0.25%) |
| Disorientation | Psychiatric disorders | 103 (0.24%) |
| Injection site pain | General disorders and administration site conditions | 103 (0.24%) |
| Arrhythmia | Cardiac disorders | 102 (0.24%) |
| Dysentery | Infections and infestations | 102 (0.24%) |
| Eye pruritus | Eye disorders | 102 (0.24%) |
| Dehydration | Metabolism and nutrition disorders | 100 (0.24%) |
| Joint range of motion decreased | Musculoskeletal and connective tissue disorders | 100 (0.24%) |
| Vaccination site inflammation | General disorders and administration site conditions | 99 (0.24%) |
| Facial pain | General disorders and administration site conditions | 98 (0.23%) |
| Vaccination site bruising | General disorders and administration site conditions | 96 (0.23%) |
| Bronchospasm | Respiratory, thoracic and mediastinal disorders | 95 (0.23%) |
| Loss of personal independence in daily activities | Social circumstances | 94 (0.22%) |
| Speech disorder | Nervous system disorders | 94 (0.22%) |
| Wrong technique in product usage process | Injury, poisoning and procedural complications | 94 (0.22%) |
| Movement disorder | Nervous system disorders | 91 (0.22%) |
| Restlessness | Psychiatric disorders | 91 (0.22%) |
| Ocular hyperaemia | Eye disorders | 90 (0.21%) |
| Cardiac arrest | Cardiac disorders | 89 (0.21%) |
| Myocardial infarction | Cardiac disorders | 89 (0.21%) |
| Sensation of foreign body | General disorders and administration site conditions | 89 (0.21%) |
| Thirst | General disorders and administration site conditions | 89 (0.21%) |
| Pain of skin | Skin and subcutaneous tissue disorders | 88 (0.21%) |
| C-reactive protein increased | Investigations | 87 (0.21%) |
| Vaccination site paraesthesia | General disorders and administration site conditions | 85 (0.20%) |
| Dyspepsia | Gastrointestinal disorders | 84 (0.20%) |
| Epilepsy | Nervous system disorders | 83 (0.20%) |
| SARS-CoV-2 antibody test negative | Investigations | 83 (0.20%) |
| Face oedema | General disorders and administration site conditions | 82 (0.19%) |
| Lacrimation increased | Eye disorders | 82 (0.19%) |
| Laryngeal oedema | Respiratory, thoracic and mediastinal disorders | 82 (0.19%) |
| Urinary tract infection | Infections and infestations | 82 (0.19%) |
| Cellulitis | Infections and infestations | 81 (0.19%) |
| Ear discomfort | Ear and labyrinth disorders | 81 (0.19%) |
| Muscle twitching | Musculoskeletal and connective tissue disorders | 81 (0.19%) |
| Poor quality sleep | Nervous system disorders | 81 (0.19%) |
| Cardiac failure | Cardiac disorders | 80 (0.19%) |
| Dysarthria | Nervous system disorders | 80 (0.19%) |
| Oral herpes | Infections and infestations | 80 (0.19%) |
| Vaccination site discomfort | General disorders and administration site conditions | 79 (0.19%) |
| Tenderness | General disorders and administration site conditions | 78 (0.19%) |
| Tension headache | Nervous system disorders | 78 (0.19%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Muscle tightness | Musculoskeletal and connective tissue disorders | 77 (0.18%) |
| Oropharyngeal discomfort | Respiratory, thoracic and mediastinal disorders | 77 (0.18%) |
| Gait inability | General disorders and administration site conditions | 76 (0.18%) |
| Hallucination | Psychiatric disorders | 76 (0.18%) |
| Lip oedema | Gastrointestinal disorders | 76 (0.18%) |
| Circulatory collapse | Vascular disorders | 75 (0.18%) |
| Productive cough | Respiratory, thoracic and mediastinal disorders | 75 (0.18%) |
| Bradycardia | Cardiac disorders | 73 (0.17%) |
| Dry throat | Respiratory, thoracic and mediastinal disorders | 73 (0.17%) |
| Muscle fatigue | Musculoskeletal and connective tissue disorders | 73 (0.17%) |
| Odynophagia | Gastrointestinal disorders | 73 (0.17%) |
| Blister | Skin and subcutaneous tissue disorders | 72 (0.17%) |
| Facial paresis | Nervous system disorders | 72 (0.17%) |
| Product administered at inappropriate site | Injury, poisoning and procedural complications | 72 (0.17%) |
| Arthritis | Musculoskeletal and connective tissue disorders | 70 (0.17%) |
| Breast pain | Reproductive system and breast disorders | 70 (0.17%) |
| Eye irritation | Eye disorders | 70 (0.17%) |
| Lymphadenitis | Blood and lymphatic system disorders | 70 (0.17%) |
| Rash papular | Skin and subcutaneous tissue disorders | 69 (0.16%) |
| Retching | Gastrointestinal disorders | 69 (0.16%) |
| Dyspnoea exertional | Respiratory, thoracic and mediastinal disorders | 68 (0.16%) |
| Oedema peripheral | General disorders and administration site conditions | 68 (0.16%) |
| Agitation | Psychiatric disorders | 66 (0.16%) |
| Musculoskeletal chest pain | Musculoskeletal and connective tissue disorders | 66 (0.16%) |
| Skin burning sensation | Skin and subcutaneous tissue disorders | 65 (0.15%) |
| Tachypnoea | Respiratory, thoracic and mediastinal disorders | 65 (0.15%) |
| Joint stiffness | Musculoskeletal and connective tissue disorders | 64 (0.15%) |
| Parosmia | Nervous system disorders | 64 (0.15%) |
| Tongue oedema | Gastrointestinal disorders | 64 (0.15%) |
| Dysstasia | Nervous system disorders | 63 (0.15%) |
| Exposure to SARS-CoV-2 | Injury, poisoning and procedural complications | 62 (0.15%) |
| Nodule | General disorders and administration site conditions | 62 (0.15%) |
| Pharyngeal paraesthesia | Respiratory, thoracic and mediastinal disorders | 62 (0.15%) |
| Hyperaesthesia | Nervous system disorders | 61 (0.14%) |
| Pulmonary embolism | Respiratory, thoracic and mediastinal disorders | 60 (0.14%) |
| Abdominal distension | Gastrointestinal disorders | 59 (0.14%) |
| Irritability | Psychiatric disorders | 59 (0.14%) |
| Local reaction | General disorders and administration site conditions | 59 (0.14%) |
| Musculoskeletal discomfort | Musculoskeletal and connective tissue disorders | 59 (0.14%) |
| Periorbital swelling | Eye disorders | 58 (0.14%) |
| Skin discolouration | Skin and subcutaneous tissue disorders | 58 (0.14%) |
| Delirium | Psychiatric disorders | 57 (0.14%) |
| Mouth ulceration | Gastrointestinal disorders | 57 (0.14%) |
| Blood glucose increased | Investigations | 56 (0.13%) |
| Deafness | Ear and labyrinth disorders | 56 (0.13%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Flatulence | Gastrointestinal disorders | 56 (0.13%) |
| Hyperventilation | Respiratory, thoracic and mediastinal disorders | 56 (0.13%) |
| Product administered to patient of inappropriate age | Injury, poisoning and procedural complications | 56 (0.13%) |
| Sensory disturbance | Nervous system disorders | 56 (0.13%) |
| Dermatitis allergic | Skin and subcutaneous tissue disorders | 55 (0.13%) |
| Exposure during pregnancy | Injury, poisoning and procedural complications | 55 (0.13%) |
| Swelling of eyelid | Eye disorders | 55 (0.13%) |
| Memory impairment | Nervous system disorders | 54 (0.13%) |
| Middle insomnia | Psychiatric disorders | 54 (0.13%) |
| Renal pain | Renal and urinary disorders | 54 (0.13%) |
| Accidental overdose | Injury, poisoning and procedural complications | 53 (0.13%) |
| Hemiparesis | Nervous system disorders | 53 (0.13%) |
| Hypoacusis | Ear and labyrinth disorders | 53 (0.13%) |
| SARS-CoV-2 antibody test positive | Investigations | 53 (0.13%) |
| Skin warm | Skin and subcutaneous tissue disorders | 53 (0.13%) |
| Unresponsive to stimuli | Nervous system disorders | 53 (0.13%) |
| Crying | General disorders and administration site conditions | 52 (0.12%) |
| Glossodynia | Gastrointestinal disorders | 52 (0.12%) |
| Sinus tachycardia | Cardiac disorders | 52 (0.12%) |
| Transient ischaemic attack | Nervous system disorders | 52 (0.12%) |
| Vaccination site urticaria | General disorders and administration site conditions | 52 (0.12%) |
| Aphasia | Nervous system disorders | 51 (0.12%) |
| COVID-19 pneumonia | Infections and infestations | 51 (0.12%) |
| Infection | Infections and infestations | 51 (0.12%) |
| Paralysis | Nervous system disorders | 51 (0.12%) |
| Spinal pain | Musculoskeletal and connective tissue disorders | 51 (0.12%) |
| Vaccination site haemorrhage | General disorders and administration site conditions | 51 (0.12%) |
| Induration | General disorders and administration site conditions | 50 (0.12%) |
| Petechiae | Skin and subcutaneous tissue disorders | 50 (0.12%) |
| Depressed mood | Psychiatric disorders | 49 (0.12%) |
| Neuropathy peripheral | Nervous system disorders | 49 (0.12%) |
| Oral pain | Gastrointestinal disorders | 49 (0.12%) |
| Angina pectoris | Cardiac disorders | 48 (0.11%) |
| Feeding disorder | Metabolism and nutrition disorders | 48 (0.11%) |
| Gastrointestinal disorder | Gastrointestinal disorders | 48 (0.11%) |
| Hypoglycaemia | Metabolism and nutrition disorders | 48 (0.11%) |
| Oral discomfort | Gastrointestinal disorders | 48 (0.11%) |
| Rash maculo-papular | Skin and subcutaneous tissue disorders | 48 (0.11%) |
| Sinus headache | Nervous system disorders | 48 (0.11%) |
| Weight decreased | Investigations | 48 (0.11%) |
| Heart rate decreased | Investigations | 47 (0.11%) |
| Respiratory rate increased | Investigations | 47 (0.11%) |
| Vaccination site hypoaesthesia | General disorders and administration site conditions | 47 (0.11%) |
| Cardiovascular disorder | Cardiac disorders | 46 (0.11%) |
| Cyanosis | Vascular disorders | 46 (0.11%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Asthenopia | Eye disorders | 45 (0.11%) |
| Body temperature abnormal | Investigations | 45 (0.11%) |
| Diplopia | Eye disorders | 45 (0.11%) |
| Hypothermia | General disorders and administration site conditions | 45 (0.11%) |
| Toothache | Gastrointestinal disorders | 45 (0.11%) |
| Body temperature decreased | Investigations | 44 (0.10%) |
| Respiratory failure | Respiratory, thoracic and mediastinal disorders | 44 (0.10%) |
| Vaccination complication | Injury, poisoning and procedural complications | 44 (0.10%) |
| Vaccination site hypersensitivity | General disorders and administration site conditions | 44 (0.10%) |
| Drug hypersensitivity | Immune system disorders | 43 (0.10%) |
| Feeling drunk | General disorders and administration site conditions | 43 (0.10%) |
| Eczema | Skin and subcutaneous tissue disorders | 42 (0.10%) |
| Eye disorder | Eye disorders | 42 (0.10%) |
| Eyelid oedema | Eye disorders | 42 (0.10%) |
| Haemorrhage | Vascular disorders | 42 (0.10%) |
| Hypoxia | Respiratory, thoracic and mediastinal disorders | 42 (0.10%) |
| Mouth swelling | Gastrointestinal disorders | 42 (0.10%) |
| Nightmare | Psychiatric disorders | 42 (0.10%) |
| No adverse event | General disorders and administration site conditions | 42 (0.10%) |
| Sensory loss | Nervous system disorders | 42 (0.10%) |
| Acute myocardial infarction | Cardiac disorders | 41 (0.10%) |
| Hyperthermia | General disorders and administration site conditions | 41 (0.10%) |
| Ischaemic stroke | Nervous system disorders | 41 (0.10%) |
| Mental impairment | Nervous system disorders | 41 (0.10%) |
| Sinusitis | Infections and infestations | 41 (0.10%) |
| Acute kidney injury | Renal and urinary disorders | 40 (0.10%) |
| Head injury | Injury, poisoning and procedural complications | 40 (0.10%) |
| Heart rate irregular | Investigations | 40 (0.10%) |
| Therapeutic response unexpected | General disorders and administration site conditions | 40 (0.10%) |
| Abdominal pain lower | Gastrointestinal disorders | 39 (0.09%) |
| Constipation | Gastrointestinal disorders | 39 (0.09%) |
| Thrombosis | Vascular disorders | 39 (0.09%) |
| Incorrect dose administered | Injury, poisoning and procedural complications | 38 (0.09%) |
| Oral pruritus | Gastrointestinal disorders | 38 (0.09%) |
| Product colour issue | Product issues | 38 (0.09%) |
| Rhinitis | Infections and infestations | 38 (0.09%) |
| Sepsis | Infections and infestations | 38 (0.09%) |
| Tongue discomfort | Gastrointestinal disorders | 38 (0.09%) |
| Vaccination site lymphadenopathy | General disorders and administration site conditions | 38 (0.09%) |
| Abnormal dreams | Psychiatric disorders | 37 (0.09%) |
| Lower respiratory tract infection | Infections and infestations | 37 (0.09%) |
| Gastrointestinal pain | Gastrointestinal disorders | 36 (0.09%) |
| Respiratory disorder | Respiratory, thoracic and mediastinal disorders | 36 (0.09%) |
| Skin disorder | Skin and subcutaneous tissue disorders | 36 (0.09%) |
| Vaccination site joint movement impairment | General disorders and administration site conditions | 36 (0.09%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|------------------------------------|--|-----------------|
| Deep vein thrombosis | Vascular disorders | 35 (0.08%) |
| Sinus pain | Respiratory, thoracic and mediastinal disorders | 35 (0.08%) |
| Blood pressure systolic increased | Investigations | 34 (0.08%) |
| Conjunctivitis | Infections and infestations | 34 (0.08%) |
| Dry skin | Skin and subcutaneous tissue disorders | 34 (0.08%) |
| Haematochezia | Gastrointestinal disorders | 34 (0.08%) |
| Migraine with aura | Nervous system disorders | 34 (0.08%) |
| Pulmonary pain | Respiratory, thoracic and mediastinal disorders | 34 (0.08%) |
| Stress | Psychiatric disorders | 34 (0.08%) |
| Sweating fever | Infections and infestations | 34 (0.08%) |
| Upper respiratory tract congestion | Respiratory, thoracic and mediastinal disorders | 34 (0.08%) |
| Vaccination site cellulitis | Infections and infestations | 34 (0.08%) |
| Amnesia | Nervous system disorders | 33 (0.08%) |
| Blindness | Eye disorders | 33 (0.08%) |
| Gastroesophageal reflux disease | Gastrointestinal disorders | 33 (0.08%) |
| Generalised tonic-clonic seizure | Nervous system disorders | 33 (0.08%) |
| Localised oedema | General disorders and administration site conditions | 33 (0.08%) |
| Lymphoedema | Vascular disorders | 33 (0.08%) |
| Sinus congestion | Respiratory, thoracic and mediastinal disorders | 33 (0.08%) |
| Thrombocytopenia | Blood and lymphatic system disorders | 33 (0.08%) |
| Cognitive disorder | Nervous system disorders | 32 (0.08%) |
| Dry eye | Eye disorders | 32 (0.08%) |
| Extrasystoles | Cardiac disorders | 32 (0.08%) |
| Impaired work ability | Social circumstances | 32 (0.08%) |
| Ocular discomfort | Eye disorders | 32 (0.08%) |
| Pericarditis | Cardiac disorders | 32 (0.08%) |
| Rash vesicular | Skin and subcutaneous tissue disorders | 32 (0.08%) |
| Tongue disorder | Gastrointestinal disorders | 32 (0.08%) |
| Vaccination site haematoma | General disorders and administration site conditions | 32 (0.08%) |
| Asymptomatic COVID-19 | Infections and infestations | 31 (0.07%) |
| Depression | Psychiatric disorders | 31 (0.07%) |
| Hemiparaesthesia | Nervous system disorders | 31 (0.07%) |
| Hyperglycaemia | Metabolism and nutrition disorders | 31 (0.07%) |
| Injected limb mobility decreased | General disorders and administration site conditions | 31 (0.07%) |
| Lip pruritus | Gastrointestinal disorders | 31 (0.07%) |
| Painful respiration | Respiratory, thoracic and mediastinal disorders | 31 (0.07%) |
| Panic attack | Psychiatric disorders | 31 (0.07%) |
| Photopsia | Eye disorders | 31 (0.07%) |
| Tongue pruritus | Gastrointestinal disorders | 31 (0.07%) |
| Accidental exposure to product | Injury, poisoning and procedural complications | 30 (0.07%) |
| Axillary mass | Musculoskeletal and connective tissue disorders | 30 (0.07%) |
| Dysaesthesia | Nervous system disorders | 30 (0.07%) |
| Groin pain | Musculoskeletal and connective tissue disorders | 30 (0.07%) |
| Renal failure | Renal and urinary disorders | 30 (0.07%) |
| Ventricular extrasystoles | Cardiac disorders | 30 (0.07%) |
| Conjunctival haemorrhage | Eye disorders | 29 (0.07%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Hypokinesia | Nervous system disorders | 29 (0.07%) |
| Liquid product physical issue | Product issues | 29 (0.07%) |
| Mental fatigue | Psychiatric disorders | 29 (0.07%) |
| Skin irritation | Skin and subcutaneous tissue disorders | 29 (0.07%) |
| Supraventricular tachycardia | Cardiac disorders | 29 (0.07%) |
| Type I hypersensitivity | Immune system disorders | 29 (0.07%) |
| Vaccination site discolouration | General disorders and administration site conditions | 29 (0.07%) |
| Vaginal haemorrhage | Reproductive system and breast disorders | 29 (0.07%) |
| Aphonia | Respiratory, thoracic and mediastinal disorders | 28 (0.07%) |
| Cardiac flutter | Cardiac disorders | 28 (0.07%) |
| Dyskinesia | Nervous system disorders | 28 (0.07%) |
| Eating disorder | Psychiatric disorders | 28 (0.07%) |
| Feeling jittery | General disorders and administration site conditions | 28 (0.07%) |
| Pharyngeal oedema | Respiratory, thoracic and mediastinal disorders | 28 (0.07%) |
| Pneumonia aspiration | Respiratory, thoracic and mediastinal disorders | 28 (0.07%) |
| Pollakiuria | Renal and urinary disorders | 28 (0.07%) |
| Pulmonary oedema | Respiratory, thoracic and mediastinal disorders | 28 (0.07%) |
| Skin reaction | Skin and subcutaneous tissue disorders | 28 (0.07%) |
| Stomatitis | Gastrointestinal disorders | 28 (0.07%) |
| Urinary incontinence | Renal and urinary disorders | 28 (0.07%) |
| Vaccination site nodule | General disorders and administration site conditions | 28 (0.07%) |
| White blood cell count increased | Investigations | 28 (0.07%) |
| Chronic obstructive pulmonary disease | Respiratory, thoracic and mediastinal disorders | 27 (0.06%) |
| Exposure via skin contact | Injury, poisoning and procedural complications | 27 (0.06%) |
| Extensive swelling of vaccinated limb | General disorders and administration site conditions | 27 (0.06%) |
| Haematoma | Vascular disorders | 27 (0.06%) |
| Haemoptysis | Respiratory, thoracic and mediastinal disorders | 27 (0.06%) |
| Menorrhagia | Reproductive system and breast disorders | 27 (0.06%) |
| Monoplegia | Nervous system disorders | 27 (0.06%) |
| Photosensitivity reaction | Skin and subcutaneous tissue disorders | 27 (0.06%) |
| Skin lesion | Skin and subcutaneous tissue disorders | 27 (0.06%) |
| Altered state of consciousness | Nervous system disorders | 26 (0.06%) |
| Anaphylactoid reaction | Immune system disorders | 26 (0.06%) |
| Arthropathy | Musculoskeletal and connective tissue disorders | 26 (0.06%) |
| Cerebral haemorrhage | Nervous system disorders | 26 (0.06%) |
| Musculoskeletal disorder | Musculoskeletal and connective tissue disorders | 26 (0.06%) |
| Pulse abnormal | Investigations | 26 (0.06%) |
| Respiratory arrest | Respiratory, thoracic and mediastinal disorders | 26 (0.06%) |
| Rheumatoid arthritis | Musculoskeletal and connective tissue disorders | 26 (0.06%) |
| Sinus disorder | Respiratory, thoracic and mediastinal disorders | 26 (0.06%) |
| Urinary retention | Renal and urinary disorders | 26 (0.06%) |
| Abortion spontaneous | Pregnancy, puerperium and perinatal conditions | 25 (0.06%) |
| Acute respiratory failure | Respiratory, thoracic and mediastinal disorders | 25 (0.06%) |
| Dysuria | Renal and urinary disorders | 25 (0.06%) |
| Eructation | Gastrointestinal disorders | 25 (0.06%) |
| Formication | Nervous system disorders | 25 (0.06%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|----------------------------------|--|-----------------|
| Haematemesis | Gastrointestinal disorders | 25 (0.06%) |
| Myocarditis | Cardiac disorders | 25 (0.06%) |
| Nasal discomfort | Respiratory, thoracic and mediastinal disorders | 25 (0.06%) |
| Nervous system disorder | Nervous system disorders | 25 (0.06%) |
| Salivary hypersecretion | Gastrointestinal disorders | 25 (0.06%) |
| Skin exfoliation | Skin and subcutaneous tissue disorders | 25 (0.06%) |
| Dermatitis | Skin and subcutaneous tissue disorders | 24 (0.06%) |
| Fear | Psychiatric disorders | 24 (0.06%) |
| Gout | Metabolism and nutrition disorders | 24 (0.06%) |
| Guillain-Barre syndrome | Nervous system disorders | 24 (0.06%) |
| Pharyngeal hypoaesthesia | Respiratory, thoracic and mediastinal disorders | 24 (0.06%) |
| Respiration abnormal | Respiratory, thoracic and mediastinal disorders | 24 (0.06%) |
| Coordination abnormal | Nervous system disorders | 23 (0.05%) |
| Eye haemorrhage | Eye disorders | 23 (0.05%) |
| Gingival pain | Gastrointestinal disorders | 23 (0.05%) |
| Hemiplegia | Nervous system disorders | 23 (0.05%) |
| Hypopnoea | Respiratory, thoracic and mediastinal disorders | 23 (0.05%) |
| Injection site erythema | General disorders and administration site conditions | 23 (0.05%) |
| Menstrual disorder | Reproductive system and breast disorders | 23 (0.05%) |
| Peripheral vascular disorder | Vascular disorders | 23 (0.05%) |
| Bedridden | Social circumstances | 22 (0.05%) |
| Cluster headache | Nervous system disorders | 22 (0.05%) |
| Incomplete course of vaccination | Injury, poisoning and procedural complications | 22 (0.05%) |
| Laryngospasm | Respiratory, thoracic and mediastinal disorders | 22 (0.05%) |
| Muscle contractions involuntary | Nervous system disorders | 22 (0.05%) |
| Paranasal sinus discomfort | Respiratory, thoracic and mediastinal disorders | 22 (0.05%) |
| Rectal haemorrhage | Gastrointestinal disorders | 22 (0.05%) |
| Stridor | Respiratory, thoracic and mediastinal disorders | 22 (0.05%) |
| Thinking abnormal | Psychiatric disorders | 22 (0.05%) |
| Upper-airway cough syndrome | Respiratory, thoracic and mediastinal disorders | 22 (0.05%) |
| Antibody test abnormal | Investigations | 21 (0.05%) |
| Apathy | Psychiatric disorders | 21 (0.05%) |
| Aphthous ulcer | Gastrointestinal disorders | 21 (0.05%) |
| Blood pressure fluctuation | Vascular disorders | 21 (0.05%) |
| Cardiac disorder | Cardiac disorders | 21 (0.05%) |
| Ear infection | Infections and infestations | 21 (0.05%) |
| Hypotonia | Nervous system disorders | 21 (0.05%) |
| Livedo reticularis | Skin and subcutaneous tissue disorders | 21 (0.05%) |
| Palatal oedema | Gastrointestinal disorders | 21 (0.05%) |
| Panic reaction | Psychiatric disorders | 21 (0.05%) |
| Product packaging quantity issue | Product issues | 21 (0.05%) |
| Blood glucose decreased | Investigations | 20 (0.05%) |
| Breast swelling | Reproductive system and breast disorders | 20 (0.05%) |
| Cardio-respiratory arrest | Cardiac disorders | 20 (0.05%) |
| Ear pruritus | Ear and labyrinth disorders | 20 (0.05%) |
| Flank pain | Musculoskeletal and connective tissue disorders | 20 (0.05%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Hangover | General disorders and administration site conditions | 20 (0.05%) |
| Immune thrombocytopenia | Blood and lymphatic system disorders | 20 (0.05%) |
| Nasal oedema | Respiratory, thoracic and mediastinal disorders | 20 (0.05%) |
| Tonsillar hypertrophy | Respiratory, thoracic and mediastinal disorders | 20 (0.05%) |
| Vaccination failure | Injury, poisoning and procedural complications | 20 (0.05%) |
| Wrong product administered | Injury, poisoning and procedural complications | 20 (0.05%) |
| Blood urine present | Investigations | 19 (0.05%) |
| Chromaturia | Renal and urinary disorders | 19 (0.05%) |
| Drug interaction | General disorders and administration site conditions | 19 (0.05%) |
| Eyelid ptosis | Eye disorders | 19 (0.05%) |
| Frequent bowel movements | Gastrointestinal disorders | 19 (0.05%) |
| Gastric disorder | Gastrointestinal disorders | 19 (0.05%) |
| Heart rate abnormal | Investigations | 19 (0.05%) |
| Hyperacusis | Ear and labyrinth disorders | 19 (0.05%) |
| Lung disorder | Respiratory, thoracic and mediastinal disorders | 19 (0.05%) |
| Platelet count decreased | Investigations | 19 (0.05%) |
| Product administration error | Injury, poisoning and procedural complications | 19 (0.05%) |
| Rhinalgia | Respiratory, thoracic and mediastinal disorders | 19 (0.05%) |
| Sciatica | Nervous system disorders | 19 (0.05%) |
| Skin swelling | Skin and subcutaneous tissue disorders | 19 (0.05%) |
| Vaccination site vesicles | General disorders and administration site conditions | 19 (0.05%) |
| Blood pressure abnormal | Investigations | 18 (0.04%) |
| Bronchitis | Infections and infestations | 18 (0.04%) |
| Deafness unilateral | Ear and labyrinth disorders | 18 (0.04%) |
| Hypokalaemia | Metabolism and nutrition disorders | 18 (0.04%) |
| International normalised ratio increased | Investigations | 18 (0.04%) |
| Multiple organ dysfunction syndrome | General disorders and administration site conditions | 18 (0.04%) |
| Oral disorder | Gastrointestinal disorders | 18 (0.04%) |
| Periorbital oedema | Eye disorders | 18 (0.04%) |
| Respiratory tract infection | Infections and infestations | 18 (0.04%) |
| Skin tightness | Skin and subcutaneous tissue disorders | 18 (0.04%) |
| Vaccination site joint pain | General disorders and administration site conditions | 18 (0.04%) |
| Cystitis | Infections and infestations | 17 (0.04%) |
| Ear swelling | Ear and labyrinth disorders | 17 (0.04%) |
| Fibromyalgia | Musculoskeletal and connective tissue disorders | 17 (0.04%) |
| Gastroenteritis | Infections and infestations | 17 (0.04%) |
| Haemoglobin decreased | Investigations | 17 (0.04%) |
| Herpes virus infection | Infections and infestations | 17 (0.04%) |
| Impaired driving ability | Social circumstances | 17 (0.04%) |
| Mass | General disorders and administration site conditions | 17 (0.04%) |
| Menstruation irregular | Reproductive system and breast disorders | 17 (0.04%) |
| Mental disorder | Psychiatric disorders | 17 (0.04%) |
| Muscle rigidity | Musculoskeletal and connective tissue disorders | 17 (0.04%) |
| Obstructive airways disorder | Respiratory, thoracic and mediastinal disorders | 17 (0.04%) |
| Rales | Respiratory, thoracic and mediastinal disorders | 17 (0.04%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Sleep disorder due to general medical condition, insomnia type | Psychiatric disorders | 17 (0.04%) |
| Temperature regulation disorder | General disorders and administration site conditions | 17 (0.04%) |
| Trigeminal neuralgia | Nervous system disorders | 17 (0.04%) |
| Tunnel vision | Nervous system disorders | 17 (0.04%) |
| Vomiting projectile | Gastrointestinal disorders | 17 (0.04%) |
| Alanine aminotransferase increased | Investigations | 16 (0.04%) |
| Diabetes mellitus | Metabolism and nutrition disorders | 16 (0.04%) |
| Dysmenorrhoea | Reproductive system and breast disorders | 16 (0.04%) |
| Encephalitis | Infections and infestations | 16 (0.04%) |
| Faeces discoloured | Gastrointestinal disorders | 16 (0.04%) |
| Haematuria | Renal and urinary disorders | 16 (0.04%) |
| Increased upper airway secretion | Respiratory, thoracic and mediastinal disorders | 16 (0.04%) |
| Initial insomnia | Psychiatric disorders | 16 (0.04%) |
| Limb injury | Injury, poisoning and procedural complications | 16 (0.04%) |
| Monoparesis | Nervous system disorders | 16 (0.04%) |
| Motor dysfunction | Nervous system disorders | 16 (0.04%) |
| Neutropenia | Blood and lymphatic system disorders | 16 (0.04%) |
| Nuchal rigidity | Musculoskeletal and connective tissue disorders | 16 (0.04%) |
| Pharyngeal erythema | Respiratory, thoracic and mediastinal disorders | 16 (0.04%) |
| Pharyngeal inflammation | Respiratory, thoracic and mediastinal disorders | 16 (0.04%) |
| Purpura | Skin and subcutaneous tissue disorders | 16 (0.04%) |
| Respiratory tract congestion | Respiratory, thoracic and mediastinal disorders | 16 (0.04%) |
| Shock | Vascular disorders | 16 (0.04%) |
| Sluggishness | General disorders and administration site conditions | 16 (0.04%) |
| Vaccination site infection | Infections and infestations | 16 (0.04%) |
| Vertigo positional | Ear and labyrinth disorders | 16 (0.04%) |
| Abnormal faeces | Gastrointestinal disorders | 15 (0.04%) |
| Appendicitis | Infections and infestations | 15 (0.04%) |
| Blepharospasm | Eye disorders | 15 (0.04%) |
| Body height decreased | Investigations | 15 (0.04%) |
| Body temperature fluctuation | Investigations | 15 (0.04%) |
| Cerebral infarction | Nervous system disorders | 15 (0.04%) |
| Choking | Respiratory, thoracic and mediastinal disorders | 15 (0.04%) |
| Dementia | Nervous system disorders | 15 (0.04%) |
| Diarrhoea haemorrhagic | Gastrointestinal disorders | 15 (0.04%) |
| Ear disorder | Ear and labyrinth disorders | 15 (0.04%) |
| Emotional distress | Psychiatric disorders | 15 (0.04%) |
| Eye movement disorder | Eye disorders | 15 (0.04%) |
| Febrile convulsion | Nervous system disorders | 15 (0.04%) |
| Gingival swelling | Gastrointestinal disorders | 15 (0.04%) |
| Hallucination, visual | Psychiatric disorders | 15 (0.04%) |
| Hyposmia | Nervous system disorders | 15 (0.04%) |
| Irritable bowel syndrome | Gastrointestinal disorders | 15 (0.04%) |
| Leukocytosis | Blood and lymphatic system disorders | 15 (0.04%) |
| Oral mucosal blistering | Gastrointestinal disorders | 15 (0.04%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------|--|-----------------|
| Pelvic pain | Reproductive system and breast disorders | 15 (0.04%) |
| Pharyngitis | Infections and infestations | 15 (0.04%) |
| | | 15 (0.04%) |
| Acne | Skin and subcutaneous tissue disorders | 14 (0.03%) |
| Alopecia | Skin and subcutaneous tissue disorders | 14 (0.03%) |
| Bursitis | Musculoskeletal and connective tissue disorders | 14 (0.03%) |
| Choking sensation | Respiratory, thoracic and mediastinal disorders | 14 (0.03%) |
| Coma | Nervous system disorders | 14 (0.03%) |
| Fibrin D dimer increased | Investigations | 14 (0.03%) |
| Gastritis | Gastrointestinal disorders | 14 (0.03%) |
| Hemianaesthesia | Nervous system disorders | 14 (0.03%) |
| Hypophagia | Metabolism and nutrition disorders | 14 (0.03%) |
| Immune system disorder | Immune system disorders | 14 (0.03%) |
| Injection site swelling | General disorders and administration site conditions | 14 (0.03%) |
| Limb mass | Musculoskeletal and connective tissue disorders | 14 (0.03%) |
| Lymphopenia | Blood and lymphatic system disorders | 14 (0.03%) |
| Metrorrhagia | Reproductive system and breast disorders | 14 (0.03%) |
| Neck mass | Musculoskeletal and connective tissue disorders | 14 (0.03%) |
| Oedema mouth | Gastrointestinal disorders | 14 (0.03%) |
| Piloerection | Skin and subcutaneous tissue disorders | 14 (0.03%) |
| Pleural effusion | Respiratory, thoracic and mediastinal disorders | 14 (0.03%) |
| Pleuritic pain | Respiratory, thoracic and mediastinal disorders | 14 (0.03%) |
| Pneumonitis | Respiratory, thoracic and mediastinal disorders | 14 (0.03%) |
| Psoriasis | Skin and subcutaneous tissue disorders | 14 (0.03%) |
| Restless legs syndrome | Nervous system disorders | 14 (0.03%) |
| Sudden hearing loss | Ear and labyrinth disorders | 14 (0.03%) |
| Tachyarrhythmia | Cardiac disorders | 14 (0.03%) |
| Vasculitis | Vascular disorders | 14 (0.03%) |
| Viral infection | Infections and infestations | 14 (0.03%) |
| Acute coronary syndrome | Cardiac disorders | 13 (0.03%) |
| Anal incontinence | Gastrointestinal disorders | 13 (0.03%) |
| Bradypnea | Psychiatric disorders | 13 (0.03%) |
| Coronavirus infection | Infections and infestations | 13 (0.03%) |
| Dermatitis bullous | Skin and subcutaneous tissue disorders | 13 (0.03%) |
| Erythema multiforme | Skin and subcutaneous tissue disorders | 13 (0.03%) |
| Eye injury | Injury, poisoning and procedural complications | 13 (0.03%) |
| Eye oedema | Eye disorders | 13 (0.03%) |
| Herpes simplex | Infections and infestations | 13 (0.03%) |
| Incontinence | Renal and urinary disorders | 13 (0.03%) |
| Joint effusion | Musculoskeletal and connective tissue disorders | 13 (0.03%) |
| Labyrinthitis | Infections and infestations | 13 (0.03%) |
| Menstruation delayed | Reproductive system and breast disorders | 13 (0.03%) |
| Motion sickness | Ear and labyrinth disorders | 13 (0.03%) |
| Muscle contracture | Musculoskeletal and connective tissue disorders | 13 (0.03%) |
| Myoclonus | Nervous system disorders | 13 (0.03%) |
| Neurogenic shock | Vascular disorders | 13 (0.03%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-----------------------------------|--|-----------------|
| Palatal swelling | Gastrointestinal disorders | 13 (0.03%) |
| Type IV hypersensitivity reaction | Immune system disorders | 13 (0.03%) |
| Upper respiratory tract infection | Infections and infestations | 13 (0.03%) |
| Vaccination site hyperaesthesia | General disorders and administration site conditions | 13 (0.03%) |
| Visual field defect | Nervous system disorders | 13 (0.03%) |
| Abnormal sensation in eye | Eye disorders | 12 (0.03%) |
| Anaemia | Blood and lymphatic system disorders | 12 (0.03%) |
| Deafness neurosensory | Ear and labyrinth disorders | 12 (0.03%) |
| Erectile dysfunction | Reproductive system and breast disorders | 12 (0.03%) |
| Erythema of eyelid | Eye disorders | 12 (0.03%) |
| Lip pain | Gastrointestinal disorders | 12 (0.03%) |
| Mechanical urticaria | Skin and subcutaneous tissue disorders | 12 (0.03%) |
| Muscle strain | Injury, poisoning and procedural complications | 12 (0.03%) |
| Nerve compression | Nervous system disorders | 12 (0.03%) |
| Neurological symptom | Nervous system disorders | 12 (0.03%) |
| Nystagmus | Nervous system disorders | 12 (0.03%) |
| Papule | Skin and subcutaneous tissue disorders | 12 (0.03%) |
| Paresis | Nervous system disorders | 12 (0.03%) |
| Periarthritis | Musculoskeletal and connective tissue disorders | 12 (0.03%) |
| Product leakage | Product issues | 12 (0.03%) |
| Pulmonary congestion | Respiratory, thoracic and mediastinal disorders | 12 (0.03%) |
| Skin mass | Skin and subcutaneous tissue disorders | 12 (0.03%) |
| Status epilepticus | Nervous system disorders | 12 (0.03%) |
| Suffocation feeling | Respiratory, thoracic and mediastinal disorders | 12 (0.03%) |
| Tension | Psychiatric disorders | 12 (0.03%) |
| Tonsillitis | Infections and infestations | 12 (0.03%) |
| Ventricular fibrillation | Cardiac disorders | 12 (0.03%) |
| Vitreous floaters | Eye disorders | 12 (0.03%) |
| Aggression | Psychiatric disorders | 11 (0.03%) |
| Asthmatic crisis | Respiratory, thoracic and mediastinal disorders | 11 (0.03%) |
| Aura | Nervous system disorders | 11 (0.03%) |
| Autoimmune disorder | Immune system disorders | 11 (0.03%) |
| Breast tenderness | Reproductive system and breast disorders | 11 (0.03%) |
| Cardiac failure acute | Cardiac disorders | 11 (0.03%) |
| Cardiac failure congestive | Cardiac disorders | 11 (0.03%) |
| Dizziness exertional | Nervous system disorders | 11 (0.03%) |
| Enlarged uvula | Gastrointestinal disorders | 11 (0.03%) |
| Eye discharge | Eye disorders | 11 (0.03%) |
| Eye inflammation | Eye disorders | 11 (0.03%) |
| Facial discomfort | General disorders and administration site conditions | 11 (0.03%) |
| Fluid retention | Metabolism and nutrition disorders | 11 (0.03%) |
| Haemorrhagic stroke | Nervous system disorders | 11 (0.03%) |
| Hypogeusia | Nervous system disorders | 11 (0.03%) |
| Jaundice | Hepatobiliary disorders | 11 (0.03%) |
| Mood altered | Psychiatric disorders | 11 (0.03%) |
| Muscle discomfort | Musculoskeletal and connective tissue disorders | 11 (0.03%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Muscle swelling | Musculoskeletal and connective tissue disorders | 11 (0.03%) |
| Myelitis transverse | Nervous system disorders | 11 (0.03%) |
| Nipple pain | Reproductive system and breast disorders | 11 (0.03%) |
| Occupational exposure to SARS-CoV-2 | Injury, poisoning and procedural complications | 11 (0.03%) |
| Oral candidiasis | Infections and infestations | 11 (0.03%) |
| Orthostatic hypotension | Vascular disorders | 11 (0.03%) |
| Polyuria | Renal and urinary disorders | 11 (0.03%) |
| Pulmonary thrombosis | Respiratory, thoracic and mediastinal disorders | 11 (0.03%) |
| Pustule | Infections and infestations | 11 (0.03%) |
| Q fever | Infections and infestations | 11 (0.03%) |
| Raynaud's phenomenon | Vascular disorders | 11 (0.03%) |
| Red blood cell sedimentation rate increased | Investigations | 11 (0.03%) |
| Sleep disorder due to a general medical condition | Psychiatric disorders | 11 (0.03%) |
| Throat clearing | Respiratory, thoracic and mediastinal disorders | 11 (0.03%) |
| Troponin increased | Investigations | 11 (0.03%) |
| Vaccination site irritation | General disorders and administration site conditions | 11 (0.03%) |
| White blood cell count decreased | Investigations | 11 (0.03%) |
| Acute pulmonary oedema | Respiratory, thoracic and mediastinal disorders | 10 (0.02%) |
| Acute respiratory distress syndrome | Respiratory, thoracic and mediastinal disorders | 10 (0.02%) |
| Arthritis reactive | Musculoskeletal and connective tissue disorders | 10 (0.02%) |
| Aspiration | Respiratory, thoracic and mediastinal disorders | 10 (0.02%) |
| Blindness transient | Eye disorders | 10 (0.02%) |
| Communication disorder | Psychiatric disorders | 10 (0.02%) |
| Dissociation | Psychiatric disorders | 10 (0.02%) |
| Dyspnoea at rest | Respiratory, thoracic and mediastinal disorders | 10 (0.02%) |
| Electrocardiogram abnormal | Investigations | 10 (0.02%) |
| Eye contusion | Injury, poisoning and procedural complications | 10 (0.02%) |
| Gingival bleeding | Gastrointestinal disorders | 10 (0.02%) |
| Hunger | General disorders and administration site conditions | 10 (0.02%) |
| Hypotonic-hyporesponsive episode | Nervous system disorders | 10 (0.02%) |
| Lip blister | Gastrointestinal disorders | 10 (0.02%) |
| Lip disorder | Gastrointestinal disorders | 10 (0.02%) |
| Lip dry | Gastrointestinal disorders | 10 (0.02%) |
| Lung infiltration | Respiratory, thoracic and mediastinal disorders | 10 (0.02%) |
| Lymphangitis | Infections and infestations | 10 (0.02%) |
| Mastitis | Infections and infestations | 10 (0.02%) |
| Melaena | Gastrointestinal disorders | 10 (0.02%) |
| Miliaria | Skin and subcutaneous tissue disorders | 10 (0.02%) |
| Multiple sclerosis relapse | Nervous system disorders | 10 (0.02%) |
| Needle issue | Product issues | 10 (0.02%) |
| Ophthalmic herpes zoster | Infections and infestations | 10 (0.02%) |
| Optic neuritis | Nervous system disorders | 10 (0.02%) |
| Personality change | Psychiatric disorders | 10 (0.02%) |
| Pleurisy | Respiratory, thoracic and mediastinal disorders | 10 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-------------------------------------|--|-----------------|
| Polydipsia | Metabolism and nutrition disorders | 10 (0.02%) |
| Psychomotor hyperactivity | Nervous system disorders | 10 (0.02%) |
| Respiratory tract oedema | Respiratory, thoracic and mediastinal disorders | 10 (0.02%) |
| Scratch | Injury, poisoning and procedural complications | 10 (0.02%) |
| Seasonal allergy | Immune system disorders | 10 (0.02%) |
| Synovial cyst | Musculoskeletal and connective tissue disorders | 10 (0.02%) |
| Tendonitis | Musculoskeletal and connective tissue disorders | 10 (0.02%) |
| Tongue dry | Gastrointestinal disorders | 10 (0.02%) |
| Tongue ulceration | Gastrointestinal disorders | 10 (0.02%) |
| Trismus | Musculoskeletal and connective tissue disorders | 10 (0.02%) |
| Anaesthesia | Nervous system disorders | 9 (0.02%) |
| Anger | Psychiatric disorders | 9 (0.02%) |
| Atrial flutter | Cardiac disorders | 9 (0.02%) |
| Blood potassium decreased | Investigations | 9 (0.02%) |
| Blood pressure diastolic increased | Investigations | 9 (0.02%) |
| Bone swelling | Musculoskeletal and connective tissue disorders | 9 (0.02%) |
| Cheilitis | Gastrointestinal disorders | 9 (0.02%) |
| Costochondritis | Musculoskeletal and connective tissue disorders | 9 (0.02%) |
| Crohn's disease | Gastrointestinal disorders | 9 (0.02%) |
| Diverticulitis | Infections and infestations | 9 (0.02%) |
| Drooling | Nervous system disorders | 9 (0.02%) |
| Drug eruption | Skin and subcutaneous tissue disorders | 9 (0.02%) |
| Emotional disorder | Psychiatric disorders | 9 (0.02%) |
| Erysipelas | Infections and infestations | 9 (0.02%) |
| Euphoric mood | Psychiatric disorders | 9 (0.02%) |
| Facial neuralgia | Nervous system disorders | 9 (0.02%) |
| Facial spasm | Nervous system disorders | 9 (0.02%) |
| Gastrointestinal haemorrhage | Gastrointestinal disorders | 9 (0.02%) |
| General physical condition abnormal | Investigations | 9 (0.02%) |
| Grip strength decreased | Investigations | 9 (0.02%) |
| Hepatic pain | Hepatobiliary disorders | 9 (0.02%) |
| Hypernatraemia | Metabolism and nutrition disorders | 9 (0.02%) |
| Hypoaesthesia eye | Eye disorders | 9 (0.02%) |
| Injection site rash | General disorders and administration site conditions | 9 (0.02%) |
| Injection site warmth | General disorders and administration site conditions | 9 (0.02%) |
| Localised infection | Infections and infestations | 9 (0.02%) |
| Micturition urgency | Renal and urinary disorders | 9 (0.02%) |
| Myelitis | Infections and infestations | 9 (0.02%) |
| Neuralgic amyotrophy | Nervous system disorders | 9 (0.02%) |
| Occupational exposure to product | Injury, poisoning and procedural complications | 9 (0.02%) |
| Oropharyngeal blistering | Respiratory, thoracic and mediastinal disorders | 9 (0.02%) |
| Oropharyngeal oedema | Respiratory, thoracic and mediastinal disorders | 9 (0.02%) |
| Petit mal epilepsy | Nervous system disorders | 9 (0.02%) |
| Polymyalgia rheumatica | Musculoskeletal and connective tissue disorders | 9 (0.02%) |
| Reaction to excipient | Immune system disorders | 9 (0.02%) |
| Renal disorder | Renal and urinary disorders | 9 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Sedation | Nervous system disorders | 9 (0.02%) |
| Skin laceration | Injury, poisoning and procedural complications | 9 (0.02%) |
| Temperature intolerance | General disorders and administration site conditions | 9 (0.02%) |
| Tonic convulsion | Nervous system disorders | 9 (0.02%) |
| Transaminases increased | Investigations | 9 (0.02%) |
| Uveitis | Eye disorders | 9 (0.02%) |
| Ventricular tachycardia | Cardiac disorders | 9 (0.02%) |
| Wound | Injury, poisoning and procedural complications | 9 (0.02%) |
| Anaesthesia oral | Gastrointestinal disorders | 8 (0.02%) |
| Asphyxia | Respiratory, thoracic and mediastinal disorders | 8 (0.02%) |
| Ataxia | Nervous system disorders | 8 (0.02%) |
| Diabetes mellitus inadequate control | Metabolism and nutrition disorders | 8 (0.02%) |
| Diabetic ketoacidosis | Metabolism and nutrition disorders | 8 (0.02%) |
| Eyelid pain | Eye disorders | 8 (0.02%) |
| Eyelids pruritus | Eye disorders | 8 (0.02%) |
| Face injury | Injury, poisoning and procedural complications | 8 (0.02%) |
| Faeces soft | Gastrointestinal disorders | 8 (0.02%) |
| Foreign body sensation in eyes | Eye disorders | 8 (0.02%) |
| Hallucination, auditory | Psychiatric disorders | 8 (0.02%) |
| Hordeolum | Infections and infestations | 8 (0.02%) |
| Hyponatraemia | Metabolism and nutrition disorders | 8 (0.02%) |
| Immunisation anxiety related reaction | Psychiatric disorders | 8 (0.02%) |
| Injection related reaction | Injury, poisoning and procedural complications | 8 (0.02%) |
| Kidney infection | Infections and infestations | 8 (0.02%) |
| Liver function test increased | Investigations | 8 (0.02%) |
| Maternal exposure timing unspecified | Injury, poisoning and procedural complications | 8 (0.02%) |
| Myositis | Musculoskeletal and connective tissue disorders | 8 (0.02%) |
| Nasal pruritus | Respiratory, thoracic and mediastinal disorders | 8 (0.02%) |
| Nerve injury | Injury, poisoning and procedural complications | 8 (0.02%) |
| Neutrophil count increased | Investigations | 8 (0.02%) |
| Pancreatitis acute | Gastrointestinal disorders | 8 (0.02%) |
| Parotitis | Infections and infestations | 8 (0.02%) |
| Platelet count increased | Investigations | 8 (0.02%) |
| Product quality issue | Product issues | 8 (0.02%) |
| Rash morbilliform | Skin and subcutaneous tissue disorders | 8 (0.02%) |
| Rash pustular | Infections and infestations | 8 (0.02%) |
| Rhinitis allergic | Respiratory, thoracic and mediastinal disorders | 8 (0.02%) |
| Secretion discharge | General disorders and administration site conditions | 8 (0.02%) |
| Septic shock | Infections and infestations | 8 (0.02%) |
| Tendon pain | Musculoskeletal and connective tissue disorders | 8 (0.02%) |
| Tongue erythema | Gastrointestinal disorders | 8 (0.02%) |
| Urosepsis | Infections and infestations | 8 (0.02%) |
| Vaccination site coldness | General disorders and administration site conditions | 8 (0.02%) |
| Vaccination site joint erythema | General disorders and administration site conditions | 8 (0.02%) |
| Vasodilatation | Vascular disorders | 8 (0.02%) |
| Weight increased | Investigations | 8 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Abdominal rigidity | Gastrointestinal disorders | 7 (0.02%) |
| Abnormal behaviour | Psychiatric disorders | 7 (0.02%) |
| Aspartate aminotransferase increased | Investigations | 7 (0.02%) |
| Atelectasis | Respiratory, thoracic and mediastinal disorders | 7 (0.02%) |
| Atrioventricular block complete | Cardiac disorders | 7 (0.02%) |
| Blood creatinine increased | Investigations | 7 (0.02%) |
| Blood lactic acid increased | Investigations | 7 (0.02%) |
| Breast mass | Reproductive system and breast disorders | 7 (0.02%) |
| Bundle branch block right | Cardiac disorders | 7 (0.02%) |
| Cardiogenic shock | Cardiac disorders | 7 (0.02%) |
| Cardiopulmonary failure | Cardiac disorders | 7 (0.02%) |
| Chapped lips | Gastrointestinal disorders | 7 (0.02%) |
| Chillblains | Injury, poisoning and procedural complications | 7 (0.02%) |
| Defaecation urgency | Gastrointestinal disorders | 7 (0.02%) |
| Dystonia | Nervous system disorders | 7 (0.02%) |
| Encephalopathy | Nervous system disorders | 7 (0.02%) |
| Episcleritis | Eye disorders | 7 (0.02%) |
| Eye infection | Infections and infestations | 7 (0.02%) |
| Food refusal | Metabolism and nutrition disorders | 7 (0.02%) |
| Gastrointestinal sounds abnormal | Gastrointestinal disorders | 7 (0.02%) |
| Hiccups | Respiratory, thoracic and mediastinal disorders | 7 (0.02%) |
| Hypertensive emergency | Vascular disorders | 7 (0.02%) |
| Increased bronchial secretion | Respiratory, thoracic and mediastinal disorders | 7 (0.02%) |
| Inflammatory marker increased | Investigations | 7 (0.02%) |
| Intestinal ischaemia | Gastrointestinal disorders | 7 (0.02%) |
| Intranasal paraesthesia | Respiratory, thoracic and mediastinal disorders | 7 (0.02%) |
| Irregular breathing | Respiratory, thoracic and mediastinal disorders | 7 (0.02%) |
| Laryngitis | Infections and infestations | 7 (0.02%) |
| Liver function test abnormal | Investigations | 7 (0.02%) |
| Mouth haemorrhage | Gastrointestinal disorders | 7 (0.02%) |
| Mydriasis | Eye disorders | 7 (0.02%) |
| Myocardial ischaemia | Cardiac disorders | 7 (0.02%) |
| Nasal dryness | Respiratory, thoracic and mediastinal disorders | 7 (0.02%) |
| Neuritis | Nervous system disorders | 7 (0.02%) |
| Oesophageal pain | Gastrointestinal disorders | 7 (0.02%) |
| Oral mucosal eruption | Gastrointestinal disorders | 7 (0.02%) |
| Oral mucosal erythema | Gastrointestinal disorders | 7 (0.02%) |
| Osteoarthritis | Musculoskeletal and connective tissue disorders | 7 (0.02%) |
| Oxygen saturation abnormal | Investigations | 7 (0.02%) |
| Pancreatitis | Gastrointestinal disorders | 7 (0.02%) |
| Peroneal nerve palsy | Nervous system disorders | 7 (0.02%) |
| Pharyngeal disorder | Respiratory, thoracic and mediastinal disorders | 7 (0.02%) |
| Postural orthostatic tachycardia syndrome | Cardiac disorders | 7 (0.02%) |
| Product prescribing error | Injury, poisoning and procedural complications | 7 (0.02%) |
| Renal impairment | Renal and urinary disorders | 7 (0.02%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Respiratory rate decreased | Investigations | 7 (0.02%) |
| Rhabdomyolysis | Musculoskeletal and connective tissue disorders | 7 (0.02%) |
| SARS-CoV-2 test false positive | Investigations | 7 (0.02%) |
| Stevens-Johnson syndrome | Skin and subcutaneous tissue disorders | 7 (0.02%) |
| Stupor | Nervous system disorders | 7 (0.02%) |
| Temporomandibular joint syndrome | Musculoskeletal and connective tissue disorders | 7 (0.02%) |
| Terminal insomnia | Psychiatric disorders | 7 (0.02%) |
| Tongue discolouration | Gastrointestinal disorders | 7 (0.02%) |
| Tonic clonic movements | Nervous system disorders | 7 (0.02%) |
| Trigeminal nerve disorder | Nervous system disorders | 7 (0.02%) |
| Urinary tract infection bacterial | Infections and infestations | 7 (0.02%) |
| Vaccination site extravasation | General disorders and administration site conditions | 7 (0.02%) |
| Vaccination site macule | General disorders and administration site conditions | 7 (0.02%) |
| Vestibular neuronitis | Infections and infestations | 7 (0.02%) |
| Viral rash | Infections and infestations | 7 (0.02%) |
| Adnexa uteri pain | Reproductive system and breast disorders | 6 (0.01%) |
| Adverse drug reaction | General disorders and administration site conditions | 6 (0.01%) |
| Allodynia | Nervous system disorders | 6 (0.01%) |
| Anal haemorrhage | Gastrointestinal disorders | 6 (0.01%) |
| Ankylosing spondylitis | Musculoskeletal and connective tissue disorders | 6 (0.01%) |
| Apnoea | Respiratory, thoracic and mediastinal disorders | 6 (0.01%) |
| Arrhythmia supraventricular | Cardiac disorders | 6 (0.01%) |
| Auricular swelling | Ear and labyrinth disorders | 6 (0.01%) |
| Autoimmune thyroiditis | Endocrine disorders | 6 (0.01%) |
| Blood creatine phosphokinase increased | Investigations | 6 (0.01%) |
| Blood pressure diastolic decreased | Investigations | 6 (0.01%) |
| Blood sodium decreased | Investigations | 6 (0.01%) |
| Bowel movement irregularity | Gastrointestinal disorders | 6 (0.01%) |
| Brain oedema | Nervous system disorders | 6 (0.01%) |
| Breast discomfort | Reproductive system and breast disorders | 6 (0.01%) |
| Breath odour | Gastrointestinal disorders | 6 (0.01%) |
| Catarrh | Respiratory, thoracic and mediastinal disorders | 6 (0.01%) |
| Clonus | Nervous system disorders | 6 (0.01%) |
| Coronary artery disease | Cardiac disorders | 6 (0.01%) |
| Coronavirus test positive | Investigations | 6 (0.01%) |
| Cranial nerve disorder | Nervous system disorders | 6 (0.01%) |
| Derealisation | Psychiatric disorders | 6 (0.01%) |
| Diet refusal | Metabolism and nutrition disorders | 6 (0.01%) |
| Disease progression | General disorders and administration site conditions | 6 (0.01%) |
| Dysphemia | Psychiatric disorders | 6 (0.01%) |
| Eosinophil count increased | Investigations | 6 (0.01%) |
| Eyelid function disorder | Eye disorders | 6 (0.01%) |
| Eyelid irritation | Eye disorders | 6 (0.01%) |
| Facial nerve disorder | Nervous system disorders | 6 (0.01%) |
| Fungal infection | Infections and infestations | 6 (0.01%) |
| Furuncle | Infections and infestations | 6 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Gamma-glutamyltransferase increased | Investigations | 6 (0.01%) |
| Gastroenteritis viral | Infections and infestations | 6 (0.01%) |
| Glomerular filtration rate decreased | Investigations | 6 (0.01%) |
| Hepatic enzyme increased | Investigations | 6 (0.01%) |
| Hepatitis | Hepatobiliary disorders | 6 (0.01%) |
| Herpes ophthalmic | Infections and infestations | 6 (0.01%) |
| Herpes zoster reactivation | Infections and infestations | 6 (0.01%) |
| Hyperaemia | Vascular disorders | 6 (0.01%) |
| Hyperaesthesia teeth | Gastrointestinal disorders | 6 (0.01%) |
| Hyperkalaemia | Metabolism and nutrition disorders | 6 (0.01%) |
| Hyperleukocytosis | Blood and lymphatic system disorders | 6 (0.01%) |
| Hypothyroidism | Endocrine disorders | 6 (0.01%) |
| Incoherent | Nervous system disorders | 6 (0.01%) |
| Injection site pruritus | General disorders and administration site conditions | 6 (0.01%) |
| Joint warmth | Musculoskeletal and connective tissue disorders | 6 (0.01%) |
| Medication error | Injury, poisoning and procedural complications | 6 (0.01%) |
| Mood swings | Psychiatric disorders | 6 (0.01%) |
| Noninfective gingivitis | Gastrointestinal disorders | 6 (0.01%) |
| Palmar erythema | Skin and subcutaneous tissue disorders | 6 (0.01%) |
| Pancytopenia | Blood and lymphatic system disorders | 6 (0.01%) |
| Peripheral sensory neuropathy | Nervous system disorders | 6 (0.01%) |
| Product dose omission issue | Injury, poisoning and procedural complications | 6 (0.01%) |
| Reduced facial expression | Nervous system disorders | 6 (0.01%) |
| Respiratory depression | Respiratory, thoracic and mediastinal disorders | 6 (0.01%) |
| Respiratory fatigue | Respiratory, thoracic and mediastinal disorders | 6 (0.01%) |
| Skin abrasion | Injury, poisoning and procedural complications | 6 (0.01%) |
| Skin ulcer | Skin and subcutaneous tissue disorders | 6 (0.01%) |
| Sleep paralysis | Nervous system disorders | 6 (0.01%) |
| Staring | Psychiatric disorders | 6 (0.01%) |
| Systemic inflammatory response syndrome | General disorders and administration site conditions | 6 (0.01%) |
| Systemic lupus erythematosus | Musculoskeletal and connective tissue disorders | 6 (0.01%) |
| Tachypnea | Psychiatric disorders | 6 (0.01%) |
| Thrombophlebitis superficial | Vascular disorders | 6 (0.01%) |
| Upper airway obstruction | Respiratory, thoracic and mediastinal disorders | 6 (0.01%) |
| Upper gastrointestinal haemorrhage | Gastrointestinal disorders | 6 (0.01%) |
| Vaccination site abscess | Infections and infestations | 6 (0.01%) |
| Visual acuity reduced | Eye disorders | 6 (0.01%) |
| Vlth nerve paralysis | Nervous system disorders | 6 (0.01%) |
| Yellow skin | Skin and subcutaneous tissue disorders | 6 (0.01%) |
| Abdominal tenderness | Gastrointestinal disorders | 5 (0.01%) |
| Adverse event | General disorders and administration site conditions | 5 (0.01%) |
| Arteriosclerosis | Vascular disorders | 5 (0.01%) |
| Arthropod bite | Injury, poisoning and procedural complications | 5 (0.01%) |
| Autonomic nervous system imbalance | Nervous system disorders | 5 (0.01%) |
| Back disorder | Musculoskeletal and connective tissue disorders | 5 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Bladder disorder | Renal and urinary disorders | 5 (0.01%) |
| Blepharitis | Eye disorders | 5 (0.01%) |
| Blood alkaline phosphatase increased | Investigations | 5 (0.01%) |
| Blood glucose abnormal | Investigations | 5 (0.01%) |
| Bradykinesia | Nervous system disorders | 5 (0.01%) |
| Brain injury | Nervous system disorders | 5 (0.01%) |
| Breath sounds abnormal | Investigations | 5 (0.01%) |
| Cerebral disorder | Nervous system disorders | 5 (0.01%) |
| Colitis | Gastrointestinal disorders | 5 (0.01%) |
| Colitis ulcerative | Gastrointestinal disorders | 5 (0.01%) |
| Coma scale abnormal | Investigations | 5 (0.01%) |
| Contraindicated product administered | Injury, poisoning and procedural complications | 5 (0.01%) |
| Disorganised speech | Psychiatric disorders | 5 (0.01%) |
| Epigastric discomfort | Gastrointestinal disorders | 5 (0.01%) |
| Erythema nodosum | Skin and subcutaneous tissue disorders | 5 (0.01%) |
| Expired product administered | Injury, poisoning and procedural complications | 5 (0.01%) |
| Fine motor skill dysfunction | Nervous system disorders | 5 (0.01%) |
| Fluid intake reduced | Metabolism and nutrition disorders | 5 (0.01%) |
| Foaming at mouth | General disorders and administration site conditions | 5 (0.01%) |
| Frustration tolerance decreased | Psychiatric disorders | 5 (0.01%) |
| Gastrointestinal motility disorder | Gastrointestinal disorders | 5 (0.01%) |
| Generalised oedema | General disorders and administration site conditions | 5 (0.01%) |
| Glaucoma | Eye disorders | 5 (0.01%) |
| Glossitis | Gastrointestinal disorders | 5 (0.01%) |
| Haematocrit decreased | Investigations | 5 (0.01%) |
| Haemorrhage intracranial | Nervous system disorders | 5 (0.01%) |
| Haemorrhoids | Gastrointestinal disorders | 5 (0.01%) |
| Hallucinations, mixed | Psychiatric disorders | 5 (0.01%) |
| Hepatitis acute | Hepatobiliary disorders | 5 (0.01%) |
| Hypertonia | Nervous system disorders | 5 (0.01%) |
| Hypoaesthesia teeth | Gastrointestinal disorders | 5 (0.01%) |
| Hyporeflexia | Nervous system disorders | 5 (0.01%) |
| Immobile | Social circumstances | 5 (0.01%) |
| Immunodeficiency | Immune system disorders | 5 (0.01%) |
| Incorrect dosage administered | Injury, poisoning and procedural complications | 5 (0.01%) |
| International normalised ratio decreased | Investigations | 5 (0.01%) |
| Intestinal obstruction | Gastrointestinal disorders | 5 (0.01%) |
| Intraocular pressure increased | Investigations | 5 (0.01%) |
| Iridocyclitis | Eye disorders | 5 (0.01%) |
| Joint dislocation | Injury, poisoning and procedural complications | 5 (0.01%) |
| Joint injury | Injury, poisoning and procedural complications | 5 (0.01%) |
| Language disorder | Nervous system disorders | 5 (0.01%) |
| Laryngeal pain | Respiratory, thoracic and mediastinal disorders | 5 (0.01%) |
| Lip erythema | Gastrointestinal disorders | 5 (0.01%) |
| Listless | Psychiatric disorders | 5 (0.01%) |
| Liver injury | Hepatobiliary disorders | 5 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------------|---|-----------------|
| Lividity | Skin and subcutaneous tissue disorders | 5 (0.01%) |
| Loss of control of legs | General disorders and administration site conditions | 5 (0.01%) |
| Lymphoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 (0.01%) |
| Macroglossia | Congenital, familial and genetic disorders | 5 (0.01%) |
| Mastication disorder | Musculoskeletal and connective tissue disorders | 5 (0.01%) |
| Metamorphopsia | Eye disorders | 5 (0.01%) |
| Metastases to lymph nodes | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 (0.01%) |
| Miosis | Eye disorders | 5 (0.01%) |
| Mononeuropathy | Nervous system disorders | 5 (0.01%) |
| Mucous stools | Gastrointestinal disorders | 5 (0.01%) |
| Muscle disorder | Musculoskeletal and connective tissue disorders | 5 (0.01%) |
| Myocardial necrosis marker increased | Investigations | 5 (0.01%) |
| Occipital neuralgia | Nervous system disorders | 5 (0.01%) |
| Oedema mucosal | General disorders and administration site conditions | 5 (0.01%) |
| Oral dysaesthesia | Gastrointestinal disorders | 5 (0.01%) |
| Oropharyngeal spasm | Respiratory, thoracic and mediastinal disorders | 5 (0.01%) |
| Orthopnoea | Respiratory, thoracic and mediastinal disorders | 5 (0.01%) |
| Paranasal sinus hypersecretion | Respiratory, thoracic and mediastinal disorders | 5 (0.01%) |
| Paraparesis | Nervous system disorders | 5 (0.01%) |
| Pemphigoid | Skin and subcutaneous tissue disorders | 5 (0.01%) |
| Pericardial effusion | Cardiac disorders | 5 (0.01%) |
| Pharyngeal ulceration | Respiratory, thoracic and mediastinal disorders | 5 (0.01%) |
| Pharyngitis streptococcal | Infections and infestations | 5 (0.01%) |
| Phlebitis | Vascular disorders | 5 (0.01%) |
| Polyarthritis | Musculoskeletal and connective tissue disorders | 5 (0.01%) |
| Product label confusion | Injury, poisoning and procedural complications | 5 (0.01%) |
| Respiratory symptom | Respiratory, thoracic and mediastinal disorders | 5 (0.01%) |
| Rhonchi | Respiratory, thoracic and mediastinal disorders | 5 (0.01%) |
| Rosacea | Skin and subcutaneous tissue disorders | 5 (0.01%) |
| Sense of oppression | General disorders and administration site conditions | 5 (0.01%) |
| Shock symptom | Vascular disorders | 5 (0.01%) |
| Sialoadenitis | Infections and infestations | 5 (0.01%) |
| Skin erosion | Skin and subcutaneous tissue disorders | 5 (0.01%) |
| Slow speech | Nervous system disorders | 5 (0.01%) |
| Splenomegaly | Blood and lymphatic system disorders | 5 (0.01%) |
| Subarachnoid haemorrhage | Nervous system disorders | 5 (0.01%) |
| Suicidal ideation | Psychiatric disorders | 5 (0.01%) |
| Suspected product quality issue | Product issues | 5 (0.01%) |
| Synovitis | Musculoskeletal and connective tissue disorders | 5 (0.01%) |
| Syringe issue | Product issues | 5 (0.01%) |
| Systolic hypertension | Vascular disorders | 5 (0.01%) |
| Tearfulness | Psychiatric disorders | 5 (0.01%) |
| Tongue movement disturbance | Gastrointestinal disorders | 5 (0.01%) |
| Torticollis | Musculoskeletal and connective tissue disorders | 5 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Upper limb fracture | Injury, poisoning and procedural complications | 5 (0.01%) |
| Vaccination site papule | General disorders and administration site conditions | 5 (0.01%) |
| Vaccination site scab | General disorders and administration site conditions | 5 (0.01%) |
| Vasoconstriction | Vascular disorders | 5 (0.01%) |
| Vitreous detachment | Eye disorders | 5 (0.01%) |
| Vulvovaginal candidiasis | Infections and infestations | 5 (0.01%) |
| Abscess | Infections and infestations | 4 (0.01%) |
| Anuria | Renal and urinary disorders | 4 (0.01%) |
| Appetite disorder | Metabolism and nutrition disorders | 4 (0.01%) |
| Atrial tachycardia | Cardiac disorders | 4 (0.01%) |
| Autoimmune haemolytic anaemia | Blood and lymphatic system disorders | 4 (0.01%) |
| Behaviour disorder | Psychiatric disorders | 4 (0.01%) |
| Blindness unilateral | Eye disorders | 4 (0.01%) |
| Blood chloride increased | Investigations | 4 (0.01%) |
| Blood glucose fluctuation | Investigations | 4 (0.01%) |
| Blood iron decreased | Investigations | 4 (0.01%) |
| Blood test abnormal | Investigations | 4 (0.01%) |
| Blood thyroid stimulating hormone increased | Investigations | 4 (0.01%) |
| Body temperature | Investigations | 4 (0.01%) |
| Breast discharge | Reproductive system and breast disorders | 4 (0.01%) |
| Butterfly rash | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Cachexia | Metabolism and nutrition disorders | 4 (0.01%) |
| Cardiac fibrillation | Cardiac disorders | 4 (0.01%) |
| Central nervous system lesion | Nervous system disorders | 4 (0.01%) |
| Cerebral haematoma | Nervous system disorders | 4 (0.01%) |
| Chronic fatigue syndrome | General disorders and administration site conditions | 4 (0.01%) |
| Coagulopathy | Blood and lymphatic system disorders | 4 (0.01%) |
| Conjunctival hyperaemia | Eye disorders | 4 (0.01%) |
| Conjunctival irritation | Eye disorders | 4 (0.01%) |
| Conjunctivitis allergic | Eye disorders | 4 (0.01%) |
| Consciousness fluctuating | Nervous system disorders | 4 (0.01%) |
| Crepitations | General disorders and administration site conditions | 4 (0.01%) |
| Cutaneous vasculitis | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Cystitis haemorrhagic | Renal and urinary disorders | 4 (0.01%) |
| Decreased interest | Psychiatric disorders | 4 (0.01%) |
| Dermatitis atopic | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Dermatitis contact | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Ear congestion | Ear and labyrinth disorders | 4 (0.01%) |
| Energy increased | General disorders and administration site conditions | 4 (0.01%) |
| Epicondylitis | Injury, poisoning and procedural complications | 4 (0.01%) |
| Eye allergy | Eye disorders | 4 (0.01%) |
| Eye haematoma | Eye disorders | 4 (0.01%) |
| Eyelid rash | Eye disorders | 4 (0.01%) |
| Faeces pale | Gastrointestinal disorders | 4 (0.01%) |
| Folliculitis | Infections and infestations | 4 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Food aversion | Metabolism and nutrition disorders | 4 (0.01%) |
| Gastrointestinal hypermotility | Gastrointestinal disorders | 4 (0.01%) |
| Gaze palsy | Eye disorders | 4 (0.01%) |
| Gingival blister | Gastrointestinal disorders | 4 (0.01%) |
| Gingival discomfort | Gastrointestinal disorders | 4 (0.01%) |
| Gingival erythema | Gastrointestinal disorders | 4 (0.01%) |
| Gingivitis | Infections and infestations | 4 (0.01%) |
| Glassy eyes | General disorders and administration site conditions | 4 (0.01%) |
| Goitre | Endocrine disorders | 4 (0.01%) |
| Haemorrhage urinary tract | Renal and urinary disorders | 4 (0.01%) |
| Hemidysaesthesia | Nervous system disorders | 4 (0.01%) |
| Herpes zoster oticus | Infections and infestations | 4 (0.01%) |
| Huntington's disease | Congenital, familial and genetic disorders | 4 (0.01%) |
| Hyperchlorhydria | Gastrointestinal disorders | 4 (0.01%) |
| Hypocalcaemia | Metabolism and nutrition disorders | 4 (0.01%) |
| Hypoperfusion | Vascular disorders | 4 (0.01%) |
| Hypovolaemic shock | Vascular disorders | 4 (0.01%) |
| Illrd nerve paralysis | Nervous system disorders | 4 (0.01%) |
| Increased tendency to bruise | Blood and lymphatic system disorders | 4 (0.01%) |
| Increased viscosity of upper respiratory secretion | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Injection site extravasation | General disorders and administration site conditions | 4 (0.01%) |
| Injection site mass | General disorders and administration site conditions | 4 (0.01%) |
| Injection site urticaria | General disorders and administration site conditions | 4 (0.01%) |
| Interstitial lung disease | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Irritability postvaccinal | General disorders and administration site conditions | 4 (0.01%) |
| Jaw disorder | Musculoskeletal and connective tissue disorders | 4 (0.01%) |
| Laryngeal dyspnoea | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Left ventricular failure | Cardiac disorders | 4 (0.01%) |
| Leukopenia | Blood and lymphatic system disorders | 4 (0.01%) |
| Ligament sprain | Injury, poisoning and procedural complications | 4 (0.01%) |
| Limb immobilisation | Surgical and medical procedures | 4 (0.01%) |
| Lymphocyte count decreased | Investigations | 4 (0.01%) |
| Macule | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Malignant hypertension | Vascular disorders | 4 (0.01%) |
| Malnutrition | Metabolism and nutrition disorders | 4 (0.01%) |
| Meniere's disease | Ear and labyrinth disorders | 4 (0.01%) |
| Meningitis viral | Infections and infestations | 4 (0.01%) |
| Micturition disorder | Renal and urinary disorders | 4 (0.01%) |
| Mucosal disorder | General disorders and administration site conditions | 4 (0.01%) |
| Mucosal dryness | General disorders and administration site conditions | 4 (0.01%) |
| Multiple sclerosis | Nervous system disorders | 4 (0.01%) |
| Muscle spasticity | Nervous system disorders | 4 (0.01%) |
| Myofascial pain syndrome | Musculoskeletal and connective tissue disorders | 4 (0.01%) |
| Nail discolouration | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Narcolepsy | Nervous system disorders | 4 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------|--|-----------------|
| Nasal obstruction | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Near death experience | Psychiatric disorders | 4 (0.01%) |
| Neutrophil count decreased | Investigations | 4 (0.01%) |
| Nipple swelling | Reproductive system and breast disorders | 4 (0.01%) |
| Non-cardiac chest pain | General disorders and administration site conditions | 4 (0.01%) |
| Noninfective encephalitis | Nervous system disorders | 4 (0.01%) |
| Oversensing | Product issues | 4 (0.01%) |
| Paranoia | Psychiatric disorders | 4 (0.01%) |
| Partial seizures | Nervous system disorders | 4 (0.01%) |
| Phonophobia | Psychiatric disorders | 4 (0.01%) |
| Pneumonia bacterial | Infections and infestations | 4 (0.01%) |
| Polyneuropathy | Nervous system disorders | 4 (0.01%) |
| Poor peripheral circulation | Vascular disorders | 4 (0.01%) |
| Post viral fatigue syndrome | Infections and infestations | 4 (0.01%) |
| Product complaint | Product issues | 4 (0.01%) |
| Product storage error | Injury, poisoning and procedural complications | 4 (0.01%) |
| Product supply issue | Product issues | 4 (0.01%) |
| Psychotic disorder | Psychiatric disorders | 4 (0.01%) |
| Pulmonary infarction | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Pulpitis dental | Infections and infestations | 4 (0.01%) |
| Pyelonephritis | Infections and infestations | 4 (0.01%) |
| Radiculopathy | Nervous system disorders | 4 (0.01%) |
| Red blood cell count decreased | Investigations | 4 (0.01%) |
| Retinal migraine | Nervous system disorders | 4 (0.01%) |
| Scab | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Scar | Injury, poisoning and procedural complications | 4 (0.01%) |
| Screaming | General disorders and administration site conditions | 4 (0.01%) |
| Scrotal pain | Reproductive system and breast disorders | 4 (0.01%) |
| Sensation of blood flow | General disorders and administration site conditions | 4 (0.01%) |
| Sinus bradycardia | Cardiac disorders | 4 (0.01%) |
| Sjogren's syndrome | Musculoskeletal and connective tissue disorders | 4 (0.01%) |
| Skin plaque | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Slow response to stimuli | Nervous system disorders | 4 (0.01%) |
| Snoring | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Somatic symptom disorder | Psychiatric disorders | 4 (0.01%) |
| Stiff tongue | Gastrointestinal disorders | 4 (0.01%) |
| Subcutaneous abscess | Infections and infestations | 4 (0.01%) |
| Sudden cardiac death | General disorders and administration site conditions | 4 (0.01%) |
| Suppressed lactation | Reproductive system and breast disorders | 4 (0.01%) |
| Supraventricular extrasystoles | Cardiac disorders | 4 (0.01%) |
| Tachycardia paroxysmal | Cardiac disorders | 4 (0.01%) |
| Tenosynovitis | Musculoskeletal and connective tissue disorders | 4 (0.01%) |
| Thermal burn | Injury, poisoning and procedural complications | 4 (0.01%) |
| Thyroid disorder | Endocrine disorders | 4 (0.01%) |
| Tongue coated | Gastrointestinal disorders | 4 (0.01%) |
| Tongue eruption | Gastrointestinal disorders | 4 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Toxic epidermal necrolysis | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Urine output increased | Investigations | 4 (0.01%) |
| Urticaria papular | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Vaccination site discharge | General disorders and administration site conditions | 4 (0.01%) |
| Vaginal discharge | Reproductive system and breast disorders | 4 (0.01%) |
| Varicella | Infections and infestations | 4 (0.01%) |
| Vascular dementia | Nervous system disorders | 4 (0.01%) |
| Vasculitic rash | Skin and subcutaneous tissue disorders | 4 (0.01%) |
| Vein discolouration | Vascular disorders | 4 (0.01%) |
| Vein disorder | Vascular disorders | 4 (0.01%) |
| Venous thrombosis limb | Vascular disorders | 4 (0.01%) |
| Viral pharyngitis | Infections and infestations | 4 (0.01%) |
| Vocal cord disorder | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Yawning | Respiratory, thoracic and mediastinal disorders | 4 (0.01%) |
| Abnormal weight gain | Metabolism and nutrition disorders | 3 (0.01%) |
| Accidental underdose | Injury, poisoning and procedural complications | 3 (0.01%) |
| Acidosis | Metabolism and nutrition disorders | 3 (0.01%) |
| Acute abdomen | Gastrointestinal disorders | 3 (0.01%) |
| Acute vestibular syndrome | Ear and labyrinth disorders | 3 (0.01%) |
| Adrenocortical insufficiency acute | Endocrine disorders | 3 (0.01%) |
| Affect lability | Psychiatric disorders | 3 (0.01%) |
| Allergic cough | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Allergic oedema | Immune system disorders | 3 (0.01%) |
| Allergic reaction to excipient | Immune system disorders | 3 (0.01%) |
| Anal sphincter atony | Gastrointestinal disorders | 3 (0.01%) |
| Aortic aneurysm | Vascular disorders | 3 (0.01%) |
| Aortic dissection | Vascular disorders | 3 (0.01%) |
| Ascites | Gastrointestinal disorders | 3 (0.01%) |
| Atrioventricular block | Cardiac disorders | 3 (0.01%) |
| Back injury | Injury, poisoning and procedural complications | 3 (0.01%) |
| Bacterial infection | Infections and infestations | 3 (0.01%) |
| Band sensation | Nervous system disorders | 3 (0.01%) |
| Bladder discomfort | Renal and urinary disorders | 3 (0.01%) |
| Bladder pain | Renal and urinary disorders | 3 (0.01%) |
| Blood bilirubin increased | Investigations | 3 (0.01%) |
| Blood chloride decreased | Investigations | 3 (0.01%) |
| Blood cholesterol increased | Investigations | 3 (0.01%) |
| Blood count abnormal | Investigations | 3 (0.01%) |
| Blood lactate dehydrogenase increased | Investigations | 3 (0.01%) |
| Blood pressure systolic decreased | Investigations | 3 (0.01%) |
| Bronchial disorder | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Bronchiectasis | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Bundle branch block left | Cardiac disorders | 3 (0.01%) |
| Burning sensation mucosal | Nervous system disorders | 3 (0.01%) |
| Candida infection | Infections and infestations | 3 (0.01%) |
| Cardiovascular insufficiency | Cardiac disorders | 3 (0.01%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Cartilage injury | Injury, poisoning and procedural complications | 3 (0.01%) |
| Cerebellar syndrome | Nervous system disorders | 3 (0.01%) |
| Cerebral ischaemia | Nervous system disorders | 3 (0.01%) |
| Cerebral thrombosis | Nervous system disorders | 3 (0.01%) |
| Cerebral venous sinus thrombosis | Nervous system disorders | 3 (0.01%) |
| Cervicobrachial syndrome | Nervous system disorders | 3 (0.01%) |
| Chest X-ray abnormal | Investigations | 3 (0.01%) |
| Cholinergic syndrome | Nervous system disorders | 3 (0.01%) |
| Chronic respiratory failure | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Circumoral swelling | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Clumsiness | Nervous system disorders | 3 (0.01%) |
| Complex regional pain syndrome | Nervous system disorders | 3 (0.01%) |
| Costovertebral angle tenderness | Renal and urinary disorders | 3 (0.01%) |
| Cyst | General disorders and administration site conditions | 3 (0.01%) |
| Deafness bilateral | Ear and labyrinth disorders | 3 (0.01%) |
| Decreased activity | General disorders and administration site conditions | 3 (0.01%) |
| Delusion | Psychiatric disorders | 3 (0.01%) |
| Delusional perception | Psychiatric disorders | 3 (0.01%) |
| Demyelination | Nervous system disorders | 3 (0.01%) |
| Depersonalisation/derealisation disorder | Psychiatric disorders | 3 (0.01%) |
| Dermatitis exfoliative | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Diplegia | Nervous system disorders | 3 (0.01%) |
| Ecchymosis | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Electrocardiogram QT prolonged | Investigations | 3 (0.01%) |
| Embolism | Vascular disorders | 3 (0.01%) |
| Enanthema | General disorders and administration site conditions | 3 (0.01%) |
| Enuresis | Psychiatric disorders | 3 (0.01%) |
| Eosinophilia | Blood and lymphatic system disorders | 3 (0.01%) |
| Epiglottic oedema | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Escherichia infection | Infections and infestations | 3 (0.01%) |
| Exercise tolerance decreased | General disorders and administration site conditions | 3 (0.01%) |
| Extensor plantar response | Nervous system disorders | 3 (0.01%) |
| External ear pain | Ear and labyrinth disorders | 3 (0.01%) |
| Extrapyramidal disorder | Nervous system disorders | 3 (0.01%) |
| Eyelid disorder | Eye disorders | 3 (0.01%) |
| Eye paraesthesia | Eye disorders | 3 (0.01%) |
| Facial asymmetry | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Feeling of despair | Psychiatric disorders | 3 (0.01%) |
| Food allergy | Immune system disorders | 3 (0.01%) |
| Fracture | Injury, poisoning and procedural complications | 3 (0.01%) |
| Frostbite | Injury, poisoning and procedural complications | 3 (0.01%) |
| Gallbladder disorder | Hepatobiliary disorders | 3 (0.01%) |
| Gastric haemorrhage | Gastrointestinal disorders | 3 (0.01%) |
| Genital herpes | Infections and infestations | 3 (0.01%) |
| Genital ulceration | Reproductive system and breast disorders | 3 (0.01%) |
| Giant cell arteritis | Vascular disorders | 3 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Glycosylated haemoglobin increased | Investigations | 3 (0.01%) |
| Grunting | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Haemolytic anaemia | Blood and lymphatic system disorders | 3 (0.01%) |
| Haemorrhage subcutaneous | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Head titubation | Nervous system disorders | 3 (0.01%) |
| Hepatocellular injury | Hepatobiliary disorders | 3 (0.01%) |
| Hip fracture | Injury, poisoning and procedural complications | 3 (0.01%) |
| Hormone level abnormal | Investigations | 3 (0.01%) |
| Hyperreflexia | Nervous system disorders | 3 (0.01%) |
| Hypertransaminasaemia | Hepatobiliary disorders | 3 (0.01%) |
| Hyporesponsive to stimuli | Nervous system disorders | 3 (0.01%) |
| Hypotensive crisis | Vascular disorders | 3 (0.01%) |
| Hypoventilation | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Immunisation reaction | Immune system disorders | 3 (0.01%) |
| Increased appetite | Metabolism and nutrition disorders | 3 (0.01%) |
| Infantile vomiting | Gastrointestinal disorders | 3 (0.01%) |
| Infant irritability | Nervous system disorders | 3 (0.01%) |
| Infarction | Vascular disorders | 3 (0.01%) |
| Infective exacerbation of chronic obstructive airways disease | Infections and infestations | 3 (0.01%) |
| Inflammatory pain | General disorders and administration site conditions | 3 (0.01%) |
| Injury | Injury, poisoning and procedural complications | 3 (0.01%) |
| Insulin resistance | Metabolism and nutrition disorders | 3 (0.01%) |
| Intercostal neuralgia | Nervous system disorders | 3 (0.01%) |
| Intranasal hypoaesthesia | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Ischaemic cerebral infarction | Nervous system disorders | 3 (0.01%) |
| IVth nerve paralysis | Nervous system disorders | 3 (0.01%) |
| Joint instability | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Joint noise | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Lacunar infarction | Nervous system disorders | 3 (0.01%) |
| Laryngeal discomfort | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Laryngeal obstruction | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Laziness | Psychiatric disorders | 3 (0.01%) |
| Lipase increased | Investigations | 3 (0.01%) |
| Lip discolouration | Gastrointestinal disorders | 3 (0.01%) |
| Lip exfoliation | Gastrointestinal disorders | 3 (0.01%) |
| Logorrhoea | Psychiatric disorders | 3 (0.01%) |
| Lower respiratory tract congestion | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Lymph node palpable | Investigations | 3 (0.01%) |
| Lymphocytosis | Blood and lymphatic system disorders | 3 (0.01%) |
| Mean cell haemoglobin decreased | Investigations | 3 (0.01%) |
| Meningism | Nervous system disorders | 3 (0.01%) |
| Meningitis | Infections and infestations | 3 (0.01%) |
| Menopausal symptoms | Reproductive system and breast disorders | 3 (0.01%) |
| Metabolic acidosis | Metabolism and nutrition disorders | 3 (0.01%) |
| Microembolism | Vascular disorders | 3 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------|--|-----------------|
| Monocyte count increased | Investigations | 3 (0.01%) |
| Morning sickness | Pregnancy, puerperium and perinatal conditions | 3 (0.01%) |
| Mutism | Psychiatric disorders | 3 (0.01%) |
| Myalgia intercostal | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Myasthenia gravis | Nervous system disorders | 3 (0.01%) |
| Myelosuppression | Blood and lymphatic system disorders | 3 (0.01%) |
| Myosclerosis | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Nasal disorder | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Nephrolithiasis | Renal and urinary disorders | 3 (0.01%) |
| Nephrotic syndrome | Renal and urinary disorders | 3 (0.01%) |
| Neurodermatitis | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Ophthalmic herpes simplex | Infections and infestations | 3 (0.01%) |
| Optic neuropathy | Eye disorders | 3 (0.01%) |
| Oral blood blister | Gastrointestinal disorders | 3 (0.01%) |
| Orchitis | Infections and infestations | 3 (0.01%) |
| Otitis externa | Infections and infestations | 3 (0.01%) |
| Paraesthesia ear | Ear and labyrinth disorders | 3 (0.01%) |
| Parkinsonism | Nervous system disorders | 3 (0.01%) |
| Parkinson's disease | Nervous system disorders | 3 (0.01%) |
| Parotid gland enlargement | Gastrointestinal disorders | 3 (0.01%) |
| Peripheral circulatory failure | Vascular disorders | 3 (0.01%) |
| Peripheral ischaemia | Vascular disorders | 3 (0.01%) |
| Pertussis | Infections and infestations | 3 (0.01%) |
| Pharyngeal mass | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Plicated tongue | Gastrointestinal disorders | 3 (0.01%) |
| Polymenorrhoea | Reproductive system and breast disorders | 3 (0.01%) |
| Postictal state | Nervous system disorders | 3 (0.01%) |
| Postmenopausal haemorrhage | Reproductive system and breast disorders | 3 (0.01%) |
| Pre-existing condition improved | General disorders and administration site conditions | 3 (0.01%) |
| Primary cough headache | Nervous system disorders | 3 (0.01%) |
| Procedural nausea | Injury, poisoning and procedural complications | 3 (0.01%) |
| Procedural pain | Injury, poisoning and procedural complications | 3 (0.01%) |
| Prostatomegaly | Reproductive system and breast disorders | 3 (0.01%) |
| Proteinuria | Renal and urinary disorders | 3 (0.01%) |
| Psoriatic arthropathy | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Psychiatric symptom | Psychiatric disorders | 3 (0.01%) |
| Pulseless electrical activity | Cardiac disorders | 3 (0.01%) |
| Pupillary disorder | Eye disorders | 3 (0.01%) |
| Pupils unequal | Eye disorders | 3 (0.01%) |
| Quality of life decreased | Investigations | 3 (0.01%) |
| Reaction to preservatives | Immune system disorders | 3 (0.01%) |
| Respiratory alkalosis | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Respiratory tract irritation | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Retinal tear | Eye disorders | 3 (0.01%) |
| Retrograde amnesia | Nervous system disorders | 3 (0.01%) |
| Road traffic accident | Injury, poisoning and procedural complications | 3 (0.01%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|------------------------------|--|-----------------|
| Sacroiliitis | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| SARS-CoV-2 test negative | Investigations | 3 (0.01%) |
| Seizure like phenomena | Nervous system disorders | 3 (0.01%) |
| Sensitisation | Immune system disorders | 3 (0.01%) |
| Serum ferritin increased | Investigations | 3 (0.01%) |
| Serum sickness | Immune system disorders | 3 (0.01%) |
| Skin haemorrhage | Skin and subcutaneous tissue disorders | 3 (0.01%) |
| Skin injury | Injury, poisoning and procedural complications | 3 (0.01%) |
| Sleep attacks | Psychiatric disorders | 3 (0.01%) |
| Sleep talking | Psychiatric disorders | 3 (0.01%) |
| Sleep terror | Psychiatric disorders | 3 (0.01%) |
| Small intestinal obstruction | Gastrointestinal disorders | 3 (0.01%) |
| Soft tissue infection | Infections and infestations | 3 (0.01%) |
| Sopor | Psychiatric disorders | 3 (0.01%) |
| Spinal disorder | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Sputum discoloured | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Sunburn | Injury, poisoning and procedural complications | 3 (0.01%) |
| Superficial vein prominence | Vascular disorders | 3 (0.01%) |
| Testicular pain | Reproductive system and breast disorders | 3 (0.01%) |
| Tetany | Metabolism and nutrition disorders | 3 (0.01%) |
| Thrombophlebitis | Vascular disorders | 3 (0.01%) |
| Thyroid pain | Endocrine disorders | 3 (0.01%) |
| Tic | Psychiatric disorders | 3 (0.01%) |
| Tongue biting | Nervous system disorders | 3 (0.01%) |
| Tongue haematoma | Gastrointestinal disorders | 3 (0.01%) |
| Tonsillar erythema | Respiratory, thoracic and mediastinal disorders | 3 (0.01%) |
| Tooth infection | Infections and infestations | 3 (0.01%) |
| Tracheitis | Infections and infestations | 3 (0.01%) |
| Transient global amnesia | Nervous system disorders | 3 (0.01%) |
| Type 1 diabetes mellitus | Metabolism and nutrition disorders | 3 (0.01%) |
| Ulcer | General disorders and administration site conditions | 3 (0.01%) |
| Ulnar nerve injury | Injury, poisoning and procedural complications | 3 (0.01%) |
| Urine odour abnormal | Renal and urinary disorders | 3 (0.01%) |
| Urine output decreased | Investigations | 3 (0.01%) |
| Uterine haemorrhage | Reproductive system and breast disorders | 3 (0.01%) |
| Vaccination site necrosis | General disorders and administration site conditions | 3 (0.01%) |
| Varicose vein | Vascular disorders | 3 (0.01%) |
| Venous thrombosis | Vascular disorders | 3 (0.01%) |
| Vestibular disorder | Ear and labyrinth disorders | 3 (0.01%) |
| Volvulus | Gastrointestinal disorders | 3 (0.01%) |
| Vulvovaginal pruritus | Reproductive system and breast disorders | 3 (0.01%) |
| Walking disability | Social circumstances | 3 (0.01%) |
| Weight bearing difficulty | Musculoskeletal and connective tissue disorders | 3 (0.01%) |
| Abdominal wall haemorrhage | Gastrointestinal disorders | 2 (0.00%) |
| Abortion | Pregnancy, puerperium and perinatal conditions | 2 (0.00%) |
| Abscess oral | Infections and infestations | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Acarodermatitis | Infections and infestations | 2 (0.00%) |
| Accommodation disorder | Eye disorders | 2 (0.00%) |
| Acute cardiac event | Cardiac disorders | 2 (0.00%) |
| Acute disseminated encephalomyelitis | Nervous system disorders | 2 (0.00%) |
| Acute febrile neutrophilic dermatosis | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Acute leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Acute myeloid leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Administration site movement impairment | General disorders and administration site conditions | 2 (0.00%) |
| Adverse reaction | General disorders and administration site conditions | 2 (0.00%) |
| Alcohol interaction | General disorders and administration site conditions | 2 (0.00%) |
| Amaurosis fugax | Eye disorders | 2 (0.00%) |
| Amylase increased | Investigations | 2 (0.00%) |
| Anaphylactoid shock | Immune system disorders | 2 (0.00%) |
| Angiopathy | Vascular disorders | 2 (0.00%) |
| Angle closure glaucoma | Eye disorders | 2 (0.00%) |
| Anterograde amnesia | Nervous system disorders | 2 (0.00%) |
| Antibody test negative | Investigations | 2 (0.00%) |
| Aortic aneurysm rupture | Vascular disorders | 2 (0.00%) |
| Application site coldness | General disorders and administration site conditions | 2 (0.00%) |
| Aptyalism | Gastrointestinal disorders | 2 (0.00%) |
| Areflexia | Nervous system disorders | 2 (0.00%) |
| Arterial occlusive disease | Vascular disorders | 2 (0.00%) |
| Arteriosclerosis coronary artery | Cardiac disorders | 2 (0.00%) |
| Atrioventricular block first degree | Cardiac disorders | 2 (0.00%) |
| Atypical pneumonia | Infections and infestations | 2 (0.00%) |
| Autoscopy | Psychiatric disorders | 2 (0.00%) |
| Axonal neuropathy | Nervous system disorders | 2 (0.00%) |
| Bacille Calmette-Guerin scar reactivation | Immune system disorders | 2 (0.00%) |
| Basal ganglia haemorrhage | Nervous system disorders | 2 (0.00%) |
| Basal ganglia stroke | Nervous system disorders | 2 (0.00%) |
| Behcet's syndrome | Vascular disorders | 2 (0.00%) |
| Blood albumin decreased | Investigations | 2 (0.00%) |
| Blood blister | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Blood calcium decreased | Investigations | 2 (0.00%) |
| Blood creatine phosphokinase MB increased | Investigations | 2 (0.00%) |
| Blood immunoglobulin G decreased | Investigations | 2 (0.00%) |
| Blood immunoglobulin G increased | Investigations | 2 (0.00%) |
| Blood ketone body increased | Investigations | 2 (0.00%) |
| Blood pH increased | Investigations | 2 (0.00%) |
| Blood pressure immeasurable | Investigations | 2 (0.00%) |
| Blood pressure inadequately controlled | Vascular disorders | 2 (0.00%) |
| Blood urea increased | Investigations | 2 (0.00%) |
| Blue toe syndrome | Vascular disorders | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-------------------------------------|---|-----------------|
| Bone disorder | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Booster dose missed | Injury, poisoning and procedural complications | 2 (0.00%) |
| Brachial plexopathy | Nervous system disorders | 2 (0.00%) |
| Brachial plexus injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Brain stem syndrome | Nervous system disorders | 2 (0.00%) |
| Breast abscess | Infections and infestations | 2 (0.00%) |
| Breast cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Breast cyst | Reproductive system and breast disorders | 2 (0.00%) |
| Breast enlargement | Reproductive system and breast disorders | 2 (0.00%) |
| Breast inflammation | Reproductive system and breast disorders | 2 (0.00%) |
| Breath sounds | Investigations | 2 (0.00%) |
| Bruxism | Psychiatric disorders | 2 (0.00%) |
| Capillary nail refill test abnormal | Investigations | 2 (0.00%) |
| Cardiac discomfort | Cardiac disorders | 2 (0.00%) |
| Cardiomegaly | Cardiac disorders | 2 (0.00%) |
| Carotid bruit | Investigations | 2 (0.00%) |
| Carpal tunnel syndrome | Nervous system disorders | 2 (0.00%) |
| Cataract | Eye disorders | 2 (0.00%) |
| Cerebellar haemorrhage | Nervous system disorders | 2 (0.00%) |
| Cerebellar infarction | Nervous system disorders | 2 (0.00%) |
| Cerebrovascular disorder | Nervous system disorders | 2 (0.00%) |
| Chalazion | Eye disorders | 2 (0.00%) |
| Chest injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Cholecystitis | Hepatobiliary disorders | 2 (0.00%) |
| Chorea | Nervous system disorders | 2 (0.00%) |
| Choroidal neovascularisation | Eye disorders | 2 (0.00%) |
| Chronic kidney disease | Renal and urinary disorders | 2 (0.00%) |
| Circumoral oedema | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Clonic convulsion | Nervous system disorders | 2 (0.00%) |
| Coagulation time prolonged | Investigations | 2 (0.00%) |
| Concomitant disease aggravated | General disorders and administration site conditions | 2 (0.00%) |
| Conjunctival oedema | Eye disorders | 2 (0.00%) |
| Conjunctivitis bacterial | Infections and infestations | 2 (0.00%) |
| Contraindication to vaccination | Social circumstances | 2 (0.00%) |
| Corneal reflex decreased | Investigations | 2 (0.00%) |
| Coronary artery occlusion | Cardiac disorders | 2 (0.00%) |
| Deafness transitory | Ear and labyrinth disorders | 2 (0.00%) |
| Decreased immune responsiveness | Immune system disorders | 2 (0.00%) |
| Dementia Alzheimer's type | Nervous system disorders | 2 (0.00%) |
| Demyelinating polyneuropathy | Nervous system disorders | 2 (0.00%) |
| Dental paraesthesia | Gastrointestinal disorders | 2 (0.00%) |
| Dental restoration failure | Injury, poisoning and procedural complications | 2 (0.00%) |
| Dermatitis exfoliative generalised | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Dermatosis | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Dermo-hypodermitis | Infections and infestations | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Diabetic complication | Metabolism and nutrition disorders | 2 (0.00%) |
| Diaphragmatic spasm | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Diastolic hypotension | Vascular disorders | 2 (0.00%) |
| Discharge | General disorders and administration site conditions | 2 (0.00%) |
| Discoloured vomit | Gastrointestinal disorders | 2 (0.00%) |
| Disseminated varicella zoster virus infection | Infections and infestations | 2 (0.00%) |
| Drowning | General disorders and administration site conditions | 2 (0.00%) |
| Duodenogastric reflux | Gastrointestinal disorders | 2 (0.00%) |
| Dyschromatopsia | Eye disorders | 2 (0.00%) |
| Dysgraphia | Nervous system disorders | 2 (0.00%) |
| Dyslexia | Nervous system disorders | 2 (0.00%) |
| Ear canal erythema | Ear and labyrinth disorders | 2 (0.00%) |
| Ear haemorrhage | Ear and labyrinth disorders | 2 (0.00%) |
| Eating disorder symptom | Metabolism and nutrition disorders | 2 (0.00%) |
| Ejection fraction decreased | Investigations | 2 (0.00%) |
| Electrocardiogram repolarisation abnormality | Investigations | 2 (0.00%) |
| Electrocardiogram ST segment abnormal | Investigations | 2 (0.00%) |
| Electrolyte imbalance | Metabolism and nutrition disorders | 2 (0.00%) |
| Encephalitis post immunisation | Nervous system disorders | 2 (0.00%) |
| Enteritis | Gastrointestinal disorders | 2 (0.00%) |
| Eosinophil count decreased | Investigations | 2 (0.00%) |
| Epstein-Barr virus infection | Infections and infestations | 2 (0.00%) |
| Escherichia sepsis | Infections and infestations | 2 (0.00%) |
| Essential tremor | Nervous system disorders | 2 (0.00%) |
| Eustachian tube disorder | Ear and labyrinth disorders | 2 (0.00%) |
| Excessive cerumen production | Ear and labyrinth disorders | 2 (0.00%) |
| Exertional headache | Nervous system disorders | 2 (0.00%) |
| Exfoliative rash | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Exposure via eye contact | Injury, poisoning and procedural complications | 2 (0.00%) |
| Extraocular muscle paresis | Eye disorders | 2 (0.00%) |
| Extremity contracture | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Eyelid sensory disorder | Eye disorders | 2 (0.00%) |
| Facial bones fracture | Injury, poisoning and procedural complications | 2 (0.00%) |
| Faecal vomiting | Gastrointestinal disorders | 2 (0.00%) |
| Fasciitis | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Fear of injection | Psychiatric disorders | 2 (0.00%) |
| Febrile infection | Infections and infestations | 2 (0.00%) |
| Femoral neck fracture | Injury, poisoning and procedural complications | 2 (0.00%) |
| Femur fracture | Injury, poisoning and procedural complications | 2 (0.00%) |
| Foetal growth restriction | Pregnancy, puerperium and perinatal conditions | 2 (0.00%) |
| Food craving | Metabolism and nutrition disorders | 2 (0.00%) |
| Food poisoning | Gastrointestinal disorders | 2 (0.00%) |
| Foot deformity | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Foreign body in throat | Injury, poisoning and procedural complications | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Functional gastrointestinal disorder | Gastrointestinal disorders | 2 (0.00%) |
| Gastrointestinal stoma complication | Injury, poisoning and procedural complications | 2 (0.00%) |
| General symptom | General disorders and administration site conditions | 2 (0.00%) |
| Genital pain | Reproductive system and breast disorders | 2 (0.00%) |
| Gingivitis ulcerative | Gastrointestinal disorders | 2 (0.00%) |
| Gonorrhoea | Infections and infestations | 2 (0.00%) |
| Granulomatous lymphadenitis | Blood and lymphatic system disorders | 2 (0.00%) |
| Haematocrit increased | Investigations | 2 (0.00%) |
| Haemoglobin increased | Investigations | 2 (0.00%) |
| Hair colour changes | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Hallucination, olfactory | Psychiatric disorders | 2 (0.00%) |
| Hand-eye coordination impaired | Nervous system disorders | 2 (0.00%) |
| Heat oedema | Injury, poisoning and procedural complications | 2 (0.00%) |
| Hemianopia homonymous | Nervous system disorders | 2 (0.00%) |
| Hemiplegic migraine | Nervous system disorders | 2 (0.00%) |
| Hepatic cirrhosis | Hepatobiliary disorders | 2 (0.00%) |
| Hepatic failure | Hepatobiliary disorders | 2 (0.00%) |
| Hepatitis cholestatic | Hepatobiliary disorders | 2 (0.00%) |
| Herpes simplex reactivation | Infections and infestations | 2 (0.00%) |
| Herpes zoster cutaneous disseminated | Infections and infestations | 2 (0.00%) |
| Herpes zoster infection neurological | Infections and infestations | 2 (0.00%) |
| Hidradenitis | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Histamine intolerance | Metabolism and nutrition disorders | 2 (0.00%) |
| Horner's syndrome | Nervous system disorders | 2 (0.00%) |
| Hypercalcaemia | Metabolism and nutrition disorders | 2 (0.00%) |
| Hypercapnia | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Hypersensitivity vasculitis | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Hypertensive urgency | Vascular disorders | 2 (0.00%) |
| Hypertonic bladder | Renal and urinary disorders | 2 (0.00%) |
| Idiopathic intracranial hypertension | Nervous system disorders | 2 (0.00%) |
| Idiosyncratic drug reaction | General disorders and administration site conditions | 2 (0.00%) |
| Ileus paralytic | Gastrointestinal disorders | 2 (0.00%) |
| Ill-defined disorder | General disorders and administration site conditions | 2 (0.00%) |
| Immune-mediated adverse reaction | Immune system disorders | 2 (0.00%) |
| Indifference | Psychiatric disorders | 2 (0.00%) |
| Infertility | Reproductive system and breast disorders | 2 (0.00%) |
| Infrequent bowel movements | Gastrointestinal disorders | 2 (0.00%) |
| Infusion related reaction | Injury, poisoning and procedural complications | 2 (0.00%) |
| Injection site bruising | General disorders and administration site conditions | 2 (0.00%) |
| Injection site discomfort | General disorders and administration site conditions | 2 (0.00%) |
| Injection site inflammation | General disorders and administration site conditions | 2 (0.00%) |
| Inner ear disorder | Ear and labyrinth disorders | 2 (0.00%) |
| Inspiratory capacity decreased | Investigations | 2 (0.00%) |
| Intercepted medication error | Injury, poisoning and procedural complications | 2 (0.00%) |
| Intercepted product preparation error | Injury, poisoning and procedural complications | 2 (0.00%) |
| Internal haemorrhage | Vascular disorders | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| International normalised ratio abnormal | Investigations | 2 (0.00%) |
| Intervertebral disc protrusion | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Intestinal perforation | Gastrointestinal disorders | 2 (0.00%) |
| Intestinal pseudo-obstruction | Gastrointestinal disorders | 2 (0.00%) |
| Intracardiac thrombus | Cardiac disorders | 2 (0.00%) |
| Intracranial pressure increased | Nervous system disorders | 2 (0.00%) |
| Intussusception | Gastrointestinal disorders | 2 (0.00%) |
| Iritis | Eye disorders | 2 (0.00%) |
| Irregular sleep wake rhythm disorder | Nervous system disorders | 2 (0.00%) |
| Jaw clicking | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Joint lock | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Ketoacidosis | Metabolism and nutrition disorders | 2 (0.00%) |
| Labile blood pressure | Vascular disorders | 2 (0.00%) |
| Lack of spontaneous speech | Psychiatric disorders | 2 (0.00%) |
| Lacrimation decreased | Eye disorders | 2 (0.00%) |
| Lactic acidosis | Metabolism and nutrition disorders | 2 (0.00%) |
| Laryngeal stenosis | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Leukoencephalopathy | Nervous system disorders | 2 (0.00%) |
| Lichen planus | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Ligament injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Lip injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Lower limb fracture | Injury, poisoning and procedural complications | 2 (0.00%) |
| Lymph gland infection | Infections and infestations | 2 (0.00%) |
| Lymphocyte count increased | Investigations | 2 (0.00%) |
| Mania | Psychiatric disorders | 2 (0.00%) |
| Mast cell activation syndrome | Blood and lymphatic system disorders | 2 (0.00%) |
| Maternal exposure during breast feeding | Injury, poisoning and procedural complications | 2 (0.00%) |
| Mean cell volume decreased | Investigations | 2 (0.00%) |
| Mean cell volume increased | Investigations | 2 (0.00%) |
| Meningeal disorder | Nervous system disorders | 2 (0.00%) |
| Meningitis aseptic | Infections and infestations | 2 (0.00%) |
| Mental status changes | Psychiatric disorders | 2 (0.00%) |
| Metastases to peritoneum | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Monocyte count decreased | Investigations | 2 (0.00%) |
| Monocytosis | Blood and lymphatic system disorders | 2 (0.00%) |
| Mouth breathing | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Mouth injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Multi-organ disorder | General disorders and administration site conditions | 2 (0.00%) |
| Muscle atrophy | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Muscle rupture | Injury, poisoning and procedural complications | 2 (0.00%) |
| Muscle tone disorder | Nervous system disorders | 2 (0.00%) |
| Myokymia | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Nasal injury | Injury, poisoning and procedural complications | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|------------------------------------|---|-----------------|
| Nasal odour | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Necrosis | General disorders and administration site conditions | 2 (0.00%) |
| Neoplasm malignant | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Neoplasm progression | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Neoplasm skin | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (0.00%) |
| Nephropathy | Renal and urinary disorders | 2 (0.00%) |
| Nerve degeneration | Nervous system disorders | 2 (0.00%) |
| Neurologic neglect syndrome | Nervous system disorders | 2 (0.00%) |
| Neurotoxicity | Nervous system disorders | 2 (0.00%) |
| Nocturia | Renal and urinary disorders | 2 (0.00%) |
| Oesophageal spasm | Gastrointestinal disorders | 2 (0.00%) |
| Oesophageal stenosis | Gastrointestinal disorders | 2 (0.00%) |
| Oral mucosa erosion | Gastrointestinal disorders | 2 (0.00%) |
| Oral mucosal exfoliation | Gastrointestinal disorders | 2 (0.00%) |
| Oropharyngeal swelling | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Otitis media | Infections and infestations | 2 (0.00%) |
| Overweight | Metabolism and nutrition disorders | 2 (0.00%) |
| Palatal disorder | Gastrointestinal disorders | 2 (0.00%) |
| Panic disorder | Psychiatric disorders | 2 (0.00%) |
| Panniculitis | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Papilloedema | Eye disorders | 2 (0.00%) |
| Paraplegia | Nervous system disorders | 2 (0.00%) |
| Peau d'orange | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Pemphigus | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Performance status decreased | General disorders and administration site conditions | 2 (0.00%) |
| Periorbital cellulitis | Infections and infestations | 2 (0.00%) |
| Periorbital discomfort | Eye disorders | 2 (0.00%) |
| Periorbital pain | Eye disorders | 2 (0.00%) |
| Peripheral nerve injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Persistent depressive disorder | Psychiatric disorders | 2 (0.00%) |
| pH urine | Investigations | 2 (0.00%) |
| Physical deconditioning | General disorders and administration site conditions | 2 (0.00%) |
| Pityriasis | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| PO2 decreased | Investigations | 2 (0.00%) |
| Polymerase chain reaction positive | Investigations | 2 (0.00%) |
| Polymyositis | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Post herpetic neuralgia | Nervous system disorders | 2 (0.00%) |
| Post procedural complication | Injury, poisoning and procedural complications | 2 (0.00%) |
| Post-traumatic stress disorder | Psychiatric disorders | 2 (0.00%) |
| Posture abnormal | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Premature baby | Pregnancy, puerperium and perinatal conditions | 2 (0.00%) |
| Premenstrual syndrome | Reproductive system and breast disorders | 2 (0.00%) |
| Pressure of speech | Psychiatric disorders | 2 (0.00%) |
| Proctalgia | Gastrointestinal disorders | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-----------------------------------|--|-----------------|
| Product container issue | Product issues | 2 (0.00%) |
| Prothrombin time prolonged | Investigations | 2 (0.00%) |
| Pruritus allergic | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Psychogenic seizure | Nervous system disorders | 2 (0.00%) |
| Psychomotor skills impaired | Nervous system disorders | 2 (0.00%) |
| Psychotic symptom | Psychiatric disorders | 2 (0.00%) |
| Pulmonary arterial hypertension | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Pulmonary artery thrombosis | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Pulmonary sepsis | Infections and infestations | 2 (0.00%) |
| Pupil fixed | Eye disorders | 2 (0.00%) |
| Quadriplegia | Nervous system disorders | 2 (0.00%) |
| Rectal discharge | Gastrointestinal disorders | 2 (0.00%) |
| Regurgitation | Gastrointestinal disorders | 2 (0.00%) |
| Renal colic | Renal and urinary disorders | 2 (0.00%) |
| Respiratory acidosis | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Retinal detachment | Eye disorders | 2 (0.00%) |
| Retinal haemorrhage | Eye disorders | 2 (0.00%) |
| Retinal vein occlusion | Eye disorders | 2 (0.00%) |
| Rheumatoid factor positive | Investigations | 2 (0.00%) |
| Rib fracture | Injury, poisoning and procedural complications | 2 (0.00%) |
| Rotator cuff syndrome | Musculoskeletal and connective tissue disorders | 2 (0.00%) |
| Salivary gland pain | Gastrointestinal disorders | 2 (0.00%) |
| Sarcoidosis | Immune system disorders | 2 (0.00%) |
| SARS-CoV-2 antibody test | Investigations | 2 (0.00%) |
| Scleral discolouration | Eye disorders | 2 (0.00%) |
| Scrotal erythema | Reproductive system and breast disorders | 2 (0.00%) |
| Sense of a foreshortened future | Psychiatric disorders | 2 (0.00%) |
| Sensitivity to weather change | General disorders and administration site conditions | 2 (0.00%) |
| Sensorimotor disorder | Nervous system disorders | 2 (0.00%) |
| Serotonin syndrome | Nervous system disorders | 2 (0.00%) |
| Severe acute respiratory syndrome | Infections and infestations | 2 (0.00%) |
| Sinus rhythm | Investigations | 2 (0.00%) |
| Skin fissures | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Skin laxity | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Skin necrosis | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Skin odour abnormal | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Skin oedema | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Skin sensitisation | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Skin temperature | Investigations | 2 (0.00%) |
| Sleep apnoea syndrome | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Sleep deficit | Nervous system disorders | 2 (0.00%) |
| Small intestinal haemorrhage | Gastrointestinal disorders | 2 (0.00%) |
| Spinal cord disorder | Nervous system disorders | 2 (0.00%) |
| Sputum abnormal | Investigations | 2 (0.00%) |
| Staphylococcal infection | Infections and infestations | 2 (0.00%) |
| Stoma site haemorrhage | Injury, poisoning and procedural complications | 2 (0.00%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------------|--|-----------------|
| Streptococcal infection | Infections and infestations | 2 (0.00%) |
| Streptococcus test positive | Investigations | 2 (0.00%) |
| Subileus | Gastrointestinal disorders | 2 (0.00%) |
| Sudden visual loss | Eye disorders | 2 (0.00%) |
| Suicide attempt | Psychiatric disorders | 2 (0.00%) |
| Tendon injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Terminal state | General disorders and administration site conditions | 2 (0.00%) |
| Thermal burns of eye | Injury, poisoning and procedural complications | 2 (0.00%) |
| Thrombocytopenic purpura | Blood and lymphatic system disorders | 2 (0.00%) |
| Thrombotic stroke | Nervous system disorders | 2 (0.00%) |
| Thrombotic thrombocytopenic purpura | Blood and lymphatic system disorders | 2 (0.00%) |
| Thunderclap headache | Nervous system disorders | 2 (0.00%) |
| Tongue blistering | Gastrointestinal disorders | 2 (0.00%) |
| Tongue injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Tongue spasm | Gastrointestinal disorders | 2 (0.00%) |
| Tonsillar disorder | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Tonsillar inflammation | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Tonsillitis bacterial | Infections and infestations | 2 (0.00%) |
| Tooth disorder | Gastrointestinal disorders | 2 (0.00%) |
| Toxic skin eruption | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Tracheal oedema | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Tracheal pain | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Traumatic lung injury | Injury, poisoning and procedural complications | 2 (0.00%) |
| Trichoglossia | Gastrointestinal disorders | 2 (0.00%) |
| Troponin T increased | Investigations | 2 (0.00%) |
| Tryptase decreased | Investigations | 2 (0.00%) |
| Tuberculosis | Infections and infestations | 2 (0.00%) |
| Type 2 diabetes mellitus | Metabolism and nutrition disorders | 2 (0.00%) |
| Ulcerative keratitis | Eye disorders | 2 (0.00%) |
| Urinary tract disorder | Renal and urinary disorders | 2 (0.00%) |
| Urine abnormality | Renal and urinary disorders | 2 (0.00%) |
| Urine analysis abnormal | Investigations | 2 (0.00%) |
| Urine flow decreased | Renal and urinary disorders | 2 (0.00%) |
| Use of accessory respiratory muscles | Respiratory, thoracic and mediastinal disorders | 2 (0.00%) |
| Vaccination error | Injury, poisoning and procedural complications | 2 (0.00%) |
| Vaccination site dysaesthesia | General disorders and administration site conditions | 2 (0.00%) |
| Vaccination site injury | General disorders and administration site conditions | 2 (0.00%) |
| Vaccination site joint inflammation | General disorders and administration site conditions | 2 (0.00%) |
| Vaccination site thrombosis | General disorders and administration site conditions | 2 (0.00%) |
| Vaccination site ulcer | General disorders and administration site conditions | 2 (0.00%) |
| Vaginal infection | Infections and infestations | 2 (0.00%) |
| Varicella zoster virus infection | Infections and infestations | 2 (0.00%) |
| Vascular headache | Nervous system disorders | 2 (0.00%) |
| Vascular pain | Vascular disorders | 2 (0.00%) |
| Vascular purpura | Skin and subcutaneous tissue disorders | 2 (0.00%) |
| Ventricular arrhythmia | Cardiac disorders | 2 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Vertigo labyrinthine | Ear and labyrinth disorders | 2 (0.00%) |
| Vestibular migraine | Nervous system disorders | 2 (0.00%) |
| Viral labyrinthitis | Infections and infestations | 2 (0.00%) |
| Viral upper respiratory tract infection | Infections and infestations | 2 (0.00%) |
| Vitreous disorder | Eye disorders | 2 (0.00%) |
| Vulval disorder | Reproductive system and breast disorders | 2 (0.00%) |
| Vulvovaginal burning sensation | Reproductive system and breast disorders | 2 (0.00%) |
| Vulvovaginal swelling | Reproductive system and breast disorders | 2 (0.00%) |
| Weight fluctuation | Metabolism and nutrition disorders | 2 (0.00%) |
| Wound complication | Injury, poisoning and procedural complications | 2 (0.00%) |
| Wound haemorrhage | Injury, poisoning and procedural complications | 2 (0.00%) |
| Wrong technique in device usage process | Injury, poisoning and procedural complications | 2 (0.00%) |
| Xanthopsia | Eye disorders | 2 (0.00%) |
| Abdominal adhesions | Gastrointestinal disorders | 1 (0.00%) |
| Abdominal symptom | Gastrointestinal disorders | 1 (0.00%) |
| Abdominal wall haematoma | Gastrointestinal disorders | 1 (0.00%) |
| Abnormal withdrawal bleeding | Reproductive system and breast disorders | 1 (0.00%) |
| Abortion missed | Pregnancy, puerperium and perinatal conditions | 1 (0.00%) |
| Accident | Injury, poisoning and procedural complications | 1 (0.00%) |
| Acetonaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Acoustic neuritis | Nervous system disorders | 1 (0.00%) |
| Acquired macroglossia | Gastrointestinal disorders | 1 (0.00%) |
| Acrochordon | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Activated partial thromboplastin time prolonged | Investigations | 1 (0.00%) |
| Acute hepatic failure | Hepatobiliary disorders | 1 (0.00%) |
| Acute left ventricular failure | Cardiac disorders | 1 (0.00%) |
| Administration site joint movement impairment | General disorders and administration site conditions | 1 (0.00%) |
| Administration site pain | General disorders and administration site conditions | 1 (0.00%) |
| Administration site reaction | General disorders and administration site conditions | 1 (0.00%) |
| Administration site warmth | General disorders and administration site conditions | 1 (0.00%) |
| Adrenal disorder | Endocrine disorders | 1 (0.00%) |
| Adult failure to thrive | Metabolism and nutrition disorders | 1 (0.00%) |
| Aerococcus urinae infection | Infections and infestations | 1 (0.00%) |
| Aerophagia | Gastrointestinal disorders | 1 (0.00%) |
| African trypanosomiasis | Infections and infestations | 1 (0.00%) |
| Age-related macular degeneration | Eye disorders | 1 (0.00%) |
| Agranulocytosis | Blood and lymphatic system disorders | 1 (0.00%) |
| Airway burns | Injury, poisoning and procedural complications | 1 (0.00%) |
| Akathisia | Nervous system disorders | 1 (0.00%) |
| Alcohol intolerance | Metabolism and nutrition disorders | 1 (0.00%) |
| Alexia | Nervous system disorders | 1 (0.00%) |
| Allergic respiratory symptom | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Allergic sinusitis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--------------------------------------|---|-----------------|
| Allergy to arthropod sting | Immune system disorders | 1 (0.00%) |
| Allergy to chemicals | Immune system disorders | 1 (0.00%) |
| Amblyopia | Eye disorders | 1 (0.00%) |
| Amyloidosis | Immune system disorders | 1 (0.00%) |
| Anal skin tags | Gastrointestinal disorders | 1 (0.00%) |
| Aneurysm | Vascular disorders | 1 (0.00%) |
| Aneurysm ruptured | Vascular disorders | 1 (0.00%) |
| Angiomyolipoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Angular cheilitis | Gastrointestinal disorders | 1 (0.00%) |
| Animal bite | Injury, poisoning and procedural complications | 1 (0.00%) |
| Anion gap abnormal | Investigations | 1 (0.00%) |
| Anisocytosis | Blood and lymphatic system disorders | 1 (0.00%) |
| Anorectal discomfort | Gastrointestinal disorders | 1 (0.00%) |
| Anorgasmia | Psychiatric disorders | 1 (0.00%) |
| Anovulatory cycle | Endocrine disorders | 1 (0.00%) |
| Anterior chamber cell | Eye disorders | 1 (0.00%) |
| Antibody test positive | Investigations | 1 (0.00%) |
| Anticholinergic syndrome | Nervous system disorders | 1 (0.00%) |
| Anticoagulation drug level increased | Investigations | 1 (0.00%) |
| Antinuclear antibody positive | Investigations | 1 (0.00%) |
| Antiphospholipid syndrome | Blood and lymphatic system disorders | 1 (0.00%) |
| Anti-thyroid antibody positive | Investigations | 1 (0.00%) |
| Anxiety disorder | Psychiatric disorders | 1 (0.00%) |
| Aortic stenosis | Vascular disorders | 1 (0.00%) |
| Apallic syndrome | Nervous system disorders | 1 (0.00%) |
| Apparent death | General disorders and administration site conditions | 1 (0.00%) |
| Application site hypersensitivity | General disorders and administration site conditions | 1 (0.00%) |
| Application site pain | General disorders and administration site conditions | 1 (0.00%) |
| Application site pruritus | General disorders and administration site conditions | 1 (0.00%) |
| Application site vesicles | General disorders and administration site conditions | 1 (0.00%) |
| Arterial rupture | Vascular disorders | 1 (0.00%) |
| Arteriospasm coronary | Cardiac disorders | 1 (0.00%) |
| Arteritis | Vascular disorders | 1 (0.00%) |
| Arthritis bacterial | Infections and infestations | 1 (0.00%) |
| Arthritis enteropathic | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Arthropod sting | Injury, poisoning and procedural complications | 1 (0.00%) |
| Asthma exercise induced | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Asthma prophylaxis | Surgical and medical procedures | 1 (0.00%) |
| Atrophic glossitis | Gastrointestinal disorders | 1 (0.00%) |
| Atrophy | General disorders and administration site conditions | 1 (0.00%) |
| Atypical femur fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Auditory disorder | Ear and labyrinth disorders | 1 (0.00%) |
| Auscultation | Investigations | 1 (0.00%) |
| Autoantibody negative | Investigations | 1 (0.00%) |
| Autoimmune demyelinating disease | Nervous system disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Autoimmune uveitis | Eye disorders | 1 (0.00%) |
| Automatism | Psychiatric disorders | 1 (0.00%) |
| Autophony | Ear and labyrinth disorders | 1 (0.00%) |
| Axillary vein thrombosis | Vascular disorders | 1 (0.00%) |
| Azotaemia | Renal and urinary disorders | 1 (0.00%) |
| Bacteraemia | Infections and infestations | 1 (0.00%) |
| Bacterial diarrhoea | Infections and infestations | 1 (0.00%) |
| Bacterial rhinitis | Infections and infestations | 1 (0.00%) |
| Bacterial sepsis | Infections and infestations | 1 (0.00%) |
| Bacterial test positive | Investigations | 1 (0.00%) |
| Barotrauma | Injury, poisoning and procedural complications | 1 (0.00%) |
| Basal ganglia infarction | Nervous system disorders | 1 (0.00%) |
| Basedow's disease | Endocrine disorders | 1 (0.00%) |
| Basilar artery thrombosis | Nervous system disorders | 1 (0.00%) |
| B-cell lymphoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| B-cell type acute leukaemia | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Belligerence | Psychiatric disorders | 1 (0.00%) |
| Benign breast neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Beta haemolytic streptococcal infection | Infections and infestations | 1 (0.00%) |
| Bile duct stone | Hepatobiliary disorders | 1 (0.00%) |
| Biliary sepsis | Infections and infestations | 1 (0.00%) |
| Bilirubin urine present | Investigations | 1 (0.00%) |
| Binocular eye movement disorder | Eye disorders | 1 (0.00%) |
| Bipolar disorder | Psychiatric disorders | 1 (0.00%) |
| Bite | Injury, poisoning and procedural complications | 1 (0.00%) |
| Bladder irritation | Renal and urinary disorders | 1 (0.00%) |
| Bleeding time abnormal | Investigations | 1 (0.00%) |
| Blepharochalasis | Eye disorders | 1 (0.00%) |
| Blood creatine increased | Investigations | 1 (0.00%) |
| Blood disorder | Blood and lymphatic system disorders | 1 (0.00%) |
| Blood electrolytes increased | Investigations | 1 (0.00%) |
| Blood fibrinogen increased | Investigations | 1 (0.00%) |
| Blood glucose | Investigations | 1 (0.00%) |
| Blood growth hormone | Investigations | 1 (0.00%) |
| Blood ketone body present | Investigations | 1 (0.00%) |
| Blood lactate dehydrogenase abnormal | Investigations | 1 (0.00%) |
| Blood magnesium decreased | Investigations | 1 (0.00%) |
| Blood potassium abnormal | Investigations | 1 (0.00%) |
| Blood potassium increased | Investigations | 1 (0.00%) |
| Blood pressure orthostatic abnormal | Investigations | 1 (0.00%) |
| Blood pressure orthostatic decreased | Investigations | 1 (0.00%) |
| Blood testosterone decreased | Investigations | 1 (0.00%) |
| Blood testosterone increased | Investigations | 1 (0.00%) |
| Blood triglycerides increased | Investigations | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|-------------------------------------|---|-----------------|
| Blood uric acid increased | Investigations | 1 (0.00%) |
| Blood viscosity increased | Investigations | 1 (0.00%) |
| Body dysmorphic disorder | Psychiatric disorders | 1 (0.00%) |
| Bone contusion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Bone neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Brain natriuretic peptide increased | Investigations | 1 (0.00%) |
| Brain neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Brain stem haemorrhage | Nervous system disorders | 1 (0.00%) |
| Brain stem stroke | Nervous system disorders | 1 (0.00%) |
| Breast milk discolouration | Reproductive system and breast disorders | 1 (0.00%) |
| Breast oedema | Reproductive system and breast disorders | 1 (0.00%) |
| Bronchial hyperreactivity | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bronchial obstruction | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bronchial oedema | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bronchiolitis | Infections and infestations | 1 (0.00%) |
| Bronchitis bacterial | Infections and infestations | 1 (0.00%) |
| Bronchopneumopathy | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bronchopulmonary aspergillosis | Infections and infestations | 1 (0.00%) |
| Bronchostenosis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Bundle branch block | Cardiac disorders | 1 (0.00%) |
| Burn oesophageal | Injury, poisoning and procedural complications | 1 (0.00%) |
| Burn oral cavity | Injury, poisoning and procedural complications | 1 (0.00%) |
| Burns second degree | Injury, poisoning and procedural complications | 1 (0.00%) |
| Bursal fluid accumulation | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Calcium ionised increased | Investigations | 1 (0.00%) |
| Capillary disorder | Vascular disorders | 1 (0.00%) |
| Cardiac aneurysm | Cardiac disorders | 1 (0.00%) |
| Cardiac death | General disorders and administration site conditions | 1 (0.00%) |
| Cardiac failure chronic | Cardiac disorders | 1 (0.00%) |
| Cardiac murmur | Investigations | 1 (0.00%) |
| Cardiac neoplasm unspecified | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Cardiac valve disease | Cardiac disorders | 1 (0.00%) |
| Cardiac valve sclerosis | Cardiac disorders | 1 (0.00%) |
| Cardiomyopathy | Cardiac disorders | 1 (0.00%) |
| Cardio-respiratory distress | Cardiac disorders | 1 (0.00%) |
| Carotid artery dissection | Nervous system disorders | 1 (0.00%) |
| Cataplexy | Nervous system disorders | 1 (0.00%) |
| Catatonias | Psychiatric disorders | 1 (0.00%) |
| Central cord syndrome | Injury, poisoning and procedural complications | 1 (0.00%) |
| Central nervous system stimulation | Surgical and medical procedures | 1 (0.00%) |
| Central vision loss | Eye disorders | 1 (0.00%) |
| Cerebellar ataxia | Nervous system disorders | 1 (0.00%) |
| Cerebellar stroke | Nervous system disorders | 1 (0.00%) |
| Cerebral artery stenosis | Nervous system disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Cerebral atrophy | Nervous system disorders | 1 (0.00%) |
| Cerebral hyperperfusion syndrome | Injury, poisoning and procedural complications | 1 (0.00%) |
| Cervical neuritis | Nervous system disorders | 1 (0.00%) |
| Cervical radiculopathy | Nervous system disorders | 1 (0.00%) |
| Cervix oedema | Reproductive system and breast disorders | 1 (0.00%) |
| Chest crushing | Injury, poisoning and procedural complications | 1 (0.00%) |
| Chest expansion decreased | Investigations | 1 (0.00%) |
| Cheyne-Stokes respiration | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Cholecystitis infective | Infections and infestations | 1 (0.00%) |
| Cholelithiasis | Hepatobiliary disorders | 1 (0.00%) |
| Cholestasis | Hepatobiliary disorders | 1 (0.00%) |
| Cholestatic liver injury | Hepatobiliary disorders | 1 (0.00%) |
| Choluria | Renal and urinary disorders | 1 (0.00%) |
| Chondritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Chorioretinitis | Infections and infestations | 1 (0.00%) |
| Choroiditis | Eye disorders | 1 (0.00%) |
| Chronic inflammatory demyelinating polyradiculoneuropathy | Nervous system disorders | 1 (0.00%) |
| Chronic myeloid leukaemia recurrent | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Chronic spontaneous urticaria | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Ciliary muscle spasm | Eye disorders | 1 (0.00%) |
| Citrobacter infection | Infections and infestations | 1 (0.00%) |
| Claustrophobia | Psychiatric disorders | 1 (0.00%) |
| Clostridium difficile colitis | Infections and infestations | 1 (0.00%) |
| Clostridium difficile infection | Infections and infestations | 1 (0.00%) |
| Coccidioidomycosis | Infections and infestations | 1 (0.00%) |
| Coccydynia | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Cold burn | Injury, poisoning and procedural complications | 1 (0.00%) |
| Colitis microscopic | Gastrointestinal disorders | 1 (0.00%) |
| Colon cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Complement factor C3 decreased | Investigations | 1 (0.00%) |
| Complication associated with device | General disorders and administration site conditions | 1 (0.00%) |
| Computerised tomogram normal | Investigations | 1 (0.00%) |
| Concussion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Congestive cardiomyopathy | Cardiac disorders | 1 (0.00%) |
| Congestive hepatopathy | Hepatobiliary disorders | 1 (0.00%) |
| Conjunctivitis viral | Infections and infestations | 1 (0.00%) |
| Contrast media allergy | Immune system disorders | 1 (0.00%) |
| Contrast media reaction | Immune system disorders | 1 (0.00%) |
| Corneal abrasion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Corneal bleeding | Eye disorders | 1 (0.00%) |
| Corneal disorder | Eye disorders | 1 (0.00%) |
| Corneal graft rejection | Immune system disorders | 1 (0.00%) |
| Corneal infiltrates | Eye disorders | 1 (0.00%) |
| Corneal oedema | Eye disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Coronary artery stenosis | Cardiac disorders | 1 (0.00%) |
| Cor pulmonale | Cardiac disorders | 1 (0.00%) |
| Cortisol decreased | Investigations | 1 (0.00%) |
| COVID-19 immunisation | Surgical and medical procedures | 1 (0.00%) |
| Cranial nerve paralysis | Nervous system disorders | 1 (0.00%) |
| Craniofacial fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| C-reactive protein decreased | Investigations | 1 (0.00%) |
| Creatinine renal clearance decreased | Investigations | 1 (0.00%) |
| Creutzfeldt-Jakob disease | Infections and infestations | 1 (0.00%) |
| Crystal arthropathy | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Crystal urine | Investigations | 1 (0.00%) |
| CSF protein increased | Investigations | 1 (0.00%) |
| CT hypotension complex | Vascular disorders | 1 (0.00%) |
| Culture negative | Investigations | 1 (0.00%) |
| Culture urine positive | Investigations | 1 (0.00%) |
| Cutaneous symptom | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Cystitis klebsiella | Infections and infestations | 1 (0.00%) |
| Cytomegalovirus infection | Infections and infestations | 1 (0.00%) |
| Daydreaming | Psychiatric disorders | 1 (0.00%) |
| Death neonatal | General disorders and administration site conditions | 1 (0.00%) |
| Decreased nasolabial fold | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Decubitus ulcer | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Deficiency of bile secretion | Hepatobiliary disorders | 1 (0.00%) |
| Delusional disorder, unspecified type | Psychiatric disorders | 1 (0.00%) |
| Dementia of the Alzheimer's type, with delirium | Nervous system disorders | 1 (0.00%) |
| Dementia with Lewy bodies | Nervous system disorders | 1 (0.00%) |
| Dental discomfort | Gastrointestinal disorders | 1 (0.00%) |
| Dermatitis acneiform | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Dermatitis diaper | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Device breakage | Product issues | 1 (0.00%) |
| Diabetic diet | Surgical and medical procedures | 1 (0.00%) |
| Diabetic foot infection | Infections and infestations | 1 (0.00%) |
| Diabetic ketosis | Metabolism and nutrition disorders | 1 (0.00%) |
| Diabetic metabolic decompensation | Metabolism and nutrition disorders | 1 (0.00%) |
| Diabetic wound | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Diaphragmalgia | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Diaphragmatic paralysis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Diastolic hypertension | Vascular disorders | 1 (0.00%) |
| Dilatation ventricular | Cardiac disorders | 1 (0.00%) |
| Disinhibition | Psychiatric disorders | 1 (0.00%) |
| Disseminated Bacillus Calmette-Guerin infection | Infections and infestations | 1 (0.00%) |
| Dissociative disorder | Psychiatric disorders | 1 (0.00%) |
| Distractibility | Psychiatric disorders | 1 (0.00%) |
| Diverticulum intestinal | Gastrointestinal disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Dreamy state | Nervous system disorders | 1 (0.00%) |
| Drug intolerance | General disorders and administration site conditions | 1 (0.00%) |
| Drug withdrawal syndrome | General disorders and administration site conditions | 1 (0.00%) |
| Dysaesthesia pharynx | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Dysbiosis | Gastrointestinal disorders | 1 (0.00%) |
| Dyschezia | Gastrointestinal disorders | 1 (0.00%) |
| Dyshidrotic eczema | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Dyslipidaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Dysmetria | Nervous system disorders | 1 (0.00%) |
| Dysmorphism | Congenital, familial and genetic disorders | 1 (0.00%) |
| Dysphoria | Psychiatric disorders | 1 (0.00%) |
| Ear infection bacterial | Infections and infestations | 1 (0.00%) |
| Ear neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Eczema herpeticum | Infections and infestations | 1 (0.00%) |
| Eczema nummular | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Eczema weeping | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Ejection fraction abnormal | Investigations | 1 (0.00%) |
| Electric shock | Injury, poisoning and procedural complications | 1 (0.00%) |
| Electrocardiogram QRS complex prolonged | Investigations | 1 (0.00%) |
| Electrocardiogram ST segment depression | Investigations | 1 (0.00%) |
| Electrocardiogram ST segment elevation | Investigations | 1 (0.00%) |
| Electrocardiogram ST-T change | Investigations | 1 (0.00%) |
| Electrocardiogram T wave inversion | Investigations | 1 (0.00%) |
| Electrocardiogram T wave peaked | Investigations | 1 (0.00%) |
| Electroencephalogram abnormal | Investigations | 1 (0.00%) |
| Embolism arterial | Vascular disorders | 1 (0.00%) |
| Endocarditis | Infections and infestations | 1 (0.00%) |
| Endodontic procedure | Surgical and medical procedures | 1 (0.00%) |
| Endolymphatic hydrops | Ear and labyrinth disorders | 1 (0.00%) |
| Endometriosis | Reproductive system and breast disorders | 1 (0.00%) |
| Enterocolitis | Gastrointestinal disorders | 1 (0.00%) |
| Eosinophilic oesophagitis | Gastrointestinal disorders | 1 (0.00%) |
| Epidermal necrosis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Epididymitis | Infections and infestations | 1 (0.00%) |
| Epiglottitis | Infections and infestations | 1 (0.00%) |
| Epinephrine increased | Investigations | 1 (0.00%) |
| Epiphyses premature fusion | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Epstein-Barr virus test positive | Investigations | 1 (0.00%) |
| Erythema annulare | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Escherichia urinary tract infection | Infections and infestations | 1 (0.00%) |
| Excessive granulation tissue | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Exercise lack of | Social circumstances | 1 (0.00%) |
| Exophthalmos | Eye disorders | 1 (0.00%) |
| External ear cellulitis | Infections and infestations | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| External ear inflammation | Ear and labyrinth disorders | 1 (0.00%) |
| Extradural haematoma | Injury, poisoning and procedural complications | 1 (0.00%) |
| Eye abscess | Infections and infestations | 1 (0.00%) |
| Eye colour change | Eye disorders | 1 (0.00%) |
| Eye complication associated with device | General disorders and administration site conditions | 1 (0.00%) |
| Eyelid exfoliation | Eye disorders | 1 (0.00%) |
| Eyelid haematoma | Eye disorders | 1 (0.00%) |
| Eyelid myoclonus | Eye disorders | 1 (0.00%) |
| Eyelid myokymia | Eye disorders | 1 (0.00%) |
| Eyelid retraction | Eye disorders | 1 (0.00%) |
| Eye opacity | Eye disorders | 1 (0.00%) |
| Face crushing | Injury, poisoning and procedural complications | 1 (0.00%) |
| Facet joint syndrome | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Familial hemiplegic migraine | Congenital, familial and genetic disorders | 1 (0.00%) |
| Fat tissue increased | General disorders and administration site conditions | 1 (0.00%) |
| Fear of death | Psychiatric disorders | 1 (0.00%) |
| Fear of falling | Psychiatric disorders | 1 (0.00%) |
| Febrile neutropenia | Blood and lymphatic system disorders | 1 (0.00%) |
| Femoral artery embolism | Vascular disorders | 1 (0.00%) |
| Fixed eruption | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Flashback | Psychiatric disorders | 1 (0.00%) |
| Fluid imbalance | Metabolism and nutrition disorders | 1 (0.00%) |
| Fluid overload | Metabolism and nutrition disorders | 1 (0.00%) |
| Foetal death | Pregnancy, puerperium and perinatal conditions | 1 (0.00%) |
| Forced expiratory volume increased | Investigations | 1 (0.00%) |
| Foreign body aspiration | Injury, poisoning and procedural complications | 1 (0.00%) |
| Fracture blisters | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Freezing phenomenon | Nervous system disorders | 1 (0.00%) |
| Full blood count abnormal | Investigations | 1 (0.00%) |
| Fungal skin infection | Infections and infestations | 1 (0.00%) |
| Gallbladder polyp | Hepatobiliary disorders | 1 (0.00%) |
| Gastric antral vascular ectasia | Gastrointestinal disorders | 1 (0.00%) |
| Gastric pH decreased | Investigations | 1 (0.00%) |
| Gastric ulcer | Gastrointestinal disorders | 1 (0.00%) |
| Gastric varices haemorrhage | Gastrointestinal disorders | 1 (0.00%) |
| Gastric volvulus | Gastrointestinal disorders | 1 (0.00%) |
| Gastritis bacterial | Infections and infestations | 1 (0.00%) |
| Gastrointestinal hypomotility | Gastrointestinal disorders | 1 (0.00%) |
| Gastrointestinal infection | Infections and infestations | 1 (0.00%) |
| Gastrointestinal inflammation | Gastrointestinal disorders | 1 (0.00%) |
| Gastrointestinal necrosis | Gastrointestinal disorders | 1 (0.00%) |
| Gastrointestinal viral infection | Infections and infestations | 1 (0.00%) |
| Gastrooesophageal sphincter insufficiency | Gastrointestinal disorders | 1 (0.00%) |
| Genital lesion | Reproductive system and breast disorders | 1 (0.00%) |
| Genitourinary symptom | Renal and urinary disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Gingival discolouration | Gastrointestinal disorders | 1 (0.00%) |
| Gingival disorder | Gastrointestinal disorders | 1 (0.00%) |
| Gingival recession | Gastrointestinal disorders | 1 (0.00%) |
| Glare | Eye disorders | 1 (0.00%) |
| Gliososis | Nervous system disorders | 1 (0.00%) |
| Glomerulonephritis | Renal and urinary disorders | 1 (0.00%) |
| Glomerulonephritis minimal lesion | Renal and urinary disorders | 1 (0.00%) |
| Glucose tolerance impaired | Metabolism and nutrition disorders | 1 (0.00%) |
| Good syndrome | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Grip strength | Investigations | 1 (0.00%) |
| Haemarthrosis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Haematoma muscle | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Haemodynamic instability | Vascular disorders | 1 (0.00%) |
| Haemophagocytic lymphohistiocytosis | Immune system disorders | 1 (0.00%) |
| Haemorrhagic diathesis | Blood and lymphatic system disorders | 1 (0.00%) |
| Haemorrhagic infarction | Vascular disorders | 1 (0.00%) |
| Haemorrhagic varicella syndrome | Infections and infestations | 1 (0.00%) |
| Haemothorax | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Hallucination, tactile | Psychiatric disorders | 1 (0.00%) |
| Halo vision | Eye disorders | 1 (0.00%) |
| Hand dermatitis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Haptoglobin increased | Investigations | 1 (0.00%) |
| Head banging | Psychiatric disorders | 1 (0.00%) |
| Heart rate | Investigations | 1 (0.00%) |
| Heart sounds abnormal | Investigations | 1 (0.00%) |
| Heat illness | Injury, poisoning and procedural complications | 1 (0.00%) |
| Heat stroke | Injury, poisoning and procedural complications | 1 (0.00%) |
| Helicobacter infection | Infections and infestations | 1 (0.00%) |
| Helplessness | Psychiatric disorders | 1 (0.00%) |
| Hemianopia heteronymous | Nervous system disorders | 1 (0.00%) |
| Hemihyperaesthesia | Nervous system disorders | 1 (0.00%) |
| Hepatic artery embolism | Hepatobiliary disorders | 1 (0.00%) |
| Hepatic function abnormal | Hepatobiliary disorders | 1 (0.00%) |
| Hepatitis infectious mononucleosis | Infections and infestations | 1 (0.00%) |
| Hepatomegaly | Hepatobiliary disorders | 1 (0.00%) |
| Hereditary haemorrhagic telangiectasia | Congenital, familial and genetic disorders | 1 (0.00%) |
| Herpes dermatitis | Infections and infestations | 1 (0.00%) |
| Herpes zoster meningitis | Infections and infestations | 1 (0.00%) |
| High-pitched crying | General disorders and administration site conditions | 1 (0.00%) |
| Histamine level increased | Investigations | 1 (0.00%) |
| Hoffmann's sign | Nervous system disorders | 1 (0.00%) |
| Hospitalisation | Surgical and medical procedures | 1 (0.00%) |
| Hydronephrosis | Renal and urinary disorders | 1 (0.00%) |
| Hydrophobia | Psychiatric disorders | 1 (0.00%) |
| Hyperbilirubinaemia | Hepatobiliary disorders | 1 (0.00%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Hyperdynamic left ventricle | Cardiac disorders | 1 (0.00%) |
| Hyperfibrinogenaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Hypergeusia | Nervous system disorders | 1 (0.00%) |
| Hyperglycinaemia | Congenital, familial and genetic disorders | 1 (0.00%) |
| Hyperkinesia | Nervous system disorders | 1 (0.00%) |
| Hyperlipidaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hyperphagia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hypersensitivity pneumonitis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Hypersexuality | Psychiatric disorders | 1 (0.00%) |
| Hyperthyroidism | Endocrine disorders | 1 (0.00%) |
| Hypertrophy of tongue papillae | Gastrointestinal disorders | 1 (0.00%) |
| Hypervigilance | Psychiatric disorders | 1 (0.00%) |
| Hypervitaminosis B12 | Metabolism and nutrition disorders | 1 (0.00%) |
| Hypoglossal nerve disorder | Nervous system disorders | 1 (0.00%) |
| Hypokalaemic syndrome | Metabolism and nutrition disorders | 1 (0.00%) |
| Hypomagnesaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hypomenorrhoea | Reproductive system and breast disorders | 1 (0.00%) |
| Hypophosphataemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Hyposomnia | Psychiatric disorders | 1 (0.00%) |
| Illness anxiety disorder | Psychiatric disorders | 1 (0.00%) |
| Illusion | Psychiatric disorders | 1 (0.00%) |
| Immune-mediated arthritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Immunosuppression | Immune system disorders | 1 (0.00%) |
| Impaired gastric emptying | Gastrointestinal disorders | 1 (0.00%) |
| Impaired healing | General disorders and administration site conditions | 1 (0.00%) |
| Impaired quality of life | Social circumstances | 1 (0.00%) |
| Impetigo | Infections and infestations | 1 (0.00%) |
| Impulsive behaviour | Psychiatric disorders | 1 (0.00%) |
| Incision site haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Incision site pain | Injury, poisoning and procedural complications | 1 (0.00%) |
| Increased insulin requirement | Metabolism and nutrition disorders | 1 (0.00%) |
| Increased viscosity of bronchial secretion | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Infected dermal cyst | Infections and infestations | 1 (0.00%) |
| Infected skin ulcer | Infections and infestations | 1 (0.00%) |
| Infection parasitic | Infections and infestations | 1 (0.00%) |
| Infectious mononucleosis | Infections and infestations | 1 (0.00%) |
| Inflammatory bowel disease | Gastrointestinal disorders | 1 (0.00%) |
| Influenza B virus test positive | Investigations | 1 (0.00%) |
| Infusion site bruising | General disorders and administration site conditions | 1 (0.00%) |
| Inguinal mass | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Inhibitory drug interaction | General disorders and administration site conditions | 1 (0.00%) |
| Injection site haemorrhage | General disorders and administration site conditions | 1 (0.00%) |
| Injection site hypersensitivity | General disorders and administration site conditions | 1 (0.00%) |
| Injection site hypoaesthesia | General disorders and administration site conditions | 1 (0.00%) |
| Injection site indentation | General disorders and administration site conditions | 1 (0.00%) |
| Injection site irritation | General disorders and administration site conditions | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|--|-----------------|
| Injection site joint movement impairment | General disorders and administration site conditions | 1 (0.00%) |
| Injection site joint pain | General disorders and administration site conditions | 1 (0.00%) |
| Injection site muscle weakness | General disorders and administration site conditions | 1 (0.00%) |
| Injection site reaction | General disorders and administration site conditions | 1 (0.00%) |
| Injury associated with device | General disorders and administration site conditions | 1 (0.00%) |
| Injury corneal | Injury, poisoning and procedural complications | 1 (0.00%) |
| Inspiratory capacity abnormal | Investigations | 1 (0.00%) |
| Insulin-requiring type 2 diabetes mellitus | Metabolism and nutrition disorders | 1 (0.00%) |
| Intentional dose omission | Injury, poisoning and procedural complications | 1 (0.00%) |
| Intentional overdose | Injury, poisoning and procedural complications | 1 (0.00%) |
| Intentional product misuse | Injury, poisoning and procedural complications | 1 (0.00%) |
| Intentional self-injury | Psychiatric disorders | 1 (0.00%) |
| Interleukin level increased | Investigations | 1 (0.00%) |
| Intervertebral discitis | Infections and infestations | 1 (0.00%) |
| Intestinal dilatation | Gastrointestinal disorders | 1 (0.00%) |
| Intestinal haemorrhage | Gastrointestinal disorders | 1 (0.00%) |
| Intracranial aneurysm | Nervous system disorders | 1 (0.00%) |
| Intracranial haematoma | Nervous system disorders | 1 (0.00%) |
| Intrusive thoughts | Psychiatric disorders | 1 (0.00%) |
| Iron deficiency | Metabolism and nutrition disorders | 1 (0.00%) |
| Iron deficiency anaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Ischaemic cardiomyopathy | Cardiac disorders | 1 (0.00%) |
| Itching scar | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| IVth nerve paresis | Nervous system disorders | 1 (0.00%) |
| Jaw fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Joint ankylosis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Joint contracture | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Jugular vein distension | Vascular disorders | 1 (0.00%) |
| Jugular vein thrombosis | Vascular disorders | 1 (0.00%) |
| Keratic precipitates | Eye disorders | 1 (0.00%) |
| Labile hypertension | Vascular disorders | 1 (0.00%) |
| Laboratory test abnormal | Investigations | 1 (0.00%) |
| Laboratory test normal | Investigations | 1 (0.00%) |
| Lack of vaccination site rotation | Injury, poisoning and procedural complications | 1 (0.00%) |
| Lacunar stroke | Nervous system disorders | 1 (0.00%) |
| Laryngeal disorder | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Laryngeal erythema | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Larynx irritation | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Lateropulsion | Nervous system disorders | 1 (0.00%) |
| Left ventricular dysfunction | Cardiac disorders | 1 (0.00%) |
| Left ventricular hypertrophy | Cardiac disorders | 1 (0.00%) |
| Leukaemoid reaction | Blood and lymphatic system disorders | 1 (0.00%) |
| Leukocyturia | Renal and urinary disorders | 1 (0.00%) |
| Leukoplakia | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Libido decreased | Psychiatric disorders | 1 (0.00%) |
| Lip haemorrhage | Gastrointestinal disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Lipids increased | Investigations | 1 (0.00%) |
| Lip infection | Infections and infestations | 1 (0.00%) |
| Lipodystrophy acquired | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Lip scab | Gastrointestinal disorders | 1 (0.00%) |
| Lip ulceration | Gastrointestinal disorders | 1 (0.00%) |
| Listeriosis | Infections and infestations | 1 (0.00%) |
| Liver disorder | Hepatobiliary disorders | 1 (0.00%) |
| Liver tenderness | Hepatobiliary disorders | 1 (0.00%) |
| Locked-in syndrome | Nervous system disorders | 1 (0.00%) |
| Long thoracic nerve palsy | Nervous system disorders | 1 (0.00%) |
| Loss of bladder sensation | Renal and urinary disorders | 1 (0.00%) |
| Loss of libido | Psychiatric disorders | 1 (0.00%) |
| Loss of proprioception | Nervous system disorders | 1 (0.00%) |
| Low density lipoprotein increased | Investigations | 1 (0.00%) |
| Lumbar puncture abnormal | Investigations | 1 (0.00%) |
| Lung abscess | Infections and infestations | 1 (0.00%) |
| Lung carcinoma cell type unspecified stage I | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Lung consolidation | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Lung neoplasm malignant | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Lymphatic disorder | Blood and lymphatic system disorders | 1 (0.00%) |
| Lymph nodes scan abnormal | Investigations | 1 (0.00%) |
| Lymphocyte count abnormal | Investigations | 1 (0.00%) |
| Lymphocyte percentage decreased | Investigations | 1 (0.00%) |
| Macular rupture | Eye disorders | 1 (0.00%) |
| Maculopathy | Eye disorders | 1 (0.00%) |
| Madarosis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Major depression | Psychiatric disorders | 1 (0.00%) |
| Malignant lymphoid neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Mallory-Weiss syndrome | Gastrointestinal disorders | 1 (0.00%) |
| Marasmus | Metabolism and nutrition disorders | 1 (0.00%) |
| Masticatory pain | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Mastoid disorder | Ear and labyrinth disorders | 1 (0.00%) |
| May-Thurner syndrome | Vascular disorders | 1 (0.00%) |
| Mean cell haemoglobin concentration decreased | Investigations | 1 (0.00%) |
| Mean platelet volume increased | Investigations | 1 (0.00%) |
| Medial tibial stress syndrome | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Medication overuse headache | Nervous system disorders | 1 (0.00%) |
| Melanocytic naevus | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Meningioma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Meningitis bacterial | Infections and infestations | 1 (0.00%) |
| Meningitis herpes | Infections and infestations | 1 (0.00%) |
| Meningitis noninfective | Nervous system disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Mesenteric vein thrombosis | Gastrointestinal disorders | 1 (0.00%) |
| Metastases to meninges | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Microcytic anaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Middle ear inflammation | Ear and labyrinth disorders | 1 (0.00%) |
| Mitral valve disease | Cardiac disorders | 1 (0.00%) |
| Mixed connective tissue disease | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Moaning | General disorders and administration site conditions | 1 (0.00%) |
| Mononucleosis syndrome | Infections and infestations | 1 (0.00%) |
| Mood disorder due to a general medical condition | Psychiatric disorders | 1 (0.00%) |
| Mouth cyst | Gastrointestinal disorders | 1 (0.00%) |
| Mucosal hyperaemia | General disorders and administration site conditions | 1 (0.00%) |
| Mucosal pain | General disorders and administration site conditions | 1 (0.00%) |
| Mucosa vesicle | General disorders and administration site conditions | 1 (0.00%) |
| Multimorbidity | General disorders and administration site conditions | 1 (0.00%) |
| Multiple allergies | Immune system disorders | 1 (0.00%) |
| Multiple injuries | Injury, poisoning and procedural complications | 1 (0.00%) |
| Muscle oedema | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Myasthenia gravis crisis | Nervous system disorders | 1 (0.00%) |
| Myocardial hypoxia | Cardiac disorders | 1 (0.00%) |
| Myocardial necrosis | Cardiac disorders | 1 (0.00%) |
| Myocardial oedema | Cardiac disorders | 1 (0.00%) |
| Myocardial rupture | Cardiac disorders | 1 (0.00%) |
| Myocarditis infectious | Infections and infestations | 1 (0.00%) |
| Myoclonic dystonia | Congenital, familial and genetic disorders | 1 (0.00%) |
| Myopia | Eye disorders | 1 (0.00%) |
| Nasal crusting | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Nasal discharge discolouration | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Neck injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Necrotising fasciitis | Infections and infestations | 1 (0.00%) |
| Negative thoughts | Psychiatric disorders | 1 (0.00%) |
| Neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Nephritis | Renal and urinary disorders | 1 (0.00%) |
| Neurogenic bladder | Renal and urinary disorders | 1 (0.00%) |
| Neurological examination normal | Investigations | 1 (0.00%) |
| Neuromuscular pain | Nervous system disorders | 1 (0.00%) |
| Neuromyopathy | Nervous system disorders | 1 (0.00%) |
| Neuropsychiatric symptoms | Psychiatric disorders | 1 (0.00%) |
| Neurosensory hypoacusis | Ear and labyrinth disorders | 1 (0.00%) |
| Neutrophil count abnormal | Investigations | 1 (0.00%) |
| Neutrophilia | Blood and lymphatic system disorders | 1 (0.00%) |
| Neutrophilic dermatosis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Neutrophil percentage increased | Investigations | 1 (0.00%) |
| Nitrite urine present | Investigations | 1 (0.00%) |
| Nocturnal dyspnoea | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Nodal rhythm | Cardiac disorders | 1 (0.00%) |
| Noninfective chorioretinitis | Eye disorders | 1 (0.00%) |
| Normocytic anaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| N-terminal prohormone brain natriuretic peptide increased | Investigations | 1 (0.00%) |
| Numb chin syndrome | Nervous system disorders | 1 (0.00%) |
| Obliterative bronchiolitis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Obsessive-compulsive symptom | Psychiatric disorders | 1 (0.00%) |
| Obstruction | General disorders and administration site conditions | 1 (0.00%) |
| Obstruction gastric | Gastrointestinal disorders | 1 (0.00%) |
| Oculogyric crisis | Eye disorders | 1 (0.00%) |
| Oedematous pancreatitis | Gastrointestinal disorders | 1 (0.00%) |
| Oesophageal disorder | Gastrointestinal disorders | 1 (0.00%) |
| Oligoarthritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Oligodipsia | Metabolism and nutrition disorders | 1 (0.00%) |
| Oligomenorrhoea | Reproductive system and breast disorders | 1 (0.00%) |
| Oliguria | Renal and urinary disorders | 1 (0.00%) |
| Ophthalmoplegia | Eye disorders | 1 (0.00%) |
| Opisthotonus | Nervous system disorders | 1 (0.00%) |
| Optic ischaemic neuropathy | Eye disorders | 1 (0.00%) |
| Optic nerve disorder | Eye disorders | 1 (0.00%) |
| Oral fungal infection | Infections and infestations | 1 (0.00%) |
| Oral papule | Gastrointestinal disorders | 1 (0.00%) |
| Oral viral infection | Infections and infestations | 1 (0.00%) |
| Orbital oedema | Eye disorders | 1 (0.00%) |
| Organising pneumonia | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Orthostatic heart rate response increased | Investigations | 1 (0.00%) |
| Orthostatic hypertension | Vascular disorders | 1 (0.00%) |
| Orthostatic intolerance | Nervous system disorders | 1 (0.00%) |
| Oscillopsia | Eye disorders | 1 (0.00%) |
| Osteochondritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Osteoporosis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Otitis media acute | Infections and infestations | 1 (0.00%) |
| Ovulation pain | Reproductive system and breast disorders | 1 (0.00%) |
| Oxygen consumption | Investigations | 1 (0.00%) |
| Oxygen saturation | Investigations | 1 (0.00%) |
| Oxygen saturation immeasurable | Investigations | 1 (0.00%) |
| Palatal ulcer | Gastrointestinal disorders | 1 (0.00%) |
| Palmar-plantar erythrodysesthesia syndrome | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Palpable purpura | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pancreatitis necrotising | Gastrointestinal disorders | 1 (0.00%) |
| Pancreatitis relapsing | Gastrointestinal disorders | 1 (0.00%) |
| Paraesthesia mucosal | Nervous system disorders | 1 (0.00%) |
| Paraganglion neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Paranasal sinus inflammation | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Paresis cranial nerve | Nervous system disorders | 1 (0.00%) |
| Pathogen resistance | Infections and infestations | 1 (0.00%) |
| Patient elopement | Nervous system disorders | 1 (0.00%) |
| Peak expiratory flow rate decreased | Investigations | 1 (0.00%) |
| Pelvic discomfort | Reproductive system and breast disorders | 1 (0.00%) |
| Pelvic fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Penile haemorrhage | Reproductive system and breast disorders | 1 (0.00%) |
| Penile swelling | Reproductive system and breast disorders | 1 (0.00%) |
| Pericardial disease | Cardiac disorders | 1 (0.00%) |
| Pericardial haemorrhage | Cardiac disorders | 1 (0.00%) |
| Perineal pain | Reproductive system and breast disorders | 1 (0.00%) |
| Periorbital haematoma | Injury, poisoning and procedural complications | 1 (0.00%) |
| Peripheral artery thrombosis | Vascular disorders | 1 (0.00%) |
| Peripheral embolism | Vascular disorders | 1 (0.00%) |
| Peripheral motor neuropathy | Nervous system disorders | 1 (0.00%) |
| Peripheral nerve paresis | Nervous system disorders | 1 (0.00%) |
| Peripheral sensorimotor neuropathy | Nervous system disorders | 1 (0.00%) |
| Peripheral venous disease | Vascular disorders | 1 (0.00%) |
| Pernio-like erythema | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Peroneal nerve injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Persistent postural-perceptual dizziness | Nervous system disorders | 1 (0.00%) |
| Phaeochromocytoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Pharyngeal enanthema | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Pharyngeal haemorrhage | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Pharyngotonsillitis | Infections and infestations | 1 (0.00%) |
| Phrenic nerve injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| pH urine increased | Investigations | 1 (0.00%) |
| Physical examination abnormal | Investigations | 1 (0.00%) |
| Pigmentation disorder | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pituitary apoplexy | Endocrine disorders | 1 (0.00%) |
| Pityriasis rosea | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Plantar erythema | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Plantar fasciitis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Plasma cell myeloma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Platelet anisocytosis | Blood and lymphatic system disorders | 1 (0.00%) |
| Platelet count abnormal | Investigations | 1 (0.00%) |
| Platelet disorder | Blood and lymphatic system disorders | 1 (0.00%) |
| Pleocytosis | Nervous system disorders | 1 (0.00%) |
| Pneumonia moraxella | Infections and infestations | 1 (0.00%) |
| Pneumonia pneumococcal | Infections and infestations | 1 (0.00%) |
| Pneumonia staphylococcal | Infections and infestations | 1 (0.00%) |
| Pneumonia streptococcal | Infections and infestations | 1 (0.00%) |
| Pneumoperitoneum | Gastrointestinal disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Poisoning | Injury, poisoning and procedural complications | 1 (0.00%) |
| Polychondritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Polycythaemia | Blood and lymphatic system disorders | 1 (0.00%) |
| Poor feeding infant | Metabolism and nutrition disorders | 1 (0.00%) |
| Posterior reversible encephalopathy syndrome | Nervous system disorders | 1 (0.00%) |
| Post laminectomy syndrome | Injury, poisoning and procedural complications | 1 (0.00%) |
| Post lumbar puncture syndrome | Injury, poisoning and procedural complications | 1 (0.00%) |
| Postoperative ileus | Injury, poisoning and procedural complications | 1 (0.00%) |
| Postoperative wound complication | Injury, poisoning and procedural complications | 1 (0.00%) |
| Postprandial hypoglycaemia | Metabolism and nutrition disorders | 1 (0.00%) |
| Post procedural haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Post-traumatic neuralgia | Nervous system disorders | 1 (0.00%) |
| Posturing | Psychiatric disorders | 1 (0.00%) |
| Premature rupture of membranes | Pregnancy, puerperium and perinatal conditions | 1 (0.00%) |
| Primary headache associated with sexual activity | Nervous system disorders | 1 (0.00%) |
| Procedural dizziness | Injury, poisoning and procedural complications | 1 (0.00%) |
| Procedural haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Procedural site reaction | Injury, poisoning and procedural complications | 1 (0.00%) |
| Proctitis ulcerative | Gastrointestinal disorders | 1 (0.00%) |
| Product communication issue | Injury, poisoning and procedural complications | 1 (0.00%) |
| Product confusion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Product deposit | Product issues | 1 (0.00%) |
| Product formulation issue | Product issues | 1 (0.00%) |
| Product lot number issue | Product issues | 1 (0.00%) |
| Product taste abnormal | Product issues | 1 (0.00%) |
| Prolonged expiration | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Prophylaxis of nausea and vomiting | Surgical and medical procedures | 1 (0.00%) |
| Prostatitis | Reproductive system and breast disorders | 1 (0.00%) |
| Protein urine present | Investigations | 1 (0.00%) |
| Prurigo | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pruritus genital | Reproductive system and breast disorders | 1 (0.00%) |
| Pseudodementia | Psychiatric disorders | 1 (0.00%) |
| Pseudolymphoma | Blood and lymphatic system disorders | 1 (0.00%) |
| Psychological factor affecting medical condition | Psychiatric disorders | 1 (0.00%) |
| Psychotic behaviour | Psychiatric disorders | 1 (0.00%) |
| Psychotic disorder due to a general medical condition | Psychiatric disorders | 1 (0.00%) |
| Pulmonary fibrosis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Pulse absent | Investigations | 1 (0.00%) |
| Pulse pressure decreased | Investigations | 1 (0.00%) |
| Pulse waveform abnormal | Investigations | 1 (0.00%) |
| Puncture site bruise | General disorders and administration site conditions | 1 (0.00%) |
| Puncture site discharge | General disorders and administration site conditions | 1 (0.00%) |
| Puncture site swelling | General disorders and administration site conditions | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| Pupillary reflex impaired | Eye disorders | 1 (0.00%) |
| Pustular psoriasis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Pyramidal tract syndrome | Nervous system disorders | 1 (0.00%) |
| Quadrantanopia | Nervous system disorders | 1 (0.00%) |
| Radial pulse abnormal | Investigations | 1 (0.00%) |
| Radiculitis brachial | Nervous system disorders | 1 (0.00%) |
| Rash rubelliform | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Reaction to previous exposure to any vaccine | Injury, poisoning and procedural complications | 1 (0.00%) |
| Reading disorder | Psychiatric disorders | 1 (0.00%) |
| Rectal tenesmus | Gastrointestinal disorders | 1 (0.00%) |
| Red blood cell count increased | Investigations | 1 (0.00%) |
| Red blood cell sedimentation rate abnormal | Investigations | 1 (0.00%) |
| Red blood cells urine positive | Investigations | 1 (0.00%) |
| Red cell distribution width increased | Investigations | 1 (0.00%) |
| Red ear syndrome | Ear and labyrinth disorders | 1 (0.00%) |
| Red man syndrome | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Renal atrophy | Renal and urinary disorders | 1 (0.00%) |
| Renal haemorrhage | Renal and urinary disorders | 1 (0.00%) |
| Repetitive speech | Nervous system disorders | 1 (0.00%) |
| Respiratory tract infection bacterial | Infections and infestations | 1 (0.00%) |
| Resting tremor | Nervous system disorders | 1 (0.00%) |
| Retinal artery occlusion | Eye disorders | 1 (0.00%) |
| Retinal degeneration | Eye disorders | 1 (0.00%) |
| Retinal disorder | Eye disorders | 1 (0.00%) |
| Retinal toxicity | Eye disorders | 1 (0.00%) |
| Retinal vascular thrombosis | Eye disorders | 1 (0.00%) |
| Retinitis | Infections and infestations | 1 (0.00%) |
| Retinopathy | Eye disorders | 1 (0.00%) |
| Reversible airways obstruction | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Reversible cerebral vasoconstriction syndrome | Nervous system disorders | 1 (0.00%) |
| Rheumatic disorder | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Rhinovirus infection | Infections and infestations | 1 (0.00%) |
| Right ventricular dysfunction | Cardiac disorders | 1 (0.00%) |
| Right ventricular enlargement | Cardiac disorders | 1 (0.00%) |
| Right ventricular failure | Cardiac disorders | 1 (0.00%) |
| Rinne tuning fork test abnormal | Investigations | 1 (0.00%) |
| Root canal infection | Infections and infestations | 1 (0.00%) |
| Rubber sensitivity | Immune system disorders | 1 (0.00%) |
| Ruptured cerebral aneurysm | Nervous system disorders | 1 (0.00%) |
| Saliva discolouration | Gastrointestinal disorders | 1 (0.00%) |
| Salivary duct obstruction | Gastrointestinal disorders | 1 (0.00%) |
| Salt craving | Metabolism and nutrition disorders | 1 (0.00%) |
| Sarcoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|---|-----------------|
| SARS-CoV-1 test positive | Investigations | 1 (0.00%) |
| SARS-CoV-2 sepsis | Infections and infestations | 1 (0.00%) |
| SARS-CoV-2 test | Investigations | 1 (0.00%) |
| Scar pain | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Sciatic nerve neuropathy | Nervous system disorders | 1 (0.00%) |
| Scleritis | Eye disorders | 1 (0.00%) |
| Scleroderma associated digital ulcer | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Scrotal disorder | Reproductive system and breast disorders | 1 (0.00%) |
| Scrotal exfoliation | Reproductive system and breast disorders | 1 (0.00%) |
| Scrotal inflammation | Reproductive system and breast disorders | 1 (0.00%) |
| Scrotal swelling | Reproductive system and breast disorders | 1 (0.00%) |
| Second primary malignancy | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Seizure cluster | Nervous system disorders | 1 (0.00%) |
| Self-injurious ideation | Psychiatric disorders | 1 (0.00%) |
| Serositis | General disorders and administration site conditions | 1 (0.00%) |
| Serum sickness-like reaction | Immune system disorders | 1 (0.00%) |
| Shoulder injury related to vaccine administration | General disorders and administration site conditions | 1 (0.00%) |
| Sinonasal obstruction | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Sinus arrest | Cardiac disorders | 1 (0.00%) |
| Sinus arrhythmia | Cardiac disorders | 1 (0.00%) |
| Sinus node dysfunction | Cardiac disorders | 1 (0.00%) |
| Sinus tarsi syndrome | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Sitophobia | Psychiatric disorders | 1 (0.00%) |
| Sitting disability | Social circumstances | 1 (0.00%) |
| Skeletal injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Skin cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Skin depigmentation | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skin discomfort | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skin hypertrophy | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skin indentation | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skin induration | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skin weeping | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Skull fracture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Sleep disorder due to general medical condition, hypersomnia type | Psychiatric disorders | 1 (0.00%) |
| Sleep inertia | Psychiatric disorders | 1 (0.00%) |
| Social avoidant behaviour | Psychiatric disorders | 1 (0.00%) |
| Social fear | Psychiatric disorders | 1 (0.00%) |
| Soft tissue injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Spinal cord injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Spinal fusion surgery | Surgical and medical procedures | 1 (0.00%) |
| Spinal osteoarthritis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Spinal stenosis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Spondylitis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---|--|-----------------|
| Sputum increased | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Sputum purulent | Infections and infestations | 1 (0.00%) |
| Staphylococcal sepsis | Infections and infestations | 1 (0.00%) |
| Staphylococcal skin infection | Infections and infestations | 1 (0.00%) |
| Status asthmaticus | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Stereotypy | Psychiatric disorders | 1 (0.00%) |
| Stertor | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Stiff leg syndrome | Nervous system disorders | 1 (0.00%) |
| Stoma site discharge | Injury, poisoning and procedural complications | 1 (0.00%) |
| Stoma site extravasation | Injury, poisoning and procedural complications | 1 (0.00%) |
| Stoma site pain | Injury, poisoning and procedural complications | 1 (0.00%) |
| Stomatitis haemorrhagic | Gastrointestinal disorders | 1 (0.00%) |
| Strabismus | Eye disorders | 1 (0.00%) |
| Strawberry tongue | Gastrointestinal disorders | 1 (0.00%) |
| Streptococcal bacteraemia | Infections and infestations | 1 (0.00%) |
| Subclavian artery thrombosis | Vascular disorders | 1 (0.00%) |
| Subclavian vein thrombosis | Vascular disorders | 1 (0.00%) |
| Subdural haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Submaxillary gland enlargement | Gastrointestinal disorders | 1 (0.00%) |
| Substance abuse | Psychiatric disorders | 1 (0.00%) |
| Sudden onset of sleep | Nervous system disorders | 1 (0.00%) |
| Superficial injury of eye | Injury, poisoning and procedural complications | 1 (0.00%) |
| Superinfection bacterial | Infections and infestations | 1 (0.00%) |
| Suprapubic pain | General disorders and administration site conditions | 1 (0.00%) |
| Suspected counterfeit product | Product issues | 1 (0.00%) |
| Suture related complication | Injury, poisoning and procedural complications | 1 (0.00%) |
| Swollen joint count increased | Investigations | 1 (0.00%) |
| Symphysisolysis | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Symptom recurrence | General disorders and administration site conditions | 1 (0.00%) |
| Synovial fluid white blood cells positive | Investigations | 1 (0.00%) |
| Synovial rupture | Injury, poisoning and procedural complications | 1 (0.00%) |
| Systemic immune activation | Immune system disorders | 1 (0.00%) |
| Systemic scleroderma | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Takayasu's arteritis | Vascular disorders | 1 (0.00%) |
| Tardive dyskinesia | Nervous system disorders | 1 (0.00%) |
| Temporal lobe epilepsy | Nervous system disorders | 1 (0.00%) |
| Tendon disorder | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Terminal ileitis | Gastrointestinal disorders | 1 (0.00%) |
| Testicular swelling | Reproductive system and breast disorders | 1 (0.00%) |
| Testicular torsion | Reproductive system and breast disorders | 1 (0.00%) |
| Therapeutic product effect increased | General disorders and administration site conditions | 1 (0.00%) |
| Thermohypoaesthesia | Nervous system disorders | 1 (0.00%) |
| Thirst decreased | General disorders and administration site conditions | 1 (0.00%) |
| Thoracic outlet syndrome | Nervous system disorders | 1 (0.00%) |
| Thrombocytosis | Blood and lymphatic system disorders | 1 (0.00%) |

| Preferred Term | System Organ Class (SOC) | Number of Cases |
|--|---|-----------------|
| Thyroid cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Thyroid function test abnormal | Investigations | 1 (0.00%) |
| Thyroid hormones increased | Investigations | 1 (0.00%) |
| Thyroiditis | Endocrine disorders | 1 (0.00%) |
| Thyroid mass | Endocrine disorders | 1 (0.00%) |
| Tongue haemorrhage | Gastrointestinal disorders | 1 (0.00%) |
| Tonsillar ulcer | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Tonsillolith | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Tooth abscess | Infections and infestations | 1 (0.00%) |
| Tooth injury | Injury, poisoning and procedural complications | 1 (0.00%) |
| Torsade de pointes | Cardiac disorders | 1 (0.00%) |
| Toxicity to various agents | Injury, poisoning and procedural complications | 1 (0.00%) |
| Tracheomalacia | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Transcription medication error | Injury, poisoning and procedural complications | 1 (0.00%) |
| Traumatic haemorrhage | Injury, poisoning and procedural complications | 1 (0.00%) |
| Treatment failure | General disorders and administration site conditions | 1 (0.00%) |
| Treatment noncompliance | General disorders and administration site conditions | 1 (0.00%) |
| Trigeminal neuritis | Nervous system disorders | 1 (0.00%) |
| Tri-iodothyronine decreased | Investigations | 1 (0.00%) |
| Troponin I increased | Investigations | 1 (0.00%) |
| Tryptase increased | Investigations | 1 (0.00%) |
| Tuberculin test positive | Investigations | 1 (0.00%) |
| Tumour perforation | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.00%) |
| Tympanic membrane disorder | Ear and labyrinth disorders | 1 (0.00%) |
| Tympanic membrane hyperaemia | Ear and labyrinth disorders | 1 (0.00%) |
| Type II hypersensitivity | Immune system disorders | 1 (0.00%) |
| Type III immune complex mediated reaction | Immune system disorders | 1 (0.00%) |
| Ulnar nerve palsy | Nervous system disorders | 1 (0.00%) |
| Undifferentiated connective tissue disease | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Upper respiratory tract inflammation | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Urethral disorder | Renal and urinary disorders | 1 (0.00%) |
| Urethral haemorrhage | Renal and urinary disorders | 1 (0.00%) |
| Urge incontinence | Renal and urinary disorders | 1 (0.00%) |
| Urinary assistance device user | Social circumstances | 1 (0.00%) |
| Urinary sediment present | Investigations | 1 (0.00%) |
| Urinary tract candidiasis | Infections and infestations | 1 (0.00%) |
| Urinary tract inflammation | Renal and urinary disorders | 1 (0.00%) |
| Urinary tract pain | Renal and urinary disorders | 1 (0.00%) |
| Urticaria cholinergic | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Urticaria chronic | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Urticular vasculitis | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Urticaria pressure | Skin and subcutaneous tissue disorders | 1 (0.00%) |
| Urticaria thermal | Skin and subcutaneous tissue disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|---------------------------------------|--|-----------------|
| Uterine contractions during pregnancy | Pregnancy, puerperium and perinatal conditions | 1 (0.00%) |
| Uterine inflammation | Reproductive system and breast disorders | 1 (0.00%) |
| Uterine pain | Reproductive system and breast disorders | 1 (0.00%) |
| Uvulitis | Gastrointestinal disorders | 1 (0.00%) |
| Vaccination site atrophy | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site dermatitis | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site dryness | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site erosion | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site exfoliation | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site ischaemia | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site joint swelling | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site joint warmth | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site pallor | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site plaque | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site pustule | Infections and infestations | 1 (0.00%) |
| Vaccination site recall reaction | General disorders and administration site conditions | 1 (0.00%) |
| Vaccination site scar | General disorders and administration site conditions | 1 (0.00%) |
| Vaginal disorder | Reproductive system and breast disorders | 1 (0.00%) |
| Vaginal lesion | Reproductive system and breast disorders | 1 (0.00%) |
| Vascular encephalopathy | Nervous system disorders | 1 (0.00%) |
| Vascular rupture | Vascular disorders | 1 (0.00%) |
| Vasomotor rhinitis | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Vasospasm | Vascular disorders | 1 (0.00%) |
| Vein rupture | Vascular disorders | 1 (0.00%) |
| Vena cava embolism | Vascular disorders | 1 (0.00%) |
| Vena cava thrombosis | Vascular disorders | 1 (0.00%) |
| Venous haemorrhage | Vascular disorders | 1 (0.00%) |
| Venous oxygen saturation decreased | Investigations | 1 (0.00%) |
| Vessel puncture site haemorrhage | General disorders and administration site conditions | 1 (0.00%) |
| Vessel puncture site injury | General disorders and administration site conditions | 1 (0.00%) |
| Viral test | Investigations | 1 (0.00%) |
| Viral tonsillitis | Infections and infestations | 1 (0.00%) |
| Virologic failure | Infections and infestations | 1 (0.00%) |
| Visual brightness | Eye disorders | 1 (0.00%) |
| Vital capacity | Investigations | 1 (0.00%) |
| Vital functions abnormal | Investigations | 1 (0.00%) |
| Vitamin B12 decreased | Investigations | 1 (0.00%) |
| Vitamin D decreased | Investigations | 1 (0.00%) |
| Vlth nerve paresis | Nervous system disorders | 1 (0.00%) |
| Vocal cord dysfunction | Respiratory, thoracic and mediastinal disorders | 1 (0.00%) |
| Vocal cord paralysis | Nervous system disorders | 1 (0.00%) |
| Vomiting psychogenic | Psychiatric disorders | 1 (0.00%) |
| Von Willebrand's disease | Congenital, familial and genetic disorders | 1 (0.00%) |
| Vulval abscess | Infections and infestations | 1 (0.00%) |
| Vulvovaginal mycotic infection | Infections and infestations | 1 (0.00%) |
| Vulvovaginal pain | Reproductive system and breast disorders | 1 (0.00%) |

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| Preferred Term | System Organ Class (SOC) | Number of Cases |
|----------------------------------|---|-----------------|
| Vulvovaginal rash | Reproductive system and breast disorders | 1 (0.00%) |
| Wandering pacemaker | Cardiac disorders | 1 (0.00%) |
| Weber tuning fork test abnormal | Investigations | 1 (0.00%) |
| Weight loss diet | Surgical and medical procedures | 1 (0.00%) |
| White blood cells urine positive | Investigations | 1 (0.00%) |
| White coat hypertension | Vascular disorders | 1 (0.00%) |
| White matter lesion | Nervous system disorders | 1 (0.00%) |
| Winged scapula | Musculoskeletal and connective tissue disorders | 1 (0.00%) |
| Withdrawal bleed | Reproductive system and breast disorders | 1 (0.00%) |
| Wound closure | Surgical and medical procedures | 1 (0.00%) |
| Wound secretion | Injury, poisoning and procedural complications | 1 (0.00%) |
| Writer's cramp | Nervous system disorders | 1 (0.00%) |
| Wrong schedule | Injury, poisoning and procedural complications | 1 (0.00%) |

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

PF-07302048 - ALL

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval)

Total Number of Cases with DME 922 (Interval)

Total Number of Adverse Events (PT) (DME only) 1,014 (Interval)

MedDRA Version: v.23.1J

| SOC and PT | Number of Events | Percentage (%) |
|---|------------------|----------------|
| Blood and lymphatic system disorders | 1 | |
| Agranulocytosis | 1 | 0.0 % |
| Cardiac disorders | 1 | |
| Torsade de pointes | 1 | 0.0 % |
| Eye disorders | 1 | |
| Angle closure glaucoma | 1 | 0.0 % |
| Gastrointestinal disorders | 62 | |
| Oedematous pancreatitis | 1 | 0.0 % |
| Pancreatitis | 4 | 0.0 % |
| Pancreatitis acute | 6 | 0.0 % |
| Pancreatitis necrotising | 1 | 0.0 % |
| Tongue oedema | 50 | 0.2 % |
| General disorders and administration site conditions | 70 | |
| Face oedema | 70 | 0.3 % |
| Hepatobiliary disorders | 2 | |
| Hepatic failure | 2 | 0.0 % |

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Multiple adverse event coding to the same Preferred Term (DME) may have been reported in some cases. Counts are provided for the number of unique Preferred Terms Reported.

| | | |
|--|-----|-------|
| Immune system disorders | 476 | |
| Anaphylactic reaction | 361 | 1.5 % |
| Anaphylactic shock | 72 | 0.3 % |
| Anaphylactoid reaction | 14 | 0.1 % |
| Anaphylactoid shock | 2 | 0.0 % |
| Type I hypersensitivity | 27 | 0.1 % |
| Injury, poisoning and procedural complications | 2 | |
| Burn oesophageal | 1 | 0.0 % |
| Contraindicated product administered | 1 | 0.0 % |
| Investigations | 2 | |
| Electrocardiogram QT prolonged | 2 | 0.0 % |
| Metabolism and nutrition disorders | 6 | |
| Hyperkalaemia | 6 | 0.0 % |
| Musculoskeletal and connective tissue disorders | 9 | |
| Myositis | 5 | 0.0 % |
| Rhabdomyolysis | 4 | 0.0 % |
| Psychiatric disorders | 8 | |
| Self-injurious ideation | 1 | 0.0 % |
| Suicidal ideation | 5 | 0.0 % |
| Suicide attempt | 2 | 0.0 % |
| Respiratory, thoracic and mediastinal disorders | 184 | |
| Laryngeal oedema | 60 | 0.3 % |
| Oropharyngeal oedema | 7 | 0.0 % |
| Pharyngeal swelling | 117 | 0.5 % |

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Multiple adverse event coding to the same Preferred Term (DME) may have been reported in some cases. Counts are provided for the number of unique Preferred Terms Reported.

| Skin and subcutaneous tissue disorders | 190 | |
|---|-----|-------|
| Angioedema | 153 | 0.6 % |
| Circumoral swelling | 1 | 0.0 % |
| Dermatitis exfoliative | 2 | 0.0 % |
| Dermatitis exfoliative generalised | 1 | 0.0 % |
| Erythema multiforme | 11 | 0.0 % |
| Skin exfoliation | 14 | 0.1 % |
| Stevens-Johnson syndrome | 5 | 0.0 % |
| Toxic epidermal necrolysis | 3 | 0.0 % |

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Multiple adverse event coding to the same Preferred Term (DME) may have been reported in some cases. Counts are provided for the number of unique Preferred Terms Reported.

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

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval) / 42,086 (Cumulative)

MedDRA Version: v.23.1J

Medically Confirmed

Region : European Countries (27 EU)

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | | | Spontaneous | | | | | |
|------------------------------|---------------------------------------|---|--------------------------|---|-------------------|-----|-------------|-----|---------------|-----|-------------------|------|
| | | | Serious Fatal | | Serious Non Fatal | | Nonserious | | Serious Fatal | | Serious Non Fatal | |
| | | | I | C | I | C | I | C | I | C | I | C |
| AUSTRIA | 199 | 218 | | | | | 52 | 62 | 16 | 23 | 131 | 133 |
| BELGIUM | 135 | 154 | | | | | 11 | 16 | 41 | 48 | 83 | 90 |
| BULGARIA | 40 | 60 | | | | | 31 | 46 | | | 9 | 14 |
| CROATIA | 104 | 118 | | | | | 44 | 54 | 2 | 2 | 58 | 62 |
| CYPRUS | 48 | 57 | | | | | 29 | 33 | | 1 | 19 | 23 |
| CZECH REPUBLIC | 250 | 265 | | | | | 170 | 178 | | | 80 | 87 |
| DENMARK | 353 | 512 | | | | | 208 | 314 | 29 | 41 | 116 | 157 |
| ESTONIA | 45 | 56 | | | | | 33 | 43 | | | 12 | 13 |
| FINLAND | 190 | 205 | | | | | 55 | 64 | 18 | 19 | 117 | 122 |
| FRANCE | 1,205 | 1,310 | | | | | 456 | 523 | 131 | 148 | 618 | 639 |
| GERMANY | 642 | 965 | | | 110 | 111 | 176 | 287 | 106 | 180 | 360 | 498 |
| GREECE | 503 | 618 | | | | | 258 | 339 | 4 | 8 | 241 | 271 |
| HUNGARY | 84 | 144 | | | | | 53 | 105 | 4 | 4 | 27 | 35 |
| IRELAND | 171 | 184 | | | | | 10 | 17 | 7 | 9 | 154 | 158 |
| ITALY | 1,744 | 2,414 | 1 | 1 | 16 | 17 | 277 | 845 | 17 | 29 | 1450 | 1540 |
| LATVIA | 66 | 81 | | | | | 43 | 53 | | | 23 | 28 |
| LITHUANIA | 12 | 16 | | | | | 2 | 6 | 1 | 1 | 9 | 9 |
| LUXEMBOURG | 9 | 10 | | | | | | 1 | 1 | 1 | 8 | 8 |
| MALTA | 20 | 25 | | | | | 11 | 12 | | | 9 | 13 |
| NETHERLANDS | 85 | 92 | | | | | 6 | 11 | 37 | 37 | 42 | 44 |
| POLAND | 208 | 299 | | | | | 90 | 163 | 9 | 9 | 109 | 127 |
| PORTUGAL | 588 | 722 | | | | | 31 | 96 | 4 | 7 | 553 | 619 |
| ROMANIA | 116 | 348 | | | | | 29 | 224 | 1 | 1 | 86 | 123 |
| SLOVAKIA | 40 | 56 | | | | | 25 | 37 | 1 | 1 | 14 | 18 |

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* I=Interval, C=Cumulative

Medically Confirmed

Region : European Countries (27 EU)

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | | | Spontaneous | | | | | |
|------------------------------|---------------------------------------|---|--------------------------|---|-------------------|-----|-------------|------|---------------|-----|-------------------|------|
| | | | Serious Fatal | | Serious Non Fatal | | Nonserious | | Serious Fatal | | Serious Non Fatal | |
| | | | I | C | I | C | I | C | I | C | I | C |
| SLOVENIA | 51 | 57 | | | | | 38 | 42 | 3 | 5 | 10 | 10 |
| SPAIN | 520 | 688 | | | | | 23 | 158 | 19 | 30 | 478 | 500 |
| SWEDEN | 335 | 435 | | | | | 96 | 160 | 52 | 75 | 187 | 200 |
| | 7,763 | 10,109 | 1 | 1 | 126 | 128 | 2257 | 3889 | 503 | 679 | 5003 | 5541 |

Region : European Economic Area (3 EEA)

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Spontaneous | | | | | |
|------------------------------|---------------------------------------|---|-------------|-----|---------------|-----|-------------------|----|
| | | | Nonserious | | Serious Fatal | | Serious Non Fatal | |
| | | | I | C | I | C | I | C |
| ICELAND | 38 | 77 | 25 | 56 | 2 | 9 | 11 | 12 |
| NORWAY | 206 | 258 | 75 | 90 | 64 | 94 | 67 | 74 |
| | 244 | 335 | 100 | 146 | 66 | 103 | 78 | 86 |

Region : Non-European Countries

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | Spontaneous | | | | | |
|-------------------------------|---------------------------------------|---|--------------------------|---|-------------|-----|---------------|----|-------------------|----|
| | | | Serious Non Fatal | | Nonserious | | Serious Fatal | | Serious Non Fatal | |
| | | | I | C | I | C | I | C | I | C |
| AFGHANISTAN | | 1 | | | | | | | | 1 |
| ANGOLA | 2 | 2 | | | 1 | 1 | | | 1 | 1 |
| BERMUDA | | 1 | | | | 1 | | | | |
| CANADA | 98 | 220 | | | 60 | 156 | | | 38 | 64 |
| CHILE | 14 | 37 | | | 12 | 30 | | | 2 | 7 |
| COLOMBIA | | 1 | | | | 1 | | | | |
| COSTA RICA | 19 | 32 | | | 14 | 26 | | | 5 | 6 |
| ECUADOR | 3 | 3 | | | 3 | 3 | | | | |
| FRENCH POLYNESIA | 1 | 1 | | | | | | | 1 | 1 |
| HOLY SEE (VATICAN CITY STATE) | 2 | 2 | | | 2 | 2 | | | | |
| ISRAEL | 52 | 208 | | 1 | 21 | 132 | 2 | 10 | 29 | 66 |
| JAPAN | 1 | 1 | | | | | | | 1 | 1 |
| JORDAN | 2 | 2 | | | 2 | 2 | | | | |
| KUWAIT | 2 | 3 | | | 1 | 2 | | | 1 | 1 |

* I=Interval, C=Cumulative

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Medically Confirmed

Region : Non-European Countries

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | Spontaneous | | | | | |
|--------------------------------------|---------------------------------------|---|--------------------------|----|-------------|------|---------------|-----|-------------------|------|
| | | | Serious Non Fatal | | Nonserious | | Serious Fatal | | Serious Non Fatal | |
| | | | I | C | I | C | I | C | I | C |
| LEBANON | 1 | 1 | | | | | | | 1 | 1 |
| MEXICO | 580 | 629 | | | 143 | 173 | | | 437 | 456 |
| NORTHERN MARIANA ISLANDS | 1 | 1 | | | 1 | 1 | | | | |
| PANAMA | 1 | 1 | | | 1 | 1 | | | | |
| PUERTO RICO | 20 | 47 | | | 19 | 44 | | | 1 | 3 |
| QATAR | 1 | 3 | | | | 1 | | | 1 | 2 |
| SAUDI ARABIA | 4 | 10 | | | 3 | 8 | | | 1 | 2 |
| SERBIA | 12 | 41 | | | 9 | 31 | | | 3 | 10 |
| SINGAPORE | 1 | 8 | | | 1 | 3 | | | | 5 |
| SWITZERLAND | 34 | 47 | | | 8 | 14 | 4 | 9 | 22 | 24 |
| UNITED ARAB EMIRATES | 8 | 10 | | | 7 | 7 | | | 1 | 3 |
| UNITED KINGDOM | 2,555 | 5,843 | 84 | 95 | 362 | 1936 | 66 | 177 | 2127 | 3730 |
| UNITED STATES | 1,756 | 7,552 | | | 1192 | 5774 | 14 | 41 | 550 | 1737 |
| UNITED STATES MINOR OUTLYING ISLANDS | | 2 | | | | 2 | | | | |
| | 5,170 | 14,709 | 84 | 96 | 1862 | 8351 | 86 | 237 | 3222 | 6121 |

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* I=Interval, C=Cumulative

Non Medically Confirmed

Region : European Countries (27 EU)

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Spontaneous | | | | | |
|------------------------------|---------------------------------------|---|-------------|------|---------------|----|-------------------|-----|
| | | | Nonserious | | Serious Fatal | | Serious Non Fatal | |
| | | | I | C | I | C | I | C |
| AUSTRIA | 68 | 70 | 19 | 21 | | | 49 | 49 |
| BELGIUM | 58 | 67 | 2 | 8 | | 2 | 56 | 57 |
| BULGARIA | 9 | 11 | 5 | 7 | | | 4 | 4 |
| CROATIA | 19 | 24 | 13 | 18 | | | 6 | 6 |
| CYPRUS | 5 | 8 | 4 | 6 | | | 1 | 2 |
| CZECH REPUBLIC | 37 | 41 | 14 | 17 | 6 | 6 | 17 | 18 |
| DENMARK | 76 | 98 | 68 | 89 | | | 8 | 9 |
| ESTONIA | 18 | 21 | 14 | 17 | 1 | 1 | 3 | 3 |
| FINLAND | 26 | 31 | 10 | 15 | | | 16 | 16 |
| FRANCE | 190 | 196 | 72 | 75 | 10 | 11 | 108 | 110 |
| GERMANY | 430 | 837 | 260 | 605 | 26 | 36 | 144 | 196 |
| GREECE | 17 | 22 | 8 | 12 | 2 | 3 | 7 | 7 |
| HUNGARY | 40 | 47 | 34 | 41 | | | 6 | 6 |
| IRELAND | 51 | 51 | 5 | 5 | | | 46 | 46 |
| ITALY | 123 | 146 | 39 | 60 | | | 84 | 86 |
| LATVIA | 48 | 53 | 34 | 37 | | | 14 | 16 |
| LITHUANIA | 5 | 11 | 1 | 7 | | | 4 | 4 |
| LUXEMBOURG | 2 | 2 | 1 | 1 | | | 1 | 1 |
| MALTA | 11 | 12 | 7 | 8 | | | 4 | 4 |
| NETHERLANDS | 84 | 88 | 21 | 24 | 8 | 8 | 55 | 56 |
| POLAND | 51 | 89 | 29 | 63 | 5 | 5 | 17 | 21 |
| PORTUGAL | 107 | 144 | 7 | 31 | 1 | 1 | 99 | 112 |
| ROMANIA | 41 | 53 | 10 | 21 | | | 31 | 32 |
| SLOVAKIA | 12 | 20 | 7 | 14 | 1 | 1 | 4 | 5 |
| SLOVENIA | 10 | 11 | 8 | 8 | | | 2 | 3 |
| SPAIN | 43 | 68 | 3 | 23 | 4 | 5 | 36 | 40 |
| SWEDEN | 186 | 213 | 151 | 173 | 4 | 5 | 31 | 35 |
| | 1,767 | 2,434 | 846 | 1406 | 68 | 84 | 853 | 944 |

Region : European Economic Area (3 EEA)

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

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* I=Interval, C=Cumulative

Non Medically Confirmed

Region : European Economic Area (3 EEA)

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Spontaneous | | | | | |
|------------------------------|---------------------------------------|---|-------------|----|---------------|---|-------------------|---|
| | | | Nonserious | | Serious Fatal | | Serious Non Fatal | |
| | | | I | C | I | C | I | C |
| ICELAND | 2 | 4 | 2 | 4 | | | | |
| NORWAY | 34 | 36 | 28 | 30 | 1 | 1 | 5 | 5 |
| | 36 | 40 | 30 | 34 | 1 | 1 | 5 | 5 |

Region : Non-European Countries

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | Spontaneous | | | | | | |
|------------------------------|---------------------------------------|---|--------------------------|---|-------------|------|---------------|----|-------------------|------|--|
| | | | Serious Non Fatal | | Nonserious | | Serious Fatal | | Serious Non Fatal | | |
| | | | I | C | I | C | I | C | I | C | |
| ANDORRA | | 1 | | | | 1 | | | | | |
| BAHRAIN | 2 | 3 | | | | 2 | 3 | | | | |
| CANADA | 23 | 56 | | | 18 | 49 | | 1 | 5 | 6 | |
| CHILE | 3 | 6 | | | | 3 | | | 3 | 3 | |
| COSTA RICA | 7 | 8 | | | 4 | 5 | | | 3 | 3 | |
| GIBRALTAR | 1 | 1 | | | | | | 1 | 1 | | |
| INDIA | | 1 | | | | 1 | | | | | |
| ISRAEL | 140 | 360 | | | 89 | 257 | 3 | 12 | 48 | 91 | |
| JAPAN | 1 | 1 | | | | | | 1 | 1 | | |
| JORDAN | 1 | 1 | | | 1 | 1 | | | | | |
| MEXICO | 5 | 73 | | | 4 | 57 | | | 1 | 16 | |
| NORTHERN MARIANA ISLANDS | 1 | 3 | | | 1 | 3 | | | | | |
| OMAN | 1 | 2 | | | 1 | 2 | | | | | |
| PUERTO RICO | 4 | 9 | | | 4 | 9 | | | | | |
| QATAR | 3 | 4 | | | 2 | 3 | | | 1 | 1 | |
| SAUDI ARABIA | 8 | 10 | | | 5 | 7 | | | 3 | 3 | |
| SERBIA | 10 | 15 | | | 7 | 11 | | | 3 | 4 | |
| SINGAPORE | 2 | 2 | | | 2 | 2 | | | | | |
| SWITZERLAND | 3 | 4 | | | 2 | 3 | | | 1 | 1 | |
| TURKS AND CAICOS ISLANDS | 1 | 1 | | | | | | | 1 | 1 | |
| UNITED ARAB EMIRATES | 10 | 19 | | | 4 | 10 | | | 6 | 9 | |
| UNITED KINGDOM | 5,183 | 7,464 | 1 | 1 | 204 | 689 | 36 | 48 | 4943 | 6727 | |
| UNITED STATES | 2,953 | 6,185 | 2 | 2 | 2127 | 4843 | 36 | 61 | 790 | 1281 | |

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* I=Interval, C=Cumulative

Non Medically Confirmed

Region : Non-European Countries

| Country where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | Spontaneous | | | | | | | |
|--------------------------------------|---------------------------------------|---|--------------------------|---|-------------|------|---------------|-----|-------------------|------|--|--|
| | | | Serious Non Fatal | | Nonserious | | Serious Fatal | | Serious Non Fatal | | | |
| | | | I | C | I | C | I | C | I | C | | |
| UNITED STATES MINOR OUTLYING ISLANDS | 1 | 1 | | | 1 | 1 | | | | | | |
| | 8,363 | 14,230 | 3 | 3 | 2478 | 5960 | 77 | 124 | 5808 | 8146 | | |

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* I=Interval, C=Cumulative

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

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 802 (Interval) / 1,229 (Cumulative)

MedDRA Version: v.23.1J

| Country Where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | Spontaneous | |
|------------------------------|---------------------------------------|---|--------------------------|---|---------------|-----|
| | | | Serious Fatal | | Serious Fatal | |
| | | | I | C | I | C |
| AUSTRIA | 16 | 23 | | | 16 | 23 |
| BELGIUM | 41 | 50 | | | 41 | 50 |
| CANADA | | 1 | | | | 1 |
| CROATIA | 2 | 2 | | | 2 | 2 |
| CYPRUS | | 1 | | | | 1 |
| CZECH REPUBLIC | 6 | 6 | | | 6 | 6 |
| DENMARK | 29 | 41 | | | 29 | 41 |
| ESTONIA | 1 | 1 | | | 1 | 1 |
| FINLAND | 18 | 19 | | | 18 | 19 |
| FRANCE | 141 | 159 | | | 141 | 159 |
| GERMANY | 132 | 216 | | | 132 | 216 |
| GIBRALTAR | 1 | 1 | | | 1 | 1 |
| GREECE | 6 | 11 | | | 6 | 11 |
| HUNGARY | 4 | 4 | | | 4 | 4 |
| ICELAND | 2 | 9 | | | 2 | 9 |
| IRELAND | 7 | 9 | | | 7 | 9 |
| ISRAEL | 5 | 22 | | | 5 | 22 |
| ITALY | 17 | 29 | 1 | 1 | 17 | 29 |
| JAPAN | 1 | 1 | | | 1 | 1 |
| LITHUANIA | 1 | 1 | | | 1 | 1 |
| LUXEMBOURG | 1 | 1 | | | 1 | 1 |
| NETHERLANDS | 45 | 45 | | | 45 | 45 |
| NORWAY | 65 | 95 | | | 65 | 95 |
| POLAND | 14 | 14 | | | 14 | 14 |
| PORTUGAL | 5 | 8 | | | 5 | 8 |

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* I=Interval, C=Cumulative

| Country Where Event Occurred | Interval Total # Spontaneous Cases | Cumulative Total # Spontaneous Cases | Non Interventional Study | | Spontaneous | |
|------------------------------|---------------------------------------|---|--------------------------|---|---------------|------|
| | | | Serious Fatal | | Serious Fatal | |
| | | | I | C | I | C |
| ROMANIA | 1 | 1 | | | 1 | 1 |
| SLOVAKIA | 2 | 2 | | | 2 | 2 |
| SLOVENIA | 3 | 5 | | | 3 | 5 |
| SPAIN | 23 | 35 | | | 23 | 35 |
| SWEDEN | 56 | 80 | | | 56 | 80 |
| SWITZERLAND | 4 | 9 | | | 4 | 9 |
| UNITED KINGDOM | 102 | 225 | | | 102 | 225 |
| UNITED STATES | 50 | 102 | | | 50 | 102 |
| | 801 | 1,228 | 1 | 1 | 801 | 1228 |

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* I=Interval, C=Cumulative

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

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval) / 42,086 (Cumulative)

Total Number of Adverse Events (PT): 91,739 (Interval) / 158,648 (Cumulative)

MedDRA Version: v.23.1J

System Organ Class

Blood and lymphatic system disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Non Interventional Study | | Spontaneous | | | |
|-------------------------------|--|--|--------------------------|---|-------------|------|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Agranulocytosis | 1 | 1 | | | | | 1 | 1 |
| Anaemia | 12 | 12 | | | 5 | 5 | 7 | 7 |
| Anisocytosis | 1 | 1 | | | | | 1 | 1 |
| Antiphospholipid syndrome | 1 | 1 | | | | | 1 | 1 |
| Autoimmune haemolytic anaemia | 4 | 4 | | | | | 4 | 4 |
| Blood disorder | | 1 | | | | 1 | | |
| Coagulopathy | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Eosinophilia | 1 | 3 | | | | 2 | 1 | 1 |
| Febrile neutropenia | | 1 | | | | | | 1 |
| Granulomatous lymphadenitis | 2 | 2 | | | | | 2 | 2 |
| Haemolytic anaemia | 1 | 3 | | | | | 1 | 3 |
| Haemorrhagic diathesis | 1 | 1 | | | | | 1 | 1 |
| Hyperfibrinogenaemia | 1 | 1 | | | | | 1 | 1 |
| Hyperleukocytosis | 5 | 6 | | | | | 5 | 6 |
| Immune thrombocytopenia | 17 | 20 | | | | | 17 | 20 |
| Increased tendency to bruise | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Iron deficiency anaemia | 1 | 1 | | | | | 1 | 1 |
| Leukaemoid reaction | 1 | 1 | | | | | 1 | 1 |
| Leukocytosis | 7 | 14 | | | 2 | 5 | 5 | 9 |
| Leukopenia | 3 | 4 | | | | | 3 | 4 |
| Lymphadenitis | 54 | 70 | | | 21 | 34 | 33 | 36 |
| Lymphadenopathy | 1,096 | 1,967 | 3 | 3 | 463 | 1122 | 633 | 845 |
| Lymphatic disorder | | 1 | | | | 1 | | |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-------------------------------------|--|--|
| Lymph node pain | 207 | 390 |
| Lymphocytosis | 2 | 3 |
| Lymphopenia | 11 | 14 |
| Mast cell activation syndrome | 1 | 2 |
| Microcytic anaemia | 1 | 1 |
| Monocytosis | 2 | 2 |
| Myelosuppression | 3 | 3 |
| Neutropenia | 15 | 16 |
| Neutrophilia | 1 | 1 |
| Normocytic anaemia | 1 | 1 |
| Pancytopenia | 4 | 6 |
| Platelet anisocytosis | 1 | 1 |
| Platelet disorder | 1 | 1 |
| Polycythaemia | 1 | 1 |
| Pseudolymphoma | | 1 |
| Splenomegaly | 4 | 5 |
| Thrombocytopenia | 24 | 33 |
| Thrombocytopenic purpura | 2 | 2 |
| Thrombocytosis | | 1 |
| Thrombotic thrombocytopenic purpura | 1 | 2 |
| | 1,498 | 2,609 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 98 | 241 | 109 | 149 |
| | | 2 | 3 | | |
| | | 4 | 5 | 7 | 9 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 15 | 16 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 4 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | 3 | 4 |
| | | | | 24 | 33 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 3 | 3 | 604 | 1428 |
| | | | | 894 | 1181 |

System Organ Class

Cardiac disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------------|--|--|
| Acute cardiac event | 1 | 2 |
| Acute coronary syndrome | 9 | 13 |
| Acute left ventricular failure | 1 | 1 |
| Acute myocardial infarction | 19 | 41 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | 9 | 13 |
| | | | | 1 | 1 |
| | | | | 19 | 41 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Angina pectoris | 40 | 48 |
| Arrhythmia | 82 | 101 |
| Arrhythmia supraventricular | 3 | 6 |
| Arteriosclerosis coronary artery | | 2 |
| Arteriospasm coronary | | 1 |
| Atrial fibrillation | 92 | 125 |
| Atrial flutter | 8 | 9 |
| Atrial tachycardia | 4 | 4 |
| Atrioventricular block | 3 | 3 |
| Atrioventricular block complete | 6 | 7 |
| Atrioventricular block first degree | 2 | 2 |
| Bradycardia | 55 | 72 |
| Bundle branch block | 1 | 1 |
| Bundle branch block left | 3 | 3 |
| Bundle branch block right | 6 | 7 |
| Cardiac aneurysm | 1 | 1 |
| Cardiac arrest | 42 | 87 |
| Cardiac discomfort | 1 | 2 |
| Cardiac disorder | 10 | 21 |
| Cardiac failure | 60 | 78 |
| Cardiac failure acute | 10 | 11 |
| Cardiac failure chronic | 1 | 1 |
| Cardiac failure congestive | 7 | 11 |
| Cardiac fibrillation | 3 | 4 |
| Cardiac flutter | 20 | 27 |
| Cardiac valve disease | | 1 |
| Cardiac valve sclerosis | | 1 |
| Cardiogenic shock | 6 | 7 |
| Cardiomegaly | 1 | 1 |
| Cardiomyopathy | 1 | 1 |
| Cardiopulmonary failure | 4 | 7 |
| Cardio-respiratory arrest | 14 | 20 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 40 | 48 |
| 1 | 1 | | | 82 | 101 |
| | | | 1 | 3 | 5 |
| | | | | | 2 |
| | | | | | 1 |
| | | | | 92 | 125 |
| | | 1 | 1 | 7 | 8 |
| | | 2 | 2 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 6 | 7 |
| | | 1 | 1 | 1 | 1 |
| 1 | 1 | | | 55 | 72 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 2 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 42 | 87 |
| | | | 1 | 1 | 1 |
| | | 2 | 8 | 8 | 13 |
| | | | | 60 | 78 |
| | | | | 10 | 11 |
| | | | | 1 | 1 |
| | | | | 7 | 11 |
| | | | | 3 | 4 |
| 1 | 1 | | | 20 | 27 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 6 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 7 |
| | | | | 14 | 20 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Cardio-respiratory distress | | 1 |
| Cardiovascular disorder | 32 | 44 |
| Cardiovascular insufficiency | 2 | 3 |
| Congestive cardiomyopathy | 1 | 1 |
| Coronary artery disease | 3 | 6 |
| Coronary artery occlusion | 2 | 2 |
| Coronary artery stenosis | 1 | 1 |
| Cor pulmonale | 1 | 1 |
| Dilatation ventricular | | 1 |
| Extrasystoles | 25 | 32 |
| Hyperdynamic left ventricle | 1 | 1 |
| Intracardiac thrombus | 1 | 2 |
| Ischaemic cardiomyopathy | 1 | 1 |
| Left ventricular dysfunction | 1 | 1 |
| Left ventricular failure | 4 | 4 |
| Left ventricular hypertrophy | 1 | 1 |
| Mitral valve disease | 1 | 1 |
| Myocardial hypoxia | 1 | 1 |
| Myocardial infarction | 55 | 89 |
| Myocardial ischaemia | 4 | 7 |
| Myocardial necrosis | 1 | 1 |
| Myocardial oedema | | 1 |
| Myocardial rupture | | 1 |
| Myocarditis | 20 | 25 |
| Nodal rhythm | | 1 |
| Palpitations | 379 | 694 |
| Pericardial disease | | 1 |
| Pericardial effusion | 4 | 5 |
| Pericardial haemorrhage | | 1 |
| Pericarditis | 23 | 32 |
| Postural orthostatic tachycardia syndrome | 6 | 7 |
| Pulseless electrical activity | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 15 | 21 | 17 | 23 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 6 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 13 | 18 | 12 | 14 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 55 | 89 |
| | | | | 4 | 7 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 20 | 25 |
| | | | 1 | | |
| 4 | 4 | 140 | 339 | 239 | 355 |
| | | | | | 1 |
| | | | | 4 | 5 |
| | | | | | 1 |
| | | | | 23 | 32 |
| | | 1 | 2 | 5 | 5 |
| | | | | 2 | 3 |

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System Organ Class

Cardiac disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------------|--|--|
| Right ventricular dysfunction | | 1 |
| Right ventricular enlargement | | 1 |
| Right ventricular failure | 1 | 1 |
| Sinus arrest | 1 | 1 |
| Sinus arrhythmia | | 1 |
| Sinus bradycardia | 3 | 4 |
| Sinus node dysfunction | 1 | 1 |
| Sinus tachycardia | 32 | 52 |
| Supraventricular extrasystoles | 3 | 4 |
| Supraventricular tachycardia | 18 | 29 |
| Tachyarrhythmia | 10 | 14 |
| Tachycardia | 704 | 1,089 |
| Tachycardia paroxysmal | 2 | 4 |
| Torsade de pointes | 1 | 1 |
| Ventricular arrhythmia | 2 | 2 |
| Ventricular extrasystoles | 19 | 29 |
| Ventricular fibrillation | 5 | 12 |
| Ventricular tachycardia | 7 | 9 |
| Wandering pacemaker | 1 | 1 |
| | 1,898 | 2,957 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | 6 | 16 | 26 | 36 |
| | | 2 | 2 | 1 | 2 |
| | | 2 | 5 | 16 | 24 |
| | | 4 | 4 | 6 | 10 |
| 9 | 9 | 278 | 493 | 426 | 596 |
| | | | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 4 | 10 | 15 | 19 |
| | | | | 5 | 12 |
| | | | | 7 | 9 |
| | | | | 1 | 1 |
| 16 | 16 | 475 | 932 | 1423 | 2025 |

System Organ Class

Congenital, familial and genetic disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Dysmorphism | 1 | 1 |
| Familial hemiplegic migraine | 1 | 1 |
| Hereditary haemorrhagic telangiectasia | 1 | 1 |
| Huntington's disease | | 4 |
| Hyperglycinaemia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 4 |
| | | 1 | 1 |

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System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Macroglossia | 5 | 5 | | | 5 | 5 |
| Myoclonic dystonia | 1 | 1 | | | 1 | 1 |
| Von Willebrand's disease | | 1 | | | | 1 |
| | 10 | 15 | 1 | 1 | 9 | 14 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute vestibular syndrome | 3 | 3 | | | | | 3 | 3 |
| Auditory disorder | 1 | 1 | | | | | 1 | 1 |
| Auricular swelling | 4 | 6 | | | 2 | 3 | 2 | 3 |
| Autophony | 1 | 1 | | | | | 1 | 1 |
| Deafness | 40 | 56 | | | 1 | 1 | 39 | 55 |
| Deafness bilateral | 2 | 3 | | | | | 2 | 3 |
| Deafness neurosensory | 7 | 12 | | | | | 7 | 12 |
| Deafness transitory | 2 | 2 | | | | | 2 | 2 |
| Deafness unilateral | 13 | 18 | | | | | 13 | 18 |
| Ear canal erythema | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Ear congestion | 1 | 4 | | | 1 | 3 | | 1 |
| Ear discomfort | 47 | 80 | | | 32 | 62 | 15 | 18 |
| Ear disorder | 10 | 15 | | | 4 | 8 | 6 | 7 |
| Ear haemorrhage | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Ear pain | 120 | 218 | | | 47 | 124 | 73 | 94 |
| Ear pruritus | 10 | 20 | | | 7 | 16 | 3 | 4 |
| Ear swelling | 10 | 17 | | | 4 | 10 | 6 | 7 |
| Endolymphatic hydrops | 1 | 1 | | | | | 1 | 1 |
| Eustachian tube disorder | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Excessive cerumen production | 2 | 2 | | | 2 | 2 | | |
| External ear inflammation | 1 | 1 | | | 1 | 1 | | |

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System Organ Class

Ear and labyrinth disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------|--|--|
| External ear pain | 2 | 3 |
| Hyperacusis | 11 | 19 |
| Hypoacusis | 34 | 53 |
| Inner ear disorder | 2 | 2 |
| Mastoid disorder | 1 | 1 |
| Meniere's disease | 4 | 4 |
| Middle ear inflammation | | 1 |
| Motion sickness | 5 | 13 |
| Neurosensory hypoacusis | 1 | 1 |
| Paraesthesia ear | 1 | 3 |
| Red ear syndrome | 1 | 1 |
| Sudden hearing loss | 10 | 14 |
| Tinnitus | 140 | 239 |
| Tympanic membrane disorder | 1 | 1 |
| Tympanic membrane hyperaemia | 1 | 1 |
| Vertigo | 327 | 483 |
| Vertigo labyrinthine | 2 | 2 |
| Vertigo positional | 10 | 16 |
| Vestibular disorder | 2 | 3 |
| | 836 | 1,326 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 1 | 1 |
| | | 5 | 10 | 6 | 9 |
| | | 19 | 36 | 15 | 17 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | | 1 |
| | | | 8 | 5 | 5 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 10 | 14 |
| | | 57 | 127 | 83 | 112 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| 2 | 2 | 130 | 236 | 197 | 247 |
| | | | | 2 | 2 |
| | | | 2 | 10 | 14 |
| | | | 1 | 2 | 2 |
| 2 | 2 | 319 | 660 | 517 | 666 |

System Organ Class

Endocrine disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------------|--|--|
| Adrenal disorder | 1 | 1 |
| Adrenocortical insufficiency acute | 3 | 3 |
| Anovulatory cycle | 1 | 1 |
| Autoimmune thyroiditis | 5 | 6 |
| Basedow's disease | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 5 | 6 |
| | | 1 | 1 |

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

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Goitre | 3 | 4 | | | 3 | 4 |
| Hyperthyroidism | 1 | 1 | | | 1 | 1 |
| Hypothyroidism | 3 | 6 | | | 3 | 6 |
| Pituitary apoplexy | 1 | 1 | | | 1 | 1 |
| Thyroid disorder | 2 | 4 | 2 | 4 | | |
| Thyroiditis | 1 | 1 | | | 1 | 1 |
| Thyroid mass | 1 | 1 | 1 | 1 | | |
| Thyroid pain | 2 | 3 | | 1 | 2 | 2 |
| | 25 | 33 | 3 | 6 | 22 | 27 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal sensation in eye | 4 | 12 | | | 1 | 7 | 3 | 5 |
| Accommodation disorder | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Age-related macular degeneration | | 1 | | | | | | 1 |
| Amaurosis fugax | 2 | 2 | | | | | 2 | 2 |
| Amblyopia | | 1 | | | | 1 | | |
| Angle closure glaucoma | 1 | 2 | | | | | 1 | 2 |
| Anterior chamber cell | 1 | 1 | | | | | 1 | 1 |
| Asthenopia | 30 | 45 | | | 9 | 21 | 21 | 24 |
| Autoimmune uveitis | 1 | 1 | | | | | 1 | 1 |
| Binocular eye movement disorder | 1 | 1 | | | | | 1 | 1 |
| Blepharitis | 4 | 5 | | | 3 | 4 | 1 | 1 |
| Blepharochalasis | | 1 | | | | 1 | | |
| Blepharospasm | 8 | 15 | | | 2 | 7 | 6 | 8 |
| Blindness | 26 | 33 | | | | | 26 | 33 |
| Blindness transient | 9 | 10 | | | | | 9 | 10 |
| Blindness unilateral | 4 | 4 | | | | | 4 | 4 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Cataract | 2 | 2 |
| Central vision loss | | 1 |
| Chalazion | 1 | 2 |
| Choroidal neovascularisation | 2 | 2 |
| Choroiditis | 1 | 1 |
| Ciliary muscle spasm | 1 | 1 |
| Conjunctival haemorrhage | 24 | 29 |
| Conjunctival hyperaemia | 3 | 4 |
| Conjunctival irritation | 3 | 4 |
| Conjunctival oedema | 1 | 2 |
| Conjunctivitis allergic | 2 | 4 |
| Corneal bleeding | | 1 |
| Corneal disorder | 1 | 1 |
| Corneal infiltrates | 1 | 1 |
| Corneal oedema | | 1 |
| Diplopia | 31 | 45 |
| Dry eye | 20 | 32 |
| Dyschromatopsia | 2 | 2 |
| Episcleritis | 2 | 7 |
| Erythema of eyelid | 7 | 12 |
| Exophthalmos | | 1 |
| Extraocular muscle paresis | 2 | 2 |
| Eye allergy | 1 | 4 |
| Eye colour change | 1 | 1 |
| Eye discharge | 8 | 11 |
| Eye disorder | 16 | 42 |
| Eye haematoma | 4 | 4 |
| Eye haemorrhage | 14 | 23 |
| Eye inflammation | 3 | 11 |
| Eye irritation | 32 | 69 |
| Eyelid disorder | 1 | 3 |
| Eyelid exfoliation | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 24 | 29 |
| | | 1 | 2 | 2 | 2 |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | 1 | 3 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 5 | 14 | 26 | 31 |
| | | 7 | 17 | 13 | 15 |
| | | 2 | 2 | | |
| | | | 4 | 2 | 3 |
| | | | 5 | 7 | 7 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | 1 | 3 | | 1 |
| | | | | 1 | 1 |
| | | 4 | 7 | 4 | 4 |
| | | 7 | 23 | 9 | 19 |
| | | | | 4 | 4 |
| | | | 1 | 14 | 22 |
| | | 1 | 7 | 2 | 4 |
| 1 | 1 | 18 | 46 | 14 | 23 |
| | | 1 | 3 | | |
| | | | | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Eyelid function disorder | 4 | 6 |
| Eyelid haematoma | 1 | 1 |
| Eyelid irritation | 3 | 6 |
| Eyelid myoclonus | 1 | 1 |
| Eyelid myokymia | 1 | 1 |
| Eyelid oedema | 36 | 41 |
| Eyelid pain | 5 | 8 |
| Eyelid ptosis | 13 | 19 |
| Eyelid rash | 2 | 4 |
| Eyelid retraction | 1 | 1 |
| Eyelid sensory disorder | 1 | 2 |
| Eyelids pruritus | 2 | 8 |
| Eye movement disorder | 7 | 15 |
| Eye oedema | 8 | 13 |
| Eye opacity | 1 | 1 |
| Eye pain | 167 | 282 |
| Eye paraesthesia | | 3 |
| Eye pruritus | 51 | 100 |
| Eye swelling | 88 | 174 |
| Foreign body sensation in eyes | 6 | 8 |
| Gaze palsy | 4 | 4 |
| Glare | | 1 |
| Glaucoma | 3 | 5 |
| Halo vision | 1 | 1 |
| Hypoaesthesia eye | 4 | 9 |
| Iridocyclitis | 3 | 5 |
| Iritis | 1 | 2 |
| Keratic precipitates | 1 | 1 |
| Lacrimation decreased | 2 | 2 |
| Lacrimation increased | 50 | 82 |
| Macular rupture | 1 | 1 |
| Maculopathy | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 4 | 5 |
| | | 1 | 1 | | |
| | | 1 | 4 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 14 | 17 | 22 | 24 |
| | | 2 | 4 | 3 | 4 |
| | | 5 | 8 | 8 | 11 |
| | | 1 | 1 | 1 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 4 | 2 | 4 |
| | | 2 | 4 | 5 | 11 |
| | | 5 | 9 | 3 | 4 |
| | | 1 | 1 | | |
| 1 | 1 | 66 | 139 | 101 | 143 |
| | | | 1 | | 2 |
| 2 | 2 | 26 | 55 | 25 | 45 |
| 1 | 1 | 28 | 85 | 60 | 89 |
| | | 2 | 2 | 4 | 6 |
| | | | | 4 | 4 |
| | | | 1 | | |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | 3 | 6 | 1 | 3 |
| | | | | 3 | 5 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 25 | 44 | 25 | 38 |
| | | | | 1 | 1 |
| | | | | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Metamorphopsia | 3 | 5 |
| Miosis | 5 | 5 |
| Mydriasis | 5 | 7 |
| Myopia | | 1 |
| Noninfective chorioretinitis | 1 | 1 |
| Ocular discomfort | 19 | 32 |
| Ocular hyperaemia | 50 | 90 |
| Oculogyric crisis | 1 | 1 |
| Ophthalmoplegia | 1 | 1 |
| Optic ischaemic neuropathy | 1 | 1 |
| Optic nerve disorder | 1 | 1 |
| Optic neuropathy | 3 | 3 |
| Orbital oedema | 1 | 1 |
| Oscillopsia | | 1 |
| Papilloedema | 2 | 2 |
| Periorbital discomfort | 1 | 2 |
| Periorbital oedema | 13 | 18 |
| Periorbital pain | 2 | 2 |
| Periorbital swelling | 37 | 58 |
| Photophobia | 60 | 117 |
| Photopsia | 24 | 31 |
| Pupil fixed | | 2 |
| Pupillary disorder | 2 | 3 |
| Pupillary reflex impaired | | 1 |
| Pupils unequal | 1 | 3 |
| Retinal artery occlusion | 1 | 1 |
| Retinal degeneration | 1 | 1 |
| Retinal detachment | 2 | 2 |
| Retinal disorder | 1 | 1 |
| Retinal haemorrhage | 2 | 2 |
| Retinal tear | 3 | 3 |
| Retinal toxicity | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 2 | 1 | 3 |
| | | 1 | 1 | 4 | 4 |
| | | 2 | 3 | 3 | 4 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 14 | 24 | 5 | 8 |
| | | 22 | 50 | 28 | 40 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | 4 | 7 | 9 | 11 |
| | | 1 | 1 | 1 | 1 |
| | | 16 | 33 | 21 | 25 |
| | | 19 | 53 | 41 | 64 |
| | | 8 | 14 | 16 | 17 |
| | | | | | 2 |
| | | 1 | 2 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |

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System Organ Class

Eye disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------|--|--|
| Retinal vascular thrombosis | 1 | 1 |
| Retinal vein occlusion | 2 | 2 |
| Retinopathy | 1 | 1 |
| Scleral discolouration | 2 | 2 |
| Scleritis | | 1 |
| Strabismus | 1 | 1 |
| Sudden visual loss | 2 | 2 |
| Swelling of eyelid | 21 | 55 |
| Ulcerative keratitis | 2 | 2 |
| Uveitis | 8 | 9 |
| Vision blurred | 162 | 299 |
| Visual acuity reduced | 5 | 6 |
| Visual brightness | | 1 |
| Visual impairment | 84 | 128 |
| Vitreous detachment | 5 | 5 |
| Vitreous disorder | 2 | 2 |
| Vitreous floaters | 10 | 12 |
| Xanthopsia | 2 | 2 |
| | 1,301 | 2,201 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|-----|---------|------|-----|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | | | 1 | 1 | | |
| | | | | 2 | 2 | | |
| | | | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 | | |
| | | | | | 1 | | |
| | | | | 1 | 1 | | |
| | | | | 2 | 2 | | |
| | | 5 | 33 | 16 | 22 | | |
| | | | | 2 | 2 | | |
| | | | 1 | 8 | 8 | | |
| | | 71 | 161 | 91 | 138 | | |
| | | | 1 | 5 | 5 | | |
| | | | 1 | | | | |
| | | 38 | 63 | 46 | 65 | | |
| | | | | 5 | 5 | | |
| | | | | 2 | 2 | | |
| | | 4 | 6 | 6 | 6 | | |
| | | 1 | 1 | 1 | 1 | | |
| | | 6 | 6 | 460 | 1037 | 841 | 1164 |

System Organ Class

Gastrointestinal disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------|--|--|
| Abdominal adhesions | | 1 |
| Abdominal discomfort | 121 | 211 |
| Abdominal distension | 35 | 59 |
| Abdominal pain | 347 | 538 |
| Abdominal pain lower | 22 | 39 |
| Abdominal pain upper | 326 | 508 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| 2 | 2 | 49 | 122 | 72 | 89 |
| | | 17 | 35 | 18 | 24 |
| 1 | 1 | 168 | 309 | 179 | 229 |
| | | 10 | 21 | 12 | 18 |
| | | 106 | 233 | 220 | 275 |

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

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Abdominal rigidity | 5 | 7 |
| Abdominal symptom | 1 | 1 |
| Abdominal tenderness | 1 | 5 |
| Abdominal wall haematoma | 1 | 1 |
| Abdominal wall haemorrhage | 2 | 2 |
| Abnormal faeces | 8 | 15 |
| Acquired macroglossia | 1 | 1 |
| Acute abdomen | 3 | 3 |
| Aerophagia | | 1 |
| Anaesthesia oral | 7 | 8 |
| Anal haemorrhage | 4 | 6 |
| Anal incontinence | 9 | 12 |
| Anal skin tags | 1 | 1 |
| Anal sphincter atony | 3 | 3 |
| Angular cheilitis | | 1 |
| Anorectal discomfort | 1 | 1 |
| Aphthous ulcer | 13 | 21 |
| Aptyalism | 1 | 2 |
| Ascites | 2 | 3 |
| Atrophic glossitis | 1 | 1 |
| Bowel movement irregularity | 3 | 5 |
| Breath odour | 3 | 6 |
| Chapped lips | 4 | 7 |
| Cheilitis | 7 | 9 |
| Colitis | 5 | 5 |
| Colitis microscopic | 1 | 1 |
| Colitis ulcerative | 3 | 5 |
| Constipation | 27 | 39 |
| Crohn's disease | 9 | 9 |
| Defaecation urgency | 3 | 7 |
| Dental discomfort | 1 | 1 |
| Dental paraesthesia | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | 3 | 4 |
| | | 1 | 1 | | |
| | | | 2 | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 6 | 13 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | 2 | 3 | 5 | 5 |
| | | 1 | 2 | 3 | 4 |
| 1 | 1 | 5 | 7 | 4 | 5 |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 6 | 12 | 7 | 9 |
| | | 1 | 2 | | |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 2 | 4 | 1 | 1 |
| | | 1 | 4 | 2 | 2 |
| | | 1 | 4 | 3 | 3 |
| | | 1 | 2 | 6 | 7 |
| | | 2 | 2 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| | | 12 | 21 | 15 | 18 |
| | | | | 9 | 9 |
| | | 2 | 3 | 1 | 4 |
| | | 1 | 1 | | |
| | | | 2 | | |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Diarrhoea | 1,118 | 1,865 |
| Diarrhoea haemorrhagic | 13 | 15 |
| Discoloured vomit | | 2 |
| Diverticulum intestinal | 1 | 1 |
| Dry mouth | 129 | 236 |
| Duodenogastric reflux | 2 | 2 |
| Dysbiosis | | 1 |
| Dyschezia | 1 | 1 |
| Dyspepsia | 46 | 84 |
| Dysphagia | 178 | 279 |
| Enlarged uvula | 4 | 11 |
| Enteritis | 1 | 2 |
| Enterocolitis | 1 | 1 |
| Eosinophilic oesophagitis | | 1 |
| Epigastric discomfort | 4 | 5 |
| Eructation | 17 | 25 |
| Faecal vomiting | 2 | 2 |
| Faeces discoloured | 11 | 16 |
| Faeces pale | 2 | 4 |
| Faeces soft | 7 | 8 |
| Flatulence | 40 | 55 |
| Food poisoning | 1 | 2 |
| Frequent bowel movements | 9 | 18 |
| Functional gastrointestinal disorder | 1 | 2 |
| Gastric antral vascular ectasia | 1 | 1 |
| Gastric disorder | 14 | 19 |
| Gastric haemorrhage | 3 | 3 |
| Gastric ulcer | 1 | 1 |
| Gastric varices haemorrhage | 1 | 1 |
| Gastric volvulus | 1 | 1 |
| Gastritis | 6 | 14 |
| Gastrointestinal disorder | 23 | 47 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 11 | 11 | 445 | 1002 | 673 | 863 |
| | | | | 13 | 15 |
| | | | 2 | | |
| | | | | 1 | 1 |
| 2 | 2 | 51 | 125 | 78 | 111 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 22 | 57 | 24 | 27 |
| 2 | 2 | 70 | 117 | 108 | 162 |
| | | 1 | 4 | 3 | 7 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | 3 | 3 |
| | | 6 | 9 | 11 | 16 |
| | | | | 2 | 2 |
| | | 8 | 12 | 3 | 4 |
| | | 1 | 2 | 1 | 2 |
| | | 3 | 4 | 4 | 4 |
| 1 | 1 | 17 | 29 | 23 | 26 |
| | | | 1 | 1 | 1 |
| | | 3 | 9 | 6 | 9 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 10 | 13 | 4 | 6 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 7 | 5 | 7 |
| | | 18 | 40 | 5 | 7 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Gastrointestinal haemorrhage | 8 | 9 |
| Gastrointestinal hypermotility | 3 | 4 |
| Gastrointestinal hypomotility | 1 | 1 |
| Gastrointestinal inflammation | 1 | 1 |
| Gastrointestinal motility disorder | 2 | 5 |
| Gastrointestinal necrosis | 1 | 1 |
| Gastrointestinal pain | 23 | 35 |
| Gastrointestinal sounds abnormal | 4 | 7 |
| Gastrooesophageal reflux disease | 23 | 33 |
| Gastrooesophageal sphincter insufficiency | | 1 |
| Gingival bleeding | 2 | 10 |
| Gingival blister | 1 | 4 |
| Gingival discolouration | | 1 |
| Gingival discomfort | 2 | 4 |
| Gingival disorder | | 1 |
| Gingival erythema | 2 | 4 |
| Gingival pain | 9 | 23 |
| Gingival recession | | 1 |
| Gingival swelling | 8 | 15 |
| Gingivitis ulcerative | 1 | 2 |
| Glossitis | | 5 |
| Glossodynia | 36 | 52 |
| Haematemesis | 15 | 25 |
| Haematochezia | 26 | 34 |
| Haemorrhoids | 4 | 5 |
| Hyperaesthesia teeth | 3 | 6 |
| Hyperchlorhydria | 3 | 4 |
| Hypertrophy of tongue papillae | 1 | 1 |
| Hypoaesthesia oral | 146 | 318 |
| Hypoaesthesia teeth | 4 | 5 |
| Ileus paralytic | 2 | 2 |
| Impaired gastric emptying | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 8 | 9 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 4 | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 8 | 16 | 15 | 19 |
| | | 1 | 4 | 3 | 3 |
| | | 11 | 17 | 12 | 16 |
| | | | | | 1 |
| | | 2 | 8 | | 2 |
| | | | 3 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 2 | 3 |
| | | | 1 | | |
| | | 2 | 4 | | |
| | | 3 | 11 | 6 | 12 |
| | | | 1 | | |
| | | 6 | 13 | 2 | 2 |
| | | | | 1 | 2 |
| | | | 4 | | 1 |
| | | 15 | 27 | 21 | 25 |
| | | | | 15 | 25 |
| | | | | 26 | 34 |
| | | 1 | 2 | 3 | 3 |
| | | 2 | 5 | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | 62 | 185 | 84 | 133 |
| | | 4 | 5 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Infantile vomiting | 1 | 3 |
| Inflammatory bowel disease | 1 | 1 |
| Infrequent bowel movements | 1 | 2 |
| Intestinal dilatation | | 1 |
| Intestinal haemorrhage | | 1 |
| Intestinal ischaemia | 3 | 7 |
| Intestinal obstruction | 4 | 5 |
| Intestinal perforation | 2 | 2 |
| Intestinal pseudo-obstruction | 2 | 2 |
| Intussusception | 2 | 2 |
| Irritable bowel syndrome | 8 | 15 |
| Lip blister | 5 | 10 |
| Lip discolouration | 2 | 3 |
| Lip disorder | 3 | 10 |
| Lip dry | 5 | 10 |
| Lip erythema | 2 | 5 |
| Lip exfoliation | 2 | 3 |
| Lip haemorrhage | 1 | 1 |
| Lip oedema | 51 | 76 |
| Lip pain | 6 | 12 |
| Lip pruritus | 18 | 31 |
| Lip scab | 1 | 1 |
| Lip swelling | 155 | 279 |
| Lip ulceration | 1 | 1 |
| Mallory-Weiss syndrome | 1 | 1 |
| Melaena | 8 | 10 |
| Mesenteric vein thrombosis | | 1 |
| Mouth cyst | | 1 |
| Mouth haemorrhage | 7 | 7 |
| Mouth swelling | 26 | 42 |
| Mouth ulceration | 37 | 56 |
| Mucous stools | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 3 | 7 |
| | | | | 4 | 5 |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 5 | 7 | 10 |
| | | 1 | 4 | 4 | 6 |
| | | | | 2 | 3 |
| | | 3 | 9 | | 1 |
| | | 1 | 5 | 4 | 5 |
| | | | 3 | 2 | 2 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 9 | 24 | 42 | 52 |
| | | 5 | 9 | 1 | 3 |
| | | 5 | 16 | 13 | 15 |
| | | | | 1 | 1 |
| | | 37 | 100 | 118 | 179 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 8 | 10 |
| | | | | | 1 |
| | | | 1 | | |
| | | 5 | 5 | 2 | 2 |
| | | 4 | 12 | 22 | 30 |
| | | 11 | 23 | 26 | 33 |
| | | 3 | 4 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Nausea | 2,897 | 5,129 |
| Noninfective gingivitis | 4 | 6 |
| Obstruction gastric | 1 | 1 |
| Odynophagia | 57 | 72 |
| Oedema mouth | 9 | 14 |
| Oedematous pancreatitis | 1 | 1 |
| Oesophageal disorder | 1 | 1 |
| Oesophageal pain | 5 | 7 |
| Oesophageal spasm | 1 | 2 |
| Oesophageal stenosis | 2 | 2 |
| Oral blood blister | 1 | 3 |
| Oral discomfort | 31 | 48 |
| Oral disorder | 9 | 18 |
| Oral dysaesthesia | 3 | 5 |
| Oral mucosa erosion | | 2 |
| Oral mucosal blistering | 6 | 15 |
| Oral mucosal eruption | 1 | 7 |
| Oral mucosal erythema | 3 | 7 |
| Oral mucosal exfoliation | 2 | 2 |
| Oral pain | 34 | 49 |
| Oral papule | | 1 |
| Oral pruritus | 27 | 38 |
| Palatal disorder | 1 | 2 |
| Palatal oedema | 18 | 21 |
| Palatal swelling | 8 | 13 |
| Palatal ulcer | 1 | 1 |
| Pancreatitis | 4 | 7 |
| Pancreatitis acute | 6 | 8 |
| Pancreatitis necrotising | 1 | 1 |
| Pancreatitis relapsing | 1 | 1 |
| Paraesthesia oral | 298 | 586 |
| Parotid gland enlargement | | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 44 | 47 | 1197 | 2760 | 1700 | 2369 |
| | | 2 | 4 | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | 30 | 40 | 27 | 32 |
| | | 1 | 4 | 8 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 3 | 3 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 2 |
| | | 15 | 26 | 16 | 22 |
| | | 7 | 14 | 2 | 4 |
| | | 2 | 3 | 1 | 2 |
| | | | 2 | | |
| | | 4 | 12 | 2 | 3 |
| | | 1 | 7 | | |
| | | 2 | 4 | 1 | 3 |
| | | 2 | 2 | | |
| | | 10 | 19 | 24 | 30 |
| | | | | | 1 |
| | | 6 | 15 | 21 | 23 |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | 17 | 19 |
| | | 1 | 5 | 7 | 8 |
| | | | | 1 | 1 |
| | | | | 4 | 7 |
| | | | | 6 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 3 | 3 | 101 | 302 | 197 | 284 |
| | | | 3 | | |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Plicated tongue | 1 | 3 |
| Pneumoperitoneum | 1 | 1 |
| Proctalgia | 2 | 2 |
| Proctitis ulcerative | | 1 |
| Rectal discharge | 2 | 2 |
| Rectal haemorrhage | 18 | 22 |
| Rectal tenesmus | 1 | 1 |
| Regurgitation | 1 | 2 |
| Retching | 40 | 69 |
| Saliva discolouration | 1 | 1 |
| Salivary duct obstruction | 1 | 1 |
| Salivary gland pain | | 2 |
| Salivary hypersecretion | 15 | 25 |
| Small intestinal haemorrhage | 2 | 2 |
| Small intestinal obstruction | 1 | 3 |
| Stiff tongue | 2 | 4 |
| Stomatitis | 9 | 27 |
| Stomatitis haemorrhagic | 1 | 1 |
| Strawberry tongue | | 1 |
| Subileus | 2 | 2 |
| Submaxillary gland enlargement | | 1 |
| Swollen tongue | 142 | 268 |
| Terminal ileitis | 1 | 1 |
| Tongue blistering | 1 | 2 |
| Tongue coated | 3 | 4 |
| Tongue discolouration | 4 | 7 |
| Tongue discomfort | 20 | 38 |
| Tongue disorder | 17 | 32 |
| Tongue dry | 4 | 10 |
| Tongue eruption | 1 | 4 |
| Tongue erythema | 3 | 8 |
| Tongue haematoma | | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | | | 18 | 22 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | 16 | 36 | 24 | 33 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | 5 | 12 | 10 | 13 |
| | | | | 2 | 2 |
| | | | | 1 | 3 |
| | | | | 2 | 4 |
| 1 | 1 | 5 | 21 | 4 | 6 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 34 | 86 | 108 | 182 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | 3 | 3 |
| | | 1 | 4 | 3 | 3 |
| | | 10 | 26 | 10 | 12 |
| | | 5 | 16 | 12 | 16 |
| | | 1 | 4 | 3 | 6 |
| | | | 1 | 1 | 3 |
| | | | 5 | 3 | 3 |
| | | | 3 | | |

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System Organ Class

Gastrointestinal disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------------|--|--|
| Tongue haemorrhage | | 1 |
| Tongue movement disturbance | 3 | 5 |
| Tongue oedema | 50 | 64 |
| Tongue pruritus | 16 | 31 |
| Tongue spasm | 2 | 2 |
| Tongue ulceration | 3 | 10 |
| Toothache | 22 | 45 |
| Tooth disorder | 2 | 2 |
| Trichoglossia | 2 | 2 |
| Upper gastrointestinal haemorrhage | 4 | 6 |
| Uvulitis | | 1 |
| Volvulus | 3 | 3 |
| Vomiting | 1,028 | 1,689 |
| Vomiting projectile | 11 | 17 |
| | 8,185 | 13,999 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|----|-------------|-----|---------|------|------|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | | 1 | | | | |
| | | 1 | 1 | 2 | 4 | | |
| | | 6 | 10 | 44 | 54 | | |
| | | 2 | 12 | 14 | 19 | | |
| | | | | 2 | 2 | | |
| | | 1 | 6 | 2 | 4 | | |
| | | 14 | 34 | 8 | 11 | | |
| | | 2 | 2 | | | | |
| | | 2 | 2 | | | | |
| | | | | 4 | 6 | | |
| | | | 1 | | | | |
| | | | | 3 | 3 | | |
| 10 | 11 | 391 | 836 | 637 | 853 | | |
| | | 2 | 5 | 9 | 12 | | |
| | | 80 | 84 | 3152 | 7157 | 5033 | 6842 |

System Organ Class

General disorders and administration site conditions

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Administration site joint movement impairment | 1 | 1 |
| Administration site movement impairment | 2 | 2 |
| Administration site pain | 1 | 1 |
| Administration site reaction | | 1 |
| Administration site warmth | 1 | 1 |
| Adverse drug reaction | 4 | 6 |
| Adverse event | 4 | 5 |
| Adverse reaction | 1 | 1 |
| Alcohol interaction | 1 | 2 |
| Apparent death | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 3 | 3 | 3 |
| | | 3 | 4 | 1 | 1 |
| 1 | 1 | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Application site coldness | 2 | 2 |
| Application site hypersensitivity | | 1 |
| Application site pain | 1 | 1 |
| Application site pruritus | 1 | 1 |
| Application site vesicles | 1 | 1 |
| Asthenia | 1,543 | 2,279 |
| Atrophy | | 1 |
| Axillary pain | 184 | 335 |
| Cardiac death | 1 | 1 |
| Chest discomfort | 333 | 610 |
| Chest pain | 471 | 718 |
| Chills | 2,862 | 5,475 |
| Chronic fatigue syndrome | 3 | 4 |
| Complication associated with device | 1 | 1 |
| Concomitant disease aggravated | 1 | 2 |
| Condition aggravated | 137 | 228 |
| Crepitations | 2 | 4 |
| Crying | 31 | 52 |
| Cyst | 1 | 3 |
| Death | 241 | 394 |
| Death neonatal | 1 | 1 |
| Decreased activity | 2 | 3 |
| Discharge | 2 | 2 |
| Discomfort | 135 | 223 |
| Disease progression | 4 | 6 |
| Disease recurrence | 120 | 168 |
| Drowning | 2 | 2 |
| Drug ineffective | 1,029 | 2,196 |
| Drug interaction | 6 | 19 |
| Drug intolerance | 1 | 1 |
| Drug withdrawal syndrome | 1 | 1 |
| Enanthema | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 4 | 4 | 841 | 1438 | 702 | 841 |
| | | | | | 1 |
| | | 92 | 197 | 92 | 138 |
| | | | | 1 | 1 |
| 1 | 1 | 123 | 280 | 210 | 330 |
| 3 | 3 | 155 | 286 | 316 | 432 |
| 31 | 33 | 1494 | 3520 | 1368 | 1955 |
| | | | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | 47 | 102 | 90 | 126 |
| | | | 1 | 2 | 3 |
| | | 17 | 34 | 14 | 18 |
| | | | 2 | 1 | 1 |
| | | | | 241 | 394 |
| | | | | 1 | 1 |
| | | 2 | 3 | | |
| | | 1 | 1 | 1 | 1 |
| 3 | 3 | 73 | 145 | 62 | 78 |
| | | | 1 | 4 | 5 |
| | | 30 | 61 | 90 | 107 |
| | | | | 2 | 2 |
| 3 | 4 | 11 | 31 | 1018 | 2165 |
| | | 3 | 13 | 3 | 6 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Energy increased | 1 | 4 |
| Exercise tolerance decreased | 1 | 2 |
| Extensive swelling of vaccinated limb | 26 | 27 |
| Eye complication associated with device | 1 | 1 |
| Face oedema | 70 | 82 |
| Facial discomfort | 5 | 11 |
| Facial pain | 52 | 98 |
| Fatigue | 4,125 | 7,229 |
| Fat tissue increased | 1 | 1 |
| Feeling abnormal | 396 | 784 |
| Feeling cold | 332 | 578 |
| Feeling drunk | 23 | 43 |
| Feeling hot | 416 | 784 |
| Feeling jittery | 11 | 27 |
| Feeling of body temperature change | 74 | 137 |
| Foaming at mouth | 4 | 5 |
| Gait disturbance | 168 | 255 |
| Gait inability | 51 | 75 |
| Generalised oedema | 5 | 5 |
| General physical health deterioration | 114 | 148 |
| General symptom | 2 | 2 |
| Glassy eyes | 1 | 4 |
| Hangover | 8 | 20 |
| High-pitched crying | 1 | 1 |
| Hunger | 3 | 10 |
| Hyperpyrexia | 162 | 168 |
| Hyperthermia | 37 | 41 |
| Hypothermia | 37 | 45 |
| Idiosyncratic drug reaction | 1 | 2 |
| Ill-defined disorder | 1 | 2 |
| Illness | 255 | 429 |
| Impaired healing | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 4 | | |
| 1 | 1 | 1 | 1 | | 1 |
| | | 9 | 10 | 17 | 17 |
| | | | | 1 | 1 |
| | | 8 | 12 | 62 | 70 |
| | | 4 | 7 | 1 | 4 |
| | | 22 | 53 | 30 | 45 |
| 84 | 91 | 1859 | 4173 | 2266 | 3056 |
| | | 1 | 1 | | |
| 2 | 3 | 226 | 537 | 170 | 247 |
| 1 | 2 | 145 | 317 | 187 | 261 |
| | | 13 | 25 | 10 | 18 |
| 1 | 1 | 198 | 475 | 218 | 309 |
| 1 | 1 | 5 | 18 | 6 | 9 |
| | | 26 | 67 | 48 | 70 |
| | | | 1 | 4 | 4 |
| | | 75 | 136 | 93 | 119 |
| 1 | 1 | 17 | 31 | 34 | 44 |
| | | 1 | 1 | 4 | 4 |
| | | 18 | 22 | 96 | 126 |
| | | | | 2 | 2 |
| | | | 2 | 1 | 2 |
| | | 3 | 12 | 5 | 8 |
| | | 1 | 1 | | |
| | | 1 | 8 | 2 | 2 |
| | | | | 162 | 168 |
| | | 16 | 19 | 21 | 22 |
| | | | | 37 | 45 |
| | | | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| 1 | 1 | 84 | 210 | 171 | 219 |
| | | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Induration | 45 | 50 |
| Inflammation | 93 | 132 |
| Inflammatory pain | 2 | 3 |
| Influenza like illness | 423 | 835 |
| Inhibitory drug interaction | | 1 |
| Injected limb mobility decreased | 22 | 31 |
| Injection site bruising | | 2 |
| Injection site discomfort | 1 | 2 |
| Injection site erythema | 5 | 23 |
| Injection site extravasation | 1 | 4 |
| Injection site haemorrhage | | 1 |
| Injection site hypersensitivity | 1 | 1 |
| Injection site hypoaesthesia | | 1 |
| Injection site indentation | 1 | 1 |
| Injection site inflammation | 1 | 2 |
| Injection site irritation | 1 | 1 |
| Injection site joint movement impairment | 1 | 1 |
| Injection site joint pain | | 1 |
| Injection site mass | | 4 |
| Injection site muscle weakness | | 1 |
| Injection site pain | 27 | 103 |
| Injection site pruritus | 2 | 6 |
| Injection site rash | 4 | 9 |
| Injection site reaction | | 1 |
| Injection site swelling | 2 | 14 |
| Injection site urticaria | 3 | 4 |
| Injection site warmth | 5 | 9 |
| Injury associated with device | | 1 |
| Irritability postvaccinal | 2 | 4 |
| Localised oedema | 28 | 33 |
| Local reaction | 43 | 59 |
| Loss of control of legs | 5 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 39 | 42 | 6 | 8 |
| | | 53 | 78 | 40 | 54 |
| | | | 1 | 2 | 2 |
| | | 153 | 445 | 270 | 390 |
| | | | 1 | | |
| | | 9 | 16 | 13 | 15 |
| | | | 2 | | |
| | | 1 | 2 | | |
| | | 5 | 23 | | |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 4 | | |
| | | | 1 | | |
| | | 14 | 83 | 13 | 20 |
| | | 1 | 5 | 1 | 1 |
| | | 1 | 6 | 3 | 3 |
| | | | 1 | | |
| | | 2 | 14 | | |
| | | 2 | 3 | 1 | 1 |
| | | 4 | 8 | 1 | 1 |
| | | | 1 | | |
| | | 2 | 4 | | |
| | | 8 | 13 | 20 | 20 |
| | | 30 | 41 | 13 | 18 |
| | | | | 5 | 5 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Malaise | 1,635 | 2,834 |
| Mass | 10 | 17 |
| Moaning | 1 | 1 |
| Mucosal disorder | 2 | 4 |
| Mucosal dryness | 2 | 4 |
| Mucosal hyperaemia | 1 | 1 |
| Mucosal pain | 1 | 1 |
| Mucosa vesicle | 1 | 1 |
| Multimorbidity | | 1 |
| Multi-organ disorder | 1 | 2 |
| Multiple organ dysfunction syndrome | 12 | 18 |
| Necrosis | 2 | 2 |
| No adverse event | 31 | 42 |
| Nodule | 56 | 62 |
| Non-cardiac chest pain | 4 | 4 |
| Obstruction | 1 | 1 |
| Oedema | 102 | 121 |
| Oedema mucosal | 4 | 5 |
| Oedema peripheral | 53 | 68 |
| Pain | 1,817 | 3,681 |
| Performance status decreased | 1 | 2 |
| Peripheral swelling | 345 | 645 |
| Physical deconditioning | 1 | 2 |
| Pre-existing condition improved | | 3 |
| Puncture site bruise | 1 | 1 |
| Puncture site discharge | 1 | 1 |
| Puncture site swelling | | 1 |
| Pyrexia | 4,230 | 7,618 |
| Screaming | 2 | 4 |
| Secretion discharge | 5 | 8 |
| Sensation of blood flow | 4 | 4 |
| Sensation of foreign body | 54 | 89 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 54 | 55 | 683 | 1502 | 952 | 1332 |
| | | 9 | 15 | 1 | 2 |
| | | | 2 | 2 | 2 |
| | | 1 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 12 | 18 |
| | | | | 2 | 2 |
| | | 31 | 42 | | |
| | | 49 | 54 | 7 | 8 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 70 | 85 | 32 | 36 |
| | | 1 | 1 | 3 | 4 |
| | | 20 | 29 | 33 | 39 |
| 9 | 9 | 1062 | 2600 | 755 | 1081 |
| | | | 1 | 1 | 1 |
| 1 | 1 | 133 | 345 | 212 | 300 |
| | | | 1 | 1 | 1 |
| | | | 3 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| 36 | 41 | 1821 | 4278 | 2409 | 3340 |
| | | 1 | 2 | 1 | 2 |
| | | 3 | 5 | 2 | 3 |
| | | | | 4 | 4 |
| | | 15 | 34 | 39 | 55 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Sense of oppression | 4 | 5 |
| Sensitivity to weather change | 2 | 2 |
| Serositis | | 1 |
| Shoulder injury related to vaccine administration | 1 | 1 |
| Sluggishness | 9 | 16 |
| Sudden cardiac death | 2 | 4 |
| Sudden death | 72 | 108 |
| Suprapubic pain | 1 | 1 |
| Swelling | 240 | 459 |
| Swelling face | 227 | 396 |
| Symptom recurrence | | 1 |
| Systemic inflammatory response syndrome | 2 | 6 |
| Temperature intolerance | 8 | 9 |
| Temperature regulation disorder | 12 | 17 |
| Tenderness | 34 | 75 |
| Terminal state | 2 | 2 |
| Therapeutic product effect increased | 1 | 1 |
| Therapeutic response unexpected | 26 | 40 |
| Thirst | 48 | 88 |
| Thirst decreased | 1 | 1 |
| Treatment noncompliance | 1 | 1 |
| Ulcer | 2 | 3 |
| Vaccination site atrophy | 1 | 1 |
| Vaccination site bruising | 46 | 95 |
| Vaccination site coldness | 5 | 8 |
| Vaccination site dermatitis | | 1 |
| Vaccination site discharge | 1 | 4 |
| Vaccination site discolouration | 14 | 29 |
| Vaccination site discomfort | 30 | 79 |
| Vaccination site dryness | 1 | 1 |
| Vaccination site dysaesthesia | 2 | 2 |
| Vaccination site erosion | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 8 | 15 | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 72 | 108 |
| | | 1 | 1 | | |
| 1 | 1 | 94 | 259 | 146 | 200 |
| 4 | 4 | 78 | 179 | 149 | 217 |
| | | | 1 | | |
| | | | | 2 | 6 |
| | | 7 | 8 | 1 | 1 |
| | | 6 | 9 | 6 | 8 |
| 2 | 2 | 19 | 53 | 15 | 22 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 22 | 35 | 4 | 5 |
| 1 | 1 | 19 | 48 | 29 | 40 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | 1 | 27 | 61 | 19 | 34 |
| | | 4 | 7 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | 8 | 19 | 6 | 10 |
| | | 17 | 59 | 13 | 20 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Vaccination site erythema | 470 | 929 |
| Vaccination site exfoliation | 1 | 1 |
| Vaccination site extravasation | 3 | 7 |
| Vaccination site haematoma | 26 | 32 |
| Vaccination site haemorrhage | 31 | 51 |
| Vaccination site hyperaesthesia | 7 | 13 |
| Vaccination site hypersensitivity | 40 | 44 |
| Vaccination site hypoaesthesia | 22 | 47 |
| Vaccination site induration | 64 | 122 |
| Vaccination site inflammation | 59 | 98 |
| Vaccination site injury | 1 | 2 |
| Vaccination site irritation | 7 | 11 |
| Vaccination site ischaemia | 1 | 1 |
| Vaccination site joint erythema | 7 | 8 |
| Vaccination site joint inflammation | 2 | 2 |
| Vaccination site joint movement impairment | 15 | 36 |
| Vaccination site joint pain | 6 | 18 |
| Vaccination site joint swelling | | 1 |
| Vaccination site joint warmth | | 1 |
| Vaccination site lymphadenopathy | 26 | 38 |
| Vaccination site macule | 1 | 7 |
| Vaccination site mass | 85 | 151 |
| Vaccination site movement impairment | 60 | 132 |
| Vaccination site necrosis | 3 | 3 |
| Vaccination site nodule | 12 | 28 |
| Vaccination site oedema | 90 | 114 |
| Vaccination site pain | 2,503 | 5,096 |
| Vaccination site pallor | | 1 |
| Vaccination site papule | 4 | 5 |
| Vaccination site paraesthesia | 50 | 85 |
| Vaccination site plaque | | 1 |
| Vaccination site pruritus | 165 | 332 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 281 | 667 | 189 | 262 |
| | | | | 1 | 1 |
| | | 3 | 7 | | |
| | | 15 | 19 | 11 | 13 |
| | | 21 | 38 | 10 | 13 |
| | | 3 | 9 | 4 | 4 |
| | | 37 | 41 | 3 | 3 |
| | | 12 | 32 | 10 | 15 |
| | | 42 | 95 | 22 | 27 |
| 1 | 1 | 36 | 65 | 23 | 33 |
| | | 1 | 2 | | |
| | | 2 | 5 | 5 | 6 |
| | | | | 1 | 1 |
| | | 2 | 3 | 5 | 5 |
| | | | | 2 | 2 |
| | | 12 | 24 | 3 | 12 |
| | | 5 | 11 | 1 | 7 |
| | | | 1 | | |
| | | | 1 | | |
| | | 17 | 27 | 9 | 11 |
| | | 1 | 7 | | |
| | | 37 | 85 | 48 | 66 |
| 1 | 1 | 38 | 97 | 22 | 35 |
| | | | | 3 | 3 |
| | | 8 | 24 | 4 | 4 |
| | | 48 | 66 | 42 | 48 |
| 59 | 63 | 1632 | 3839 | 871 | 1257 |
| | | | 1 | | |
| | | 2 | 3 | 2 | 2 |
| | | 32 | 59 | 18 | 26 |
| | | | 1 | | |
| | | 104 | 248 | 61 | 84 |

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System Organ Class

General disorders and administration site conditions

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|----------------------------------|--|--|
| Vaccination site rash | 60 | 126 |
| Vaccination site reaction | 96 | 139 |
| Vaccination site recall reaction | 1 | 1 |
| Vaccination site scab | 2 | 5 |
| Vaccination site scar | 1 | 1 |
| Vaccination site swelling | 450 | 897 |
| Vaccination site thrombosis | 2 | 2 |
| Vaccination site ulcer | | 2 |
| Vaccination site urticaria | 18 | 52 |
| Vaccination site vesicles | 7 | 19 |
| Vaccination site warmth | 206 | 409 |
| Vessel puncture site haemorrhage | | 1 |
| Vessel puncture site injury | | 1 |
| | 28,020 | 50,903 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|-------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 37 | 89 | 23 | 37 |
| | | 45 | 80 | 51 | 59 |
| | | 1 | 1 | | |
| | | 1 | 4 | 1 | 1 |
| | | | | 1 | 1 |
| 12 | 12 | 260 | 620 | 190 | 277 |
| | | | | 2 | 2 |
| | | | 1 | | 1 |
| | | 10 | 41 | 8 | 11 |
| | | 4 | 13 | 3 | 6 |
| 1 | 1 | 120 | 279 | 86 | 130 |
| | | | 1 | | |
| | | | 1 | | |
| | | 321 | 344 | 13053 | 29464 |
| | | | | 14967 | 21439 |

System Organ Class

Hepatobiliary disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------|--|--|
| Acute hepatic failure | | 1 |
| Bile duct stone | | 1 |
| Cholecystitis | 1 | 2 |
| Cholelithiasis | | 1 |
| Cholestasis | 1 | 1 |
| Cholestatic liver injury | 1 | 1 |
| Deficiency of bile secretion | 1 | 1 |
| Gal bladder disorder | 1 | 3 |
| Gal bladder polyp | | 1 |
| Hepatic artery embolism | | 1 |
| Hepatic cirrhosis | 1 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | | 1 |
| | | 1 | 2 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | 1 |
| | 1 | | |
| | | | 1 |
| | | 1 | 2 |

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System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hepatic failure | 2 | 2 | | | 2 | 2 |
| Hepatic function abnormal | 1 | 1 | 1 | 1 | | |
| Hepatic pain | 7 | 9 | 4 | 5 | 3 | 4 |
| Hepatitis | 4 | 6 | | | 4 | 6 |
| Hepatitis acute | 5 | 5 | | | 5 | 5 |
| Hepatitis cholestatic | 2 | 2 | | | 2 | 2 |
| Hepatocellular injury | 3 | 3 | | | 3 | 3 |
| Hepatomegaly | 1 | 1 | | | 1 | 1 |
| Hyperbilirubinaemia | 1 | 1 | | | 1 | 1 |
| Hypertransaminasaemia | 3 | 3 | | | 3 | 3 |
| Jaundice | 6 | 11 | 1 | 5 | 5 | 6 |
| Liver disorder | 1 | 1 | 1 | 1 | | |
| Liver injury | 2 | 5 | | | 2 | 5 |
| Liver tenderness | 1 | 1 | 1 | 1 | | |
| | 45 | 66 | 9 | 17 | 36 | 49 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Allergic oedema | 1 | 3 | | | | 1 | 1 | 2 |
| Allergic reaction to excipient | 3 | 3 | | | | | 3 | 3 |
| Allergy to arthropod sting | 1 | 1 | | | 1 | 1 | | |
| Allergy to chemicals | | 1 | | | | 1 | | |
| Allergy to vaccine | 54 | 125 | | | 23 | 63 | 31 | 62 |
| Amyloidosis | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 361 | 588 | | | 1 | 3 | 360 | 585 |
| Anaphylactic shock | 71 | 106 | 1 | 1 | | 1 | 71 | 105 |
| Anaphylactoid reaction | 14 | 26 | | | | | 14 | 26 |
| Anaphylactoid shock | 2 | 2 | | | | | 2 | 2 |

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* AE=Adverse Event

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Autoimmune disorder | 7 | 11 |
| Bacille Calmette-Guerin scar reactivation | 2 | 2 |
| Contrast media allergy | | 1 |
| Contrast media reaction | 1 | 1 |
| Corneal graft rejection | 1 | 1 |
| Decreased immune responsiveness | 2 | 2 |
| Drug hypersensitivity | 26 | 43 |
| Food allergy | 2 | 3 |
| Haemophagocytic lymphohistiocytosis | 1 | 1 |
| Hypersensitivity | 369 | 591 |
| Immune-mediated adverse reaction | 1 | 2 |
| Immune system disorder | 8 | 14 |
| Immunisation reaction | 2 | 3 |
| Immunodeficiency | 3 | 5 |
| Immunosuppression | 1 | 1 |
| Multiple allergies | 1 | 1 |
| Reaction to excipient | 5 | 9 |
| Reaction to preservatives | 2 | 3 |
| Rubber sensitivity | | 1 |
| Sarcoidosis | 2 | 2 |
| Seasonal allergy | 5 | 9 |
| Sensitisation | 2 | 3 |
| Serum sickness | 2 | 3 |
| Serum sickness-like reaction | 1 | 1 |
| Systemic immune activation | 1 | 1 |
| Type I hypersensitivity | 27 | 29 |
| Type II hypersensitivity | 1 | 1 |
| Type III immune complex mediated reaction | | 1 |
| Type IV hypersensitivity reaction | 7 | 13 |
| | 990 | 1,614 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 7 | 11 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 9 | 22 | 17 | 21 |
| | | 1 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| 5 | 5 | 115 | 235 | 254 | 356 |
| | | | 1 | 1 | 1 |
| | | 3 | 6 | 5 | 8 |
| | | | 1 | 2 | 2 |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 3 | 5 | 6 |
| | | | 1 | 2 | 3 |
| | | | | 2 | 2 |
| | | 2 | 6 | 3 | 3 |
| | | 2 | 3 | | |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 27 | 29 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 4 | 8 | 3 | 5 |
| 6 | 6 | 164 | 362 | 826 | 1252 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abscess | 2 | 4 | | | 1 | 1 | 1 | 3 |
| Abscess oral | 2 | 2 | | | | | 2 | 2 |
| Acarodermatitis | 1 | 2 | | | | 1 | 1 | 1 |
| Aerococcus urinae infection | 1 | 1 | | | | | 1 | 1 |
| African trypanosomiasis | | 1 | | | | | | 1 |
| Appendicitis | 7 | 14 | 1 | 1 | | | 7 | 14 |
| Arthritis bacterial | 1 | 1 | | | | | 1 | 1 |
| Asymptomatic COVID-19 | 22 | 31 | | | 2 | 2 | 20 | 29 |
| Atypical pneumonia | 1 | 2 | | | | | 1 | 2 |
| Bacteraemia | | 1 | | | | | | 1 |
| Bacterial diarrhoea | 1 | 1 | | | | | 1 | 1 |
| Bacterial infection | 2 | 3 | | | | | 2 | 3 |
| Bacterial rhinitis | 1 | 1 | | | | | 1 | 1 |
| Bacterial sepsis | 1 | 1 | | | | | 1 | 1 |
| Beta haemolytic streptococcal infection | 1 | 1 | | | | | 1 | 1 |
| Biliary sepsis | | 1 | | | | | | 1 |
| Breast abscess | 1 | 2 | | | | | 1 | 2 |
| Bronchiolitis | 1 | 1 | | | | | 1 | 1 |
| Bronchitis | 11 | 18 | | | 3 | 7 | 8 | 11 |
| Bronchitis bacterial | | 1 | | | | | | 1 |
| Bronchopulmonary aspergillosis | 1 | 1 | | | | | 1 | 1 |
| Candida infection | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Cellulitis | 58 | 81 | | | | | 58 | 81 |
| Cholecystitis infective | | 1 | | | | | | 1 |
| Chorioretinitis | 1 | 1 | | | | | 1 | 1 |
| Citrobacter infection | 1 | 1 | | | | | 1 | 1 |
| Clostridium difficile colitis | | 1 | | | | | | 1 |
| Clostridium difficile infection | 1 | 1 | | | | | 1 | 1 |
| Coccidioidomycosis | 1 | 1 | | | | | 1 | 1 |
| Conjunctivitis | 25 | 34 | | | 12 | 17 | 13 | 17 |
| Conjunctivitis bacterial | 2 | 2 | | | | | 2 | 2 |
| Conjunctivitis viral | | 1 | | | | 1 | | |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Coronavirus infection | 10 | 13 |
| COVID-19 | 1,087 | 1,918 |
| COVID-19 pneumonia | 37 | 50 |
| Creutzfeldt-Jakob disease | 1 | 1 |
| Cystitis | 14 | 17 |
| Cystitis klebsiella | 1 | 1 |
| Cytomegalovirus infection | 1 | 1 |
| Dermo-hypodermatitis | 2 | 2 |
| Diabetic foot infection | 1 | 1 |
| Disseminated Bacillus Calmette-Guerin infection | 1 | 1 |
| Disseminated varicella zoster virus infection | 1 | 2 |
| Diverticulitis | 9 | 9 |
| Dysentery | 101 | 101 |
| Ear infection | 15 | 21 |
| Ear infection bacterial | 1 | 1 |
| Eczema herpeticum | 1 | 1 |
| Encephalitis | 16 | 16 |
| Endocarditis | 1 | 1 |
| Epididymitis | 1 | 1 |
| Epiglottitis | 1 | 1 |
| Epstein-Barr virus infection | 2 | 2 |
| Erysipelas | 8 | 9 |
| Escherichia infection | 2 | 3 |
| Escherichia sepsis | 1 | 2 |
| Escherichia urinary tract infection | 1 | 1 |
| External ear cellulitis | 1 | 1 |
| Eye abscess | 1 | 1 |
| Eye infection | 4 | 7 |
| Febrile infection | | 2 |
| Folliculitis | 2 | 4 |
| Fungal infection | 2 | 5 |
| Fungal skin infection | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 3 | 7 | 10 |
| 4 | 5 | 126 | 174 | 961 | 1744 |
| | | | | 37 | 50 |
| | | | | 1 | 1 |
| | | 6 | 7 | 8 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 9 | 9 |
| 1 | 1 | | | 101 | 101 |
| | | 6 | 10 | 9 | 11 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 16 | 16 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 8 | 9 |
| | | | | 2 | 3 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 2 | 3 |
| | | | | | 2 |
| | | 2 | 3 | | 1 |
| | | 2 | 5 | | |
| | | | | 1 | 1 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Furuncle | 4 | 6 |
| Gastritis bacterial | 1 | 1 |
| Gastroenteritis | 12 | 17 |
| Gastroenteritis viral | 2 | 6 |
| Gastrointestinal infection | 1 | 1 |
| Gastrointestinal viral infection | | 1 |
| Genital herpes | 1 | 3 |
| Gingivitis | 3 | 4 |
| Gonorrhoea | 2 | 2 |
| Haemorrhagic varicella syndrome | 1 | 1 |
| Helicobacter infection | 1 | 1 |
| Hepatitis infectious mononucleosis | 1 | 1 |
| Herpes dermatitis | 1 | 1 |
| Herpes ophthalmic | 6 | 6 |
| Herpes simplex | 8 | 13 |
| Herpes simplex reactivation | 2 | 2 |
| Herpes virus infection | 7 | 17 |
| Herpes zoster | 178 | 258 |
| Herpes zoster cutaneous disseminated | 2 | 2 |
| Herpes zoster infection neurological | 2 | 2 |
| Herpes zoster meningitis | 1 | 1 |
| Herpes zoster oticus | 3 | 4 |
| Herpes zoster reactivation | 5 | 6 |
| Hordeolum | 2 | 8 |
| Impetigo | 1 | 1 |
| Infected dermal cyst | 1 | 1 |
| Infected skin ulcer | 1 | 1 |
| Infection | 33 | 50 |
| Infection parasitic | | 1 |
| Infectious mononucleosis | 1 | 1 |
| Infective exacerbation of chronic obstructive airways disease | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 3 | 3 |
| | | | | 1 | 1 |
| | | 2 | 4 | 10 | 13 |
| | | 1 | 3 | 1 | 3 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | | 1 |
| | | 3 | 4 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 6 |
| | | 3 | 7 | 5 | 6 |
| | | 2 | 2 | | |
| | | 3 | 12 | 4 | 5 |
| | | 55 | 120 | 123 | 138 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | 1 | 1 | 4 | 5 |
| | | | 5 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 6 | 10 | 27 | 40 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 3 |

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System Organ Class

Infections and infestations

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------------|--|--|
| Influenza | 198 | 290 |
| Intervertebral discitis | 1 | 1 |
| Kidney infection | 7 | 8 |
| Labyrinthitis | 8 | 13 |
| Laryngitis | 5 | 7 |
| Lip infection | | 1 |
| Listeriosis | 1 | 1 |
| Localised infection | 5 | 9 |
| Lower respiratory tract infection | 24 | 37 |
| Lung abscess | 1 | 1 |
| Lymphangitis | 9 | 10 |
| Lymph gland infection | 1 | 2 |
| Mastitis | 6 | 10 |
| Meningitis | 2 | 3 |
| Meningitis aseptic | 2 | 2 |
| Meningitis bacterial | 1 | 1 |
| Meningitis herpes | 1 | 1 |
| Meningitis viral | 2 | 4 |
| Mononucleosis syndrome | 1 | 1 |
| Myelitis | 8 | 9 |
| Myocarditis infectious | 1 | 1 |
| Nasopharyngitis | 149 | 272 |
| Necrotising fasciitis | 1 | 1 |
| Ophthalmic herpes simplex | 3 | 3 |
| Ophthalmic herpes zoster | 10 | 10 |
| Oral candidiasis | 6 | 11 |
| Oral fungal infection | 1 | 1 |
| Oral herpes | 48 | 78 |
| Oral viral infection | | 1 |
| Orchitis | 2 | 3 |
| Otitis externa | 2 | 3 |
| Otitis media | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 51 | 110 | 147 | 180 |
| | | | | 1 | 1 |
| | | | | 7 | 8 |
| | | | 1 | 8 | 12 |
| | | 2 | 4 | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 5 | 2 | 4 |
| | | | | 24 | 37 |
| | | | | 1 | 1 |
| | | | | 9 | 10 |
| | | 1 | 2 | | |
| | | | | 6 | 10 |
| | | | | 2 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | | 8 | 9 |
| | | | | 1 | 1 |
| 1 | 1 | 82 | 183 | 67 | 89 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 10 | 10 |
| | | 2 | 6 | 4 | 5 |
| | | 1 | 1 | | |
| | | 23 | 48 | 25 | 30 |
| | | | 1 | | |
| | | | 1 | 2 | 2 |
| | | 1 | 2 | 1 | 1 |
| | | | 2 | | |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Otitis media acute | 1 | 1 |
| Parotitis | 4 | 8 |
| Pathogen resistance | | 1 |
| Periorbital cellulitis | 2 | 2 |
| Pertussis | 2 | 3 |
| Pharyngitis | 9 | 15 |
| Pharyngitis streptococcal | 2 | 5 |
| Pharyngotonsillitis | 1 | 1 |
| Pneumonia | 107 | 145 |
| Pneumonia bacterial | 3 | 4 |
| Pneumonia moraxella | 1 | 1 |
| Pneumonia pneumococcal | 1 | 1 |
| Pneumonia staphylococcal | 1 | 1 |
| Pneumonia streptococcal | 1 | 1 |
| Post viral fatigue syndrome | 1 | 4 |
| Pulmonary sepsis | 1 | 2 |
| Pulpitis dental | 2 | 4 |
| Pustule | 6 | 10 |
| Pyelonephritis | 3 | 4 |
| Q fever | 10 | 11 |
| Rash pustular | 5 | 8 |
| Respiratory tract infection | 13 | 17 |
| Respiratory tract infection bacterial | 1 | 1 |
| Retinitis | 1 | 1 |
| Rhinitis | 26 | 38 |
| Rhinovirus infection | | 1 |
| Root canal infection | 1 | 1 |
| SARS-CoV-2 sepsis | 1 | 1 |
| Sepsis | 23 | 38 |
| Septic shock | 6 | 8 |
| Severe acute respiratory syndrome | 1 | 2 |
| Sialoadenitis | 5 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 1 | 3 | 3 | 5 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 3 |
| | | 3 | 8 | 6 | 7 |
| | | 2 | 3 | | 2 |
| | | | | 1 | 1 |
| | | | | 107 | 145 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 3 |
| | | | | 1 | 2 |
| | | 1 | 3 | 1 | 1 |
| 1 | 1 | 3 | 5 | 3 | 5 |
| | | | | 3 | 4 |
| | | | | 10 | 11 |
| | | 2 | 4 | 3 | 4 |
| | | | | 13 | 17 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 12 | 22 | 14 | 16 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 22 | 37 |
| | | | | 6 | 8 |
| | | | | 1 | 2 |
| | | | | 5 | 5 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Sinusitis | 19 | 39 |
| Soft tissue infection | 3 | 3 |
| Sputum purulent | | 1 |
| Staphylococcal infection | 1 | 2 |
| Staphylococcal sepsis | | 1 |
| Staphylococcal skin infection | | 1 |
| Streptococcal bacteraemia | 1 | 1 |
| Streptococcal infection | 1 | 2 |
| Subcutaneous abscess | 4 | 4 |
| Superinfection bacterial | 1 | 1 |
| Suspected COVID-19 | 142 | 270 |
| Sweating fever | 23 | 34 |
| Tonsillitis | 4 | 11 |
| Tonsillitis bacterial | 1 | 2 |
| Tooth abscess | 1 | 1 |
| Tooth infection | 2 | 3 |
| Tracheitis | 3 | 3 |
| Tuberculosis | | 2 |
| Upper respiratory tract infection | 8 | 13 |
| Urinary tract candidiasis | 1 | 1 |
| Urinary tract infection | 63 | 81 |
| Urinary tract infection bacterial | 6 | 7 |
| Urosepsis | 4 | 7 |
| Vaccination site abscess | 5 | 6 |
| Vaccination site cellulitis | 19 | 34 |
| Vaccination site infection | 6 | 16 |
| Vaccination site pustule | 1 | 1 |
| Vaginal infection | | 2 |
| Varicella | 1 | 4 |
| Varicella zoster virus infection | 1 | 2 |
| Vestibular neuronitis | 5 | 7 |
| Viral infection | 11 | 14 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 11 | 29 | 8 | 10 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 32 | 43 | 110 | 227 |
| | | | | 23 | 34 |
| | | 2 | 4 | 2 | 7 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | 2 | 2 | 1 | 1 |
| | | | | | 2 |
| | | 5 | 9 | 3 | 4 |
| | | | | 1 | 1 |
| | | 21 | 32 | 42 | 49 |
| | | | | 6 | 7 |
| | | | | 4 | 7 |
| | | 2 | 2 | 3 | 4 |
| | | 4 | 9 | 15 | 25 |
| | | 1 | 8 | 5 | 8 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | | 3 | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 5 | 7 |
| | | 5 | 8 | 6 | 6 |

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System Organ Class

Infections and infestations

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Viral labyrinthitis | 1 | 2 |
| Viral pharyngitis | 3 | 4 |
| Viral rash | 3 | 7 |
| Viral tonsillitis | | 1 |
| Viral upper respiratory tract infection | 1 | 2 |
| Virologic failure | 1 | 1 |
| Vulval abscess | 1 | 1 |
| Vulvovaginal candidiasis | 3 | 5 |
| Vulvovaginal mycotic infection | | 1 |
| | 2,857 | 4,578 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | | | 3 | 4 |
| | | 1 | 3 | 2 | 4 |
| | | | | | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 4 |
| | | | 1 | | |
| 9 | 10 | 535 | 1003 | 2322 | 3575 |

System Organ Class

Injury, poisoning and procedural complications

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------------|--|--|
| Accidental exposure to product | 14 | 30 |
| Accidental overdose | 10 | 53 |
| Accidental underdose | 1 | 3 |
| Airway burns | 1 | 1 |
| Animal bite | | 1 |
| Arthropod bite | 1 | 5 |
| Arthropod sting | 1 | 1 |
| Atypical femur fracture | 1 | 1 |
| Back injury | 2 | 3 |
| Barotrauma | 1 | 1 |
| Bite | | 1 |
| Bone contusion | 1 | 1 |
| Booster dose missed | | 2 |
| Brachial plexus injury | 2 | 2 |
| Burn oesophageal | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 14 | 29 | | 1 |
| | | 8 | 47 | 2 | 6 |
| | | 1 | 3 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 5 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Burn oral cavity | | 1 |
| Burns second degree | 1 | 1 |
| Cartilage injury | 2 | 3 |
| Central cord syndrome | 1 | 1 |
| Cerebral hyperperfusion syndrome | 1 | 1 |
| Chest crushing | 1 | 1 |
| Chest injury | 2 | 2 |
| Chillblains | 4 | 7 |
| Circumstance or information capable of leading to medication error | 31 | 144 |
| Cold burn | 1 | 1 |
| Concussion | 1 | 1 |
| Contraindicated product administered | 1 | 5 |
| Contusion | 71 | 111 |
| Corneal abrasion | 1 | 1 |
| Craniofacial fracture | 1 | 1 |
| Dental restoration failure | | 2 |
| Electric shock | 1 | 1 |
| Epicondylitis | 2 | 4 |
| Expired product administered | 2 | 5 |
| Exposure during pregnancy | 28 | 55 |
| Exposure to SARS-CoV-2 | 17 | 60 |
| Exposure via breast milk | 31 | 133 |
| Exposure via eye contact | | 2 |
| Exposure via skin contact | 13 | 27 |
| Extradural haematoma | 1 | 1 |
| Eye contusion | 2 | 9 |
| Eye injury | 12 | 13 |
| Face crushing | | 1 |
| Face injury | 4 | 8 |
| Facial bones fracture | 2 | 2 |
| Fall | 140 | 202 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 2 | 4 | 2 | 3 |
| | | 31 | 144 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 4 | | 1 |
| | | 39 | 67 | 32 | 44 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | 2 | 2 | 2 |
| | | 2 | 5 | | |
| | | 24 | 50 | 4 | 5 |
| | 1 | 13 | 45 | 4 | 15 |
| | | 28 | 130 | 3 | 3 |
| | | | 2 | | |
| | | 13 | 26 | | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | 5 | 2 | 4 |
| | | 7 | 7 | 5 | 6 |
| | | | | | 1 |
| | | 2 | 5 | 2 | 3 |
| | | | | 2 | 2 |
| | | 48 | 73 | 92 | 129 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Femoral neck fracture | 1 | 2 |
| Femur fracture | 2 | 2 |
| Foreign body aspiration | | 1 |
| Foreign body in throat | 2 | 2 |
| Fracture | 2 | 3 |
| Frostbite | 2 | 3 |
| Gastrointestinal stoma complication | 1 | 2 |
| Head injury | 23 | 40 |
| Heat illness | | 1 |
| Heat oedema | 1 | 2 |
| Heat stroke | | 1 |
| Hip fracture | 2 | 3 |
| Inappropriate schedule of product administration | 200 | 528 |
| Incision site haemorrhage | | 1 |
| Incision site pain | | 1 |
| Incomplete course of vaccination | 11 | 22 |
| Incorrect dosage administered | 5 | 5 |
| Incorrect dose administered | 13 | 38 |
| Incorrect route of product administration | 99 | 218 |
| Infusion related reaction | 2 | 2 |
| Injection related reaction | 6 | 8 |
| Injury | 1 | 3 |
| Injury corneal | | 1 |
| Intentional dose omission | | 1 |
| Intentional overdose | 1 | 1 |
| Intentional product misuse | | 1 |
| Intercepted medication error | 1 | 2 |
| Intercepted product preparation error | 1 | 2 |
| Jaw fracture | 1 | 1 |
| Joint dislocation | 3 | 5 |
| Joint injury | 4 | 5 |
| Lack of vaccination site rotation | | |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 3 |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | 5 | 13 | 18 | 27 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 3 |
| | | 198 | 526 | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | 11 | 22 | | |
| | | 5 | 5 | | |
| | | 11 | 35 | 2 | 3 |
| | | 95 | 210 | 4 | 8 |
| | | | | 2 | 2 |
| | | | 1 | 6 | 7 |
| | | | 2 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| | | 2 | 3 | 2 | 2 |
| 1 | 1 | | | | |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Ligament injury | | 2 |
| Ligament sprain | 2 | 4 |
| Limb injury | 9 | 15 |
| Lip injury | | 2 |
| Lower limb fracture | 1 | 2 |
| Maternal exposure during breast feeding | 1 | 2 |
| Maternal exposure during pregnancy | 74 | 189 |
| Maternal exposure timing unspecified | 2 | 8 |
| Medication error | 3 | 6 |
| Mouth injury | 2 | 2 |
| Multiple injuries | 1 | 1 |
| Muscle rupture | 2 | 2 |
| Muscle strain | 6 | 11 |
| Nasal injury | | 2 |
| Neck injury | | 1 |
| Nerve injury | 6 | 8 |
| Occupational exposure to product | 4 | 9 |
| Occupational exposure to SARS-CoV-2 | 3 | 11 |
| Off label use | 508 | 880 |
| Overdose | 67 | 142 |
| Pelvic fracture | | 1 |
| Periorbital haematoma | 1 | 1 |
| Peripheral nerve injury | 2 | 2 |
| Peroneal nerve injury | | 1 |
| Phrenic nerve injury | 1 | 1 |
| Poisoning | | 1 |
| Poor quality product administered | 297 | 577 |
| Post laminectomy syndrome | 1 | 1 |
| Post lumbar puncture syndrome | | 1 |
| Postoperative ileus | | 1 |
| Postoperative wound complication | 1 | 1 |
| Post procedural complication | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | | |
| | | 1 | 2 | 1 | 2 |
| | | 6 | 11 | 3 | 4 |
| | | | 1 | | 1 |
| | | | | 1 | 2 |
| | | 1 | 2 | | |
| | | 66 | 178 | 8 | 11 |
| | | 2 | 8 | | |
| | | 3 | 6 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 1 | 1 | 3 | 6 | 3 | 5 |
| | | | 2 | | |
| | | | 1 | | |
| | | 2 | 4 | 4 | 4 |
| | | 4 | 9 | | |
| | | 2 | 9 | 1 | 2 |
| | | 498 | 865 | 10 | 15 |
| | | 65 | 139 | 2 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 296 | 576 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Post procedural haemorrhage | | 1 |
| Procedural dizziness | 1 | 1 |
| Procedural haemorrhage | 1 | 1 |
| Procedural nausea | 2 | 3 |
| Procedural pain | | 3 |
| Procedural site reaction | 1 | 1 |
| Product administered at inappropriate site | 23 | 72 |
| Product administered to patient of inappropriate age | 38 | 56 |
| Product administration error | 6 | 19 |
| Product communication issue | 1 | 1 |
| Product confusion | | 1 |
| Product dose omission issue | 4 | 6 |
| Product label confusion | | 5 |
| Product preparation error | 114 | 222 |
| Product preparation issue | 37 | 137 |
| Product prescribing error | 2 | 7 |
| Product storage error | 4 | 4 |
| Product use issue | 474 | 828 |
| Reaction to previous exposure to any vaccine | 1 | 1 |
| Rib fracture | 1 | 2 |
| Road traffic accident | 3 | 3 |
| Scar | 2 | 4 |
| Scratch | 5 | 10 |
| Skeletal injury | 1 | 1 |
| Skin abrasion | 5 | 6 |
| Skin injury | | 3 |
| Skin laceration | 5 | 9 |
| Skull fracture | 1 | 1 |
| Soft tissue injury | 1 | 1 |
| Spinal cord injury | 1 | 1 |
| Stoma site discharge | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 2 | | 1 |
| | | | | 1 | 1 |
| | | 22 | 68 | 1 | 4 |
| | | 35 | 52 | 3 | 4 |
| | | 3 | 16 | 3 | 3 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 3 | 5 | 1 | 1 |
| | | | 5 | | |
| | | 114 | 221 | | 1 |
| | | 35 | 134 | 2 | 3 |
| | | 2 | 7 | | |
| | | 4 | 4 | | |
| | | 464 | 812 | 10 | 16 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | 2 | 2 | 2 |
| | | 3 | 6 | 2 | 4 |
| | | 1 | 1 | | |
| | | 2 | 2 | 3 | 4 |
| | | | 3 | | |
| | | 2 | 4 | 3 | 5 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Stoma site extravasation | | 1 |
| Stoma site haemorrhage | 1 | 2 |
| Stoma site pain | 1 | 1 |
| Subdural haemorrhage | 1 | 1 |
| Sunburn | 1 | 3 |
| Superficial injury of eye | | 1 |
| Suture related complication | | 1 |
| Synovial rupture | | 1 |
| Tendon injury | 1 | 2 |
| Thermal burn | 3 | 4 |
| Thermal burns of eye | 2 | 2 |
| Tongue injury | 1 | 2 |
| Tooth injury | | 1 |
| Toxicity to various agents | 1 | 1 |
| Transcription medication error | 1 | 1 |
| Traumatic haemorrhage | 1 | 1 |
| Traumatic lung injury | 2 | 2 |
| Ulnar nerve injury | 3 | 3 |
| Underdose | 75 | 229 |
| Upper limb fracture | 3 | 5 |
| Vaccination complication | 30 | 43 |
| Vaccination error | | 2 |
| Vaccination failure | 18 | 19 |
| Wound | 7 | 9 |
| Wound complication | 2 | 2 |
| Wound haemorrhage | 1 | 2 |
| Wound secretion | 1 | 1 |
| Wrong product administered | 8 | 20 |
| Wrong schedule | | 1 |
| Wrong technique in device usage process | 2 | 2 |
| Wrong technique in product usage process | 22 | 94 |
| | 2,712 | 5,578 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | 1 | 3 | 3 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | | 3 | 3 |
| | | 74 | 228 | 1 | 1 |
| | | | | 3 | 5 |
| 1 | 1 | 10 | 19 | 20 | 24 |
| | | | 2 | | |
| 1 | 1 | | | 18 | 19 |
| | | 4 | 6 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 8 | 20 | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | 21 | 92 | 1 | 2 |
| 5 | 6 | 2337 | 5045 | 375 | 533 |

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System Organ Class

Investigations

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 8 | 9 | 3 | 7 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 19 | 21 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 5 | 1 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 2 | 3 | 1 | 2 |
| | | 2 | 2 | 1 | 1 |
| | | | 2 | | |
| | | 2 | 3 | | |
| | | 1 | 3 | | 1 |
| | | 3 | 3 | | |
| | | 2 | 3 | | |
| | | | 1 | | |
| | | 2 | 4 | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | 3 | 5 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |

| | | |
|---|----|----|
| Activated partial thromboplastin time prolonged | 1 | 1 |
| Alanine aminotransferase increased | 11 | 16 |
| Amylase increased | 2 | 2 |
| Anion gap abnormal | 1 | 1 |
| Antibody test abnormal | 19 | 21 |
| Antibody test negative | 1 | 2 |
| Antibody test positive | | 1 |
| Anticoagulation drug level increased | | 1 |
| Antinuclear antibody positive | 1 | 1 |
| Anti-thyroid antibody positive | 1 | 1 |
| Aspartate aminotransferase increased | 5 | 7 |
| Auscultation | | 1 |
| Autoantibody negative | 1 | 1 |
| Bacterial test positive | 1 | 1 |
| Bilirubin urine present | | 1 |
| Bleeding time abnormal | 1 | 1 |
| Blood albumin decreased | 1 | 2 |
| Blood alkaline phosphatase increased | 3 | 5 |
| Blood bilirubin increased | 3 | 3 |
| Blood calcium decreased | | 2 |
| Blood chloride decreased | 2 | 3 |
| Blood chloride increased | 1 | 4 |
| Blood cholesterol increased | 3 | 3 |
| Blood count abnormal | 2 | 3 |
| Blood creatine increased | | 1 |
| Blood creatine phosphokinase increased | 3 | 6 |
| Blood creatine phosphokinase MB increased | 1 | 2 |
| Blood creatinine increased | 5 | 7 |
| Blood electrolytes increased | | 1 |
| Blood fibrinogen increased | 1 | 1 |
| Blood glucose | 1 | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Blood glucose abnormal | 3 | 5 |
| Blood glucose decreased | 11 | 20 |
| Blood glucose fluctuation | 2 | 4 |
| Blood glucose increased | 29 | 56 |
| Blood growth hormone | | 1 |
| Blood immunoglobulin G decreased | 1 | 2 |
| Blood immunoglobulin G increased | | 2 |
| Blood iron decreased | 3 | 4 |
| Blood ketone body increased | 2 | 2 |
| Blood ketone body present | | 1 |
| Blood lactate dehydrogenase abnormal | 1 | 1 |
| Blood lactate dehydrogenase increased | 3 | 3 |
| Blood lactic acid increased | 3 | 7 |
| Blood magnesium decreased | 1 | 1 |
| Blood pH increased | 1 | 2 |
| Blood potassium abnormal | | 1 |
| Blood potassium decreased | 3 | 9 |
| Blood potassium increased | 1 | 1 |
| Blood pressure abnormal | 11 | 18 |
| Blood pressure decreased | 88 | 123 |
| Blood pressure diastolic decreased | 2 | 6 |
| Blood pressure diastolic increased | 4 | 9 |
| Blood pressure immeasurable | 2 | 2 |
| Blood pressure increased | 282 | 469 |
| Blood pressure orthostatic abnormal | | 1 |
| Blood pressure orthostatic decreased | | 1 |
| Blood pressure systolic decreased | 2 | 3 |
| Blood pressure systolic increased | 20 | 33 |
| Blood sodium decreased | 3 | 6 |
| Blood test abnormal | 2 | 4 |
| Blood testosterone decreased | | 1 |
| Blood testosterone increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 4 | 1 | 1 |
| | | 6 | 10 | 5 | 10 |
| | | | 2 | 2 | 2 |
| | | 13 | 29 | 16 | 27 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | 2 | | |
| | | 1 | 2 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | 3 | 6 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | 2 | 7 | 1 | 2 |
| | | 1 | 1 | | |
| | | 5 | 10 | 6 | 8 |
| 2 | 2 | 32 | 48 | 56 | 75 |
| | | 1 | 5 | 1 | 1 |
| | | 2 | 6 | 2 | 3 |
| | | | | 2 | 2 |
| 3 | 3 | 115 | 223 | 167 | 246 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 2 |
| | | 9 | 14 | 11 | 19 |
| | | 1 | 4 | 2 | 2 |
| | | 2 | 2 | | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Blood thyroid stimulating hormone increased | 1 | 4 |
| Blood triglycerides increased | | 1 |
| Blood urea increased | 1 | 2 |
| Blood uric acid increased | | 1 |
| Blood urine present | 10 | 19 |
| Blood viscosity increased | 1 | 1 |
| Body height decreased | 8 | 15 |
| Body temperature | 1 | 4 |
| Body temperature abnormal | 20 | 45 |
| Body temperature decreased | 28 | 44 |
| Body temperature fluctuation | 8 | 15 |
| Body temperature increased | 233 | 380 |
| Brain natriuretic peptide increased | 1 | 1 |
| Breath sounds | 2 | 2 |
| Breath sounds abnormal | 5 | 5 |
| Calcium ionised increased | 1 | 1 |
| Capillary nail refill test abnormal | 1 | 2 |
| Cardiac murmur | 1 | 1 |
| Carotid bruit | 2 | 2 |
| Chest expansion decreased | 1 | 1 |
| Chest X-ray abnormal | 3 | 3 |
| Coagulation time prolonged | 1 | 2 |
| Coma scale abnormal | | 4 |
| Complement factor C3 decreased | 1 | 1 |
| Computerised tomogram normal | 1 | 1 |
| Corneal reflex decreased | 2 | 2 |
| Coronavirus test positive | 4 | 6 |
| Cortisol decreased | | 1 |
| C-reactive protein decreased | 1 | 1 |
| C-reactive protein increased | 71 | 86 |
| Creatinine renal clearance decreased | 1 | 1 |
| Crystal urine | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | 4 | 12 | 6 | 7 |
| | | 1 | 1 | | |
| | | 7 | 14 | 1 | 1 |
| | | | 1 | 1 | 3 |
| | | 11 | 24 | 9 | 21 |
| | | 9 | 21 | 19 | 23 |
| | | 3 | 7 | 5 | 8 |
| | 1 | 171 | 279 | 62 | 101 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 5 | 5 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 2 |
| | | | | | 4 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 2 | 2 | 4 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 27 | 37 | 44 | 49 |
| | | | | 1 | 1 |
| | | | 1 | | |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| CSF protein increased | 1 | 1 |
| Culture negative | | 1 |
| Culture urine positive | | 1 |
| Ejection fraction abnormal | | 1 |
| Ejection fraction decreased | 2 | 2 |
| Electrocardiogram abnormal | 7 | 10 |
| Electrocardiogram QRS complex prolonged | 1 | 1 |
| Electrocardiogram QT prolonged | 2 | 3 |
| Electrocardiogram repolarisation abnormality | 2 | 2 |
| Electrocardiogram ST segment abnormal | 1 | 2 |
| Electrocardiogram ST segment depression | 1 | 1 |
| Electrocardiogram ST segment elevation | | 1 |
| Electrocardiogram ST-T change | 1 | 1 |
| Electrocardiogram T wave inversion | 1 | 1 |
| Electrocardiogram T wave peaked | 1 | 1 |
| Electroencephalogram abnormal | 1 | 1 |
| Eosinophil count decreased | 2 | 2 |
| Eosinophil count increased | 4 | 6 |
| Epinephrine increased | | 1 |
| Epstein-Barr virus test positive | 1 | 1 |
| Fibrin D dimer increased | 10 | 14 |
| Forced expiratory volume increased | 1 | 1 |
| Full blood count abnormal | 1 | 1 |
| Gamma-glutamyltransferase increased | 5 | 6 |
| Gastric pH decreased | | 1 |
| General physical condition abnormal | 8 | 9 |
| Glomerular filtration rate decreased | 4 | 6 |
| Glycosylated haemoglobin increased | 1 | 3 |
| Grip strength | 1 | 1 |
| Grip strength decreased | 4 | 9 |
| Haematocrit decreased | 2 | 5 |
| Haematocrit increased | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 2 | 5 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 3 | 3 | 1 | 3 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 6 | 8 | 4 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | 2 | 3 |
| | | | 1 | | |
| | | | | 8 | 9 |
| | | 1 | 2 | 3 | 4 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 4 | 3 | 5 |
| | | 1 | 4 | 1 | 1 |
| | | | 1 | 1 | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Haemoglobin decreased | 11 | 17 |
| Haemoglobin increased | 1 | 2 |
| Haptoglobin increased | 1 | 1 |
| Heart rate | 1 | 1 |
| Heart rate abnormal | 12 | 19 |
| Heart rate decreased | 33 | 47 |
| Heart rate increased | 294 | 643 |
| Heart rate irregular | 26 | 40 |
| Heart sounds abnormal | 1 | 1 |
| Hepatic enzyme increased | 4 | 6 |
| Histamine level increased | | 1 |
| Hormone level abnormal | 3 | 3 |
| Inflammatory marker increased | 4 | 7 |
| Influenza B virus test positive | | 1 |
| Inspiratory capacity abnormal | | 1 |
| Inspiratory capacity decreased | 2 | 2 |
| Interleukin level increased | 1 | 1 |
| International normalised ratio abnormal | 1 | 2 |
| International normalised ratio decreased | 4 | 5 |
| International normalised ratio increased | 10 | 18 |
| Intraocular pressure increased | 2 | 5 |
| Laboratory test abnormal | | 1 |
| Laboratory test normal | 1 | 1 |
| Lipase increased | 3 | 3 |
| Lipids increased | | 1 |
| Liver function test abnormal | 4 | 6 |
| Liver function test increased | 5 | 7 |
| Low density lipoprotein increased | 1 | 1 |
| Lumbar puncture abnormal | 1 | 1 |
| Lymph node palpable | 1 | 3 |
| Lymph nodes scan abnormal | 1 | 1 |
| Lymphocyte count abnormal | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 8 | 7 | 9 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 4 | 9 | 8 | 10 |
| | | 14 | 20 | 19 | 27 |
| | | 139 | 386 | 155 | 257 |
| | | 12 | 22 | 14 | 18 |
| | | | | 1 | 1 |
| | | 2 | 3 | 2 | 3 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 2 | 3 | 5 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | 1 | 4 | 4 |
| | | 1 | 3 | 9 | 15 |
| | | | 1 | 2 | 4 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | 3 | 5 |
| | | 2 | 3 | 3 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 3 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Lymphocyte count decreased | 2 | 4 |
| Lymphocyte count increased | 1 | 2 |
| Lymphocyte percentage decreased | 1 | 1 |
| Mean cell haemoglobin concentration decreased | | 1 |
| Mean cell haemoglobin decreased | | 3 |
| Mean cell volume decreased | 1 | 2 |
| Mean cell volume increased | 1 | 2 |
| Mean platelet volume increased | | 1 |
| Monocyte count decreased | 2 | 2 |
| Monocyte count increased | 1 | 3 |
| Myocardial necrosis marker increased | 3 | 5 |
| Neurological examination normal | 1 | 1 |
| Neutrophil count abnormal | 1 | 1 |
| Neutrophil count decreased | 3 | 4 |
| Neutrophil count increased | 6 | 8 |
| Neutrophil percentage increased | 1 | 1 |
| Nitrite urine present | 1 | 1 |
| N-terminal prohormone brain natriuretic peptide increased | 1 | 1 |
| Orthostatic heart rate response increased | | 1 |
| Oxygen consumption | | 1 |
| Oxygen saturation | 1 | 1 |
| Oxygen saturation abnormal | 7 | 7 |
| Oxygen saturation decreased | 197 | 253 |
| Oxygen saturation immeasurable | 1 | 1 |
| Peak expiratory flow rate decreased | 1 | 1 |
| pH urine | 1 | 2 |
| pH urine increased | 1 | 1 |
| Physical examination abnormal | 1 | 1 |
| Platelet count abnormal | 1 | 1 |
| Platelet count decreased | 16 | 19 |
| Platelet count increased | 3 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 2 | | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 3 | | |
| | | | | 3 | 5 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | 5 | 5 | 1 | 3 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 5 | 5 | 2 | 2 |
| | | 32 | 48 | 165 | 205 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 5 | 12 | 14 |
| | | 3 | 6 | | 2 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| PO2 decreased | | 2 |
| Polymerase chain reaction positive | 2 | 2 |
| Protein urine present | | 1 |
| Prothrombin time prolonged | 2 | 2 |
| Pulse abnormal | 14 | 26 |
| Pulse absent | 1 | 1 |
| Pulse pressure decreased | 1 | 1 |
| Pulse waveform abnormal | 1 | 1 |
| Quality of life decreased | 3 | 3 |
| Radial pulse abnormal | 1 | 1 |
| Red blood cell count decreased | 1 | 4 |
| Red blood cell count increased | | 1 |
| Red blood cell sedimentation rate abnormal | 1 | 1 |
| Red blood cell sedimentation rate increased | 7 | 11 |
| Red blood cells urine positive | | 1 |
| Red cell distribution width increased | 1 | 1 |
| Respiratory rate decreased | 5 | 7 |
| Respiratory rate increased | 29 | 47 |
| Rheumatoid factor positive | 2 | 2 |
| Rinne tuning fork test abnormal | 1 | 1 |
| SARS-CoV-1 test positive | | 1 |
| SARS-CoV-2 ant body test | 2 | 2 |
| SARS-CoV-2 ant body test negative | 67 | 83 |
| SARS-CoV-2 ant body test positive | 38 | 53 |
| SARS-CoV-2 test | 1 | 1 |
| SARS-CoV-2 test false positive | 1 | 7 |
| SARS-CoV-2 test negative | 2 | 3 |
| SARS-CoV-2 test positive | 114 | 414 |
| Serum ferritin increased | 3 | 3 |
| Sinus rhythm | 1 | 2 |
| Skin temperature | 2 | 2 |
| Sputum abnormal | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 5 | 11 | 9 | 15 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | 3 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 5 | 8 | 2 | 3 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 4 | 6 |
| | | 8 | 12 | 21 | 35 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | 60 | 75 | 7 | 8 |
| | | 36 | 47 | 2 | 6 |
| | | | | 1 | 1 |
| | | 1 | 7 | | |
| | | 2 | 3 | | |
| | | 36 | 71 | 78 | 343 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 2 | 2 |
| | | | | 2 | 2 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Streptococcus test positive | 1 | 2 |
| Swollen joint count increased | 1 | 1 |
| Synovial fluid white blood cells positive | 1 | 1 |
| Thyroid function test abnormal | | 1 |
| Thyroid hormones increased | 1 | 1 |
| Transaminases increased | 8 | 9 |
| Tri-iodothyronine decreased | | 1 |
| Troponin I increased | 1 | 1 |
| Troponin increased | 7 | 11 |
| Troponin T increased | 1 | 2 |
| Tryptase decreased | 1 | 2 |
| Tryptase increased | | 1 |
| Tuberculin test positive | 1 | 1 |
| Urinary sediment present | 1 | 1 |
| Urine analysis abnormal | | 2 |
| Urine output decreased | 2 | 3 |
| Urine output increased | 2 | 4 |
| Venous oxygen saturation decreased | 1 | 1 |
| Viral test | 1 | 1 |
| Vital capacity | 1 | 1 |
| Vital functions abnormal | | 1 |
| Vitamin B12 decreased | 1 | 1 |
| Vitamin D decreased | 1 | 1 |
| Weber tuning fork test abnormal | 1 | 1 |
| Weight decreased | 25 | 47 |
| Weight increased | 2 | 8 |
| White blood cell count decreased | 9 | 11 |
| White blood cell count increased | 20 | 27 |
| White blood cells urine positive | 1 | 1 |
| | 2,109 | 3,678 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|----|---------|------|------|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | 1 | 2 | | | | |
| | | | | 1 | 1 | | |
| | | | 1 | | | | |
| | | | | 1 | 1 | | |
| | | 1 | 2 | 7 | 7 | | |
| | | | | | 1 | | |
| | | | | 1 | 1 | | |
| | | | | 7 | 11 | | |
| | | | | 1 | 2 | | |
| | | 1 | 2 | | | | |
| | | | 1 | | | | |
| | | 1 | 1 | | | | |
| | | 1 | 1 | | | | |
| | | | 1 | | 1 | | |
| | | | | 2 | 3 | | |
| | | 1 | 3 | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | 1 | 1 | | | | |
| | | 1 | 1 | | | | |
| | | 13 | 29 | 12 | 18 | | |
| | | | 6 | 2 | 2 | | |
| | | 4 | 5 | 5 | 6 | | |
| | | 9 | 11 | 11 | 16 | | |
| | | 1 | 1 | | | | |
| | | 5 | 6 | 968 | 1802 | 1141 | 1876 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal weight gain | 3 | 3 | | | | | 3 | 3 |
| Acetonaemia | | 1 | | | | 1 | | |
| Acidosis | 1 | 3 | | | | 1 | 1 | 2 |
| Adult failure to thrive | 1 | 1 | | | | | 1 | 1 |
| Alcohol intolerance | 1 | 1 | | | 1 | 1 | | |
| Appetite disorder | 2 | 4 | | | 1 | 2 | 1 | 2 |
| Cachexia | 4 | 4 | | | | | 4 | 4 |
| Decreased appetite | 396 | 632 | 3 | 3 | 179 | 319 | 217 | 313 |
| Dehydration | 52 | 98 | | | 17 | 47 | 35 | 51 |
| Diabetes mellitus | 9 | 16 | | | | | 9 | 16 |
| Diabetes mellitus inadequate control | 6 | 8 | | | | | 6 | 8 |
| Diabetic complication | 1 | 2 | | | | | 1 | 2 |
| Diabetic ketoacidosis | 5 | 8 | | | | | 5 | 8 |
| Diabetic ketosis | 1 | 1 | | | | | 1 | 1 |
| Diabetic metabolic decompensation | 1 | 1 | | | | | 1 | 1 |
| Diet refusal | 3 | 6 | | | | | 3 | 6 |
| Dyslipidaemia | 1 | 1 | | | 1 | 1 | | |
| Eating disorder symptom | 2 | 2 | | | | | 2 | 2 |
| Electrolyte imbalance | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Feeding disorder | 31 | 48 | | | 16 | 30 | 15 | 18 |
| Fluid imbalance | | 1 | | | | | | 1 |
| Fluid intake reduced | 1 | 5 | | | | 2 | 1 | 3 |
| Fluid overload | 1 | 1 | | | | | 1 | 1 |
| Fluid retention | 9 | 11 | | | 5 | 7 | 4 | 4 |
| Food aversion | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Food craving | 1 | 2 | | | | 1 | 1 | 1 |
| Food refusal | 5 | 7 | | | | | 5 | 7 |
| Glucose tolerance impaired | 1 | 1 | | | 1 | 1 | | |
| Gout | 16 | 24 | | | 4 | 10 | 12 | 14 |
| Histamine intolerance | 2 | 2 | | | | | 2 | 2 |
| Hypercalcaemia | 1 | 2 | | | | | 1 | 2 |
| Hyperglycaemia | 18 | 31 | | | 5 | 8 | 13 | 23 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyperkalaemia | 6 | 6 |
| Hyperlipidaemia | 1 | 1 |
| Hypernatraemia | 8 | 9 |
| Hyperphagia | 1 | 1 |
| Hypervitaminosis B12 | 1 | 1 |
| Hypocalcaemia | 2 | 4 |
| Hypoglycaemia | 33 | 48 |
| Hypokalaemia | 15 | 18 |
| Hypokalaemic syndrome | 1 | 1 |
| Hypomagnesaemia | | 1 |
| Hyponatraemia | 6 | 8 |
| Hypophagia | 7 | 14 |
| Hypophosphataemia | 1 | 1 |
| Increased appetite | 1 | 3 |
| Increased insulin requirement | 1 | 1 |
| Insulin-requiring type 2 diabetes mellitus | 1 | 1 |
| Insulin resistance | 2 | 3 |
| Iron deficiency | 1 | 1 |
| Ketoacidosis | 2 | 2 |
| Lactic acidosis | 2 | 2 |
| Malnutrition | 2 | 4 |
| Marasmus | 1 | 1 |
| Metabolic acidosis | 2 | 3 |
| Oligodipsia | | 1 |
| Overweight | 1 | 2 |
| Polydipsia | 7 | 10 |
| Poor feeding infant | | 1 |
| Postprandial hypoglycaemia | 1 | 1 |
| Salt craving | 1 | 1 |
| Tetany | 1 | 3 |
| Type 1 diabetes mellitus | 3 | 3 |
| Type 2 diabetes mellitus | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 6 | 6 |
| | | | | 1 | 1 |
| | | 2 | 2 | 6 | 7 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 3 |
| | | 6 | 14 | 27 | 34 |
| | | | | 15 | 18 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 2 | 4 | 6 |
| | | 1 | 4 | 6 | 10 |
| | | 1 | 1 | | |
| | | 1 | 3 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | 1 | 2 | | |
| | | 3 | 6 | 4 | 4 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Weight fluctuation | 2 | 2 | | | 2 | 2 | | |
| | 695 | 1,093 | 3 | 3 | 255 | 477 | 440 | 616 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ankylosing spondylitis | 5 | 6 | | | | | 5 | 6 |
| Arthralgia | 2,065 | 3,489 | 30 | 31 | 973 | 1982 | 1092 | 1507 |
| Arthritis | 40 | 70 | | | 15 | 36 | 25 | 34 |
| Arthritis enteropathic | 1 | 1 | | | | | 1 | 1 |
| Arthritis reactive | 7 | 10 | | | | | 7 | 10 |
| Arthropathy | 15 | 26 | | | 9 | 19 | 6 | 7 |
| Axillary mass | 10 | 30 | | | 3 | 18 | 7 | 12 |
| Back disorder | 5 | 5 | | | 5 | 5 | | |
| Back pain | 466 | 802 | 5 | 5 | 194 | 448 | 272 | 354 |
| Bone disorder | 1 | 2 | | | 1 | 2 | | |
| Bone pain | 132 | 214 | | | 69 | 131 | 63 | 83 |
| Bone swelling | 2 | 9 | | | 2 | 8 | | 1 |
| Bursal fluid accumulation | 1 | 1 | | | 1 | 1 | | |
| Bursitis | 12 | 13 | 1 | 1 | 5 | 6 | 7 | 7 |
| Chondritis | 1 | 1 | | | 1 | 1 | | |
| Coccydynia | 1 | 1 | | | 1 | 1 | | |
| Costochondritis | 6 | 9 | | | 2 | 2 | 4 | 7 |
| Crystal arthropathy | 1 | 1 | | | | | 1 | 1 |
| Decreased nasolabial fold | 1 | 1 | | | 1 | 1 | | |
| Epiphyses premature fusion | 1 | 1 | | | | | 1 | 1 |
| Extremity contracture | | 2 | | | | 2 | | |
| Facet joint syndrome | | 1 | | | | 1 | | |
| Facial asymmetry | 1 | 3 | | | 1 | 3 | | |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Fasciitis | 2 | 2 |
| Fibromyalgia | 12 | 17 |
| Flank pain | 13 | 20 |
| Foot deformity | 2 | 2 |
| Groin pain | 18 | 29 |
| Haemarthrosis | 1 | 1 |
| Haematoma muscle | | 1 |
| Immune-mediated arthritis | | 1 |
| Inguinal mass | | 1 |
| Intervertebral disc protrusion | 1 | 2 |
| Jaw clicking | | 2 |
| Jaw disorder | 3 | 4 |
| Joint ankylosis | | 1 |
| Joint contracture | | 1 |
| Joint effusion | 9 | 13 |
| Joint instability | 1 | 3 |
| Joint lock | 1 | 2 |
| Joint noise | 1 | 3 |
| Joint range of motion decreased | 57 | 99 |
| Joint stiffness | 38 | 64 |
| Joint swelling | 79 | 136 |
| Joint warmth | 4 | 6 |
| Limb discomfort | 183 | 372 |
| Limb mass | 11 | 14 |
| Mastication disorder | 3 | 5 |
| Masticatory pain | | 1 |
| Medial tibial stress syndrome | 1 | 1 |
| Mixed connective tissue disease | | 1 |
| Mobility decreased | 96 | 159 |
| Muscle atrophy | 1 | 2 |
| Muscle contracture | 11 | 13 |
| Muscle discomfort | 5 | 11 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 3 | 4 | 9 | 13 |
| | | 8 | 14 | 5 | 6 |
| | | 2 | 2 | | |
| 1 | 1 | 4 | 12 | 14 | 17 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | | 2 |
| | | 2 | 3 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 5 | 6 | 4 | 7 |
| | | | | 1 | 3 |
| | | | | 1 | 2 |
| | | 1 | 2 | | 1 |
| 1 | 1 | 25 | 54 | 32 | 45 |
| | | 12 | 27 | 26 | 37 |
| | | 34 | 72 | 45 | 64 |
| | | 2 | 4 | 2 | 2 |
| 1 | 1 | 79 | 215 | 104 | 157 |
| | | 6 | 8 | 5 | 6 |
| | | 2 | 2 | 1 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 49 | 90 | 47 | 69 |
| | | | 1 | 1 | 1 |
| | | 7 | 9 | 4 | 4 |
| | | 3 | 9 | 2 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Muscle disorder | 3 | 5 |
| Muscle fatigue | 50 | 73 |
| Muscle oedema | 1 | 1 |
| Muscle rigidity | 12 | 17 |
| Muscle spasms | 165 | 289 |
| Muscle swelling | 4 | 11 |
| Muscle tightness | 32 | 76 |
| Muscle twitching | 47 | 81 |
| Muscular weakness | 245 | 398 |
| Musculoskeletal chest pain | 37 | 66 |
| Musculoskeletal discomfort | 31 | 59 |
| Musculoskeletal disorder | 17 | 26 |
| Musculoskeletal pain | 79 | 111 |
| Musculoskeletal stiffness | 237 | 406 |
| Myalgia | 2,852 | 4,861 |
| Myalgia intercostal | 3 | 3 |
| Myofascial pain syndrome | 3 | 4 |
| Myokymia | 2 | 2 |
| Myosclerosis | 3 | 3 |
| Myositis | 4 | 7 |
| Neck mass | 6 | 14 |
| Neck pain | 341 | 669 |
| Nuchal rigidity | 10 | 16 |
| Oligoarthritis | 1 | 1 |
| Osteoarthritis | 5 | 7 |
| Osteochondritis | | 1 |
| Osteoporosis | 1 | 1 |
| Pain in extremity | 2,039 | 3,936 |
| Pain in jaw | 57 | 112 |
| Periarthritis | 6 | 12 |
| Plantar fasciitis | 1 | 1 |
| Polyarthritis | 5 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 2 | 2 |
| | | 11 | 22 | 39 | 51 |
| | | 1 | 1 | | |
| | | 4 | 4 | 8 | 13 |
| | | 61 | 155 | 104 | 134 |
| | | 1 | 6 | 3 | 5 |
| 1 | 1 | 19 | 60 | 13 | 16 |
| | | 24 | 51 | 23 | 30 |
| | | 96 | 190 | 149 | 208 |
| | | 12 | 34 | 25 | 32 |
| | | 11 | 36 | 20 | 23 |
| | | 5 | 10 | 12 | 16 |
| | | 31 | 53 | 48 | 58 |
| 3 | 3 | 96 | 214 | 141 | 192 |
| 43 | 47 | 1231 | 2655 | 1621 | 2206 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 2 | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 3 | 3 |
| 1 | 1 | 3 | 4 | 1 | 3 |
| | | 6 | 12 | | 2 |
| | | 136 | 382 | 205 | 287 |
| | | 4 | 8 | 6 | 8 |
| | | | | 1 | 1 |
| | | 2 | 4 | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| 17 | 20 | 1064 | 2584 | 975 | 1352 |
| | | 24 | 67 | 33 | 45 |
| | | 2 | 5 | 4 | 7 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Polychondritis | 1 | 1 |
| Polymyalgia rheumatica | 7 | 9 |
| Polymyositis | 2 | 2 |
| Posture abnormal | | 2 |
| Psoriatic arthropathy | 1 | 3 |
| Rhabdomyolysis | 4 | 7 |
| Rheumatic disorder | 1 | 1 |
| Rheumatoid arthritis | 20 | 26 |
| Rotator cuff syndrome | 2 | 2 |
| Sacroiliitis | 1 | 3 |
| Sinus tarsi syndrome | | 1 |
| Sjogren's syndrome | 3 | 4 |
| Spinal disorder | 1 | 3 |
| Spinal osteoarthritis | 1 | 1 |
| Spinal pain | 28 | 50 |
| Spinal stenosis | 1 | 1 |
| Spondylitis | 1 | 1 |
| Symphysiolysis | | 1 |
| Synovial cyst | 8 | 10 |
| Synovitis | 4 | 5 |
| Systemic lupus erythematosus | 4 | 6 |
| Systemic sclerosis | | 1 |
| Temporomandibular joint syndrome | 5 | 7 |
| Tendon disorder | 1 | 1 |
| Tendonitis | 6 | 10 |
| Tendon pain | 6 | 8 |
| Tenosynovitis | 2 | 4 |
| Torticollis | 2 | 5 |
| Trismus | 6 | 10 |
| Undifferentiated connective tissue disease | | 1 |
| Weight bearing difficulty | 2 | 3 |
| Winged scapula | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 7 | 9 |
| | | | | 2 | 2 |
| | | | 1 | | 1 |
| | | | | 1 | 3 |
| | | | | 4 | 7 |
| | | | | 1 | 1 |
| | | | | 20 | 26 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | 2 |
| | | | 1 | | |
| | | | | 3 | 4 |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | 17 | 35 | 11 | 15 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 3 | 7 | 7 |
| | | 2 | 2 | 2 | 3 |
| | | | | 4 | 6 |
| | | | | | 1 |
| | | 3 | 5 | 2 | 2 |
| | | 1 | 1 | | |
| | | 3 | 5 | 3 | 5 |
| | | 4 | 6 | 2 | 2 |
| | | 2 | 4 | | |
| | | 2 | 3 | | 2 |
| | | 2 | 5 | 4 | 5 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | 1 | 1 | | |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|--------------------------|-----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| | 9,747 | 17,151 | 104 | 112 | 4418 | 9848 | 5329 | 7303 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acrochordon | 1 | 1 | | | 1 | 1 |
| Acute leukaemia | 2 | 2 | | | 2 | 2 |
| Acute myeloid leukaemia | 2 | 2 | | | 2 | 2 |
| Angiomyolipoma | 1 | 1 | | | 1 | 1 |
| B-cell lymphoma | 1 | 1 | | | 1 | 1 |
| B-cell type acute leukaemia | 1 | 1 | | | 1 | 1 |
| Benign breast neoplasm | 1 | 1 | 1 | 1 | | |
| Bone neoplasm | | 1 | | 1 | | |
| Brain neoplasm | 1 | 1 | | | 1 | 1 |
| Breast cancer | 2 | 2 | | | 2 | 2 |
| Cardiac neoplasm unspecified | | 1 | | | | 1 |
| Chronic myeloid leukaemia recurrent | 1 | 1 | | | 1 | 1 |
| Colon cancer | 1 | 1 | | | 1 | 1 |
| Ear neoplasm | | 1 | | 1 | | |
| Good syndrome | 1 | 1 | | | 1 | 1 |
| Leukaemia | 1 | 2 | | | 1 | 2 |
| Lung carcinoma cell type unspecified stage I | 1 | 1 | | | 1 | 1 |
| Lung neoplasm malignant | | 1 | | | | 1 |
| Lymphoma | 5 | 5 | | | 5 | 5 |
| Malignant lymphoid neoplasm | 1 | 1 | | | 1 | 1 |
| Melanocytic naevus | 1 | 1 | | | 1 | 1 |
| Metastases to lymph nodes | 5 | 5 | | | 5 | 5 |
| Metastases to meninges | | 1 | | | | 1 |
| Metastases to peritoneum | 2 | 2 | | | 2 | 2 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neoplasm | 1 | 1 | 1 | 1 | | |
| Neoplasm malignant | 2 | 2 | | | 2 | 2 |
| Neoplasm progression | 1 | 2 | | | 1 | 2 |
| Neoplasm skin | 1 | 2 | 1 | 2 | | |
| Paraganglion neoplasm | 1 | 1 | | | 1 | 1 |
| Phaeochromocytoma | 1 | 1 | | | 1 | 1 |
| Plasma cell myeloma | 1 | 1 | | | 1 | 1 |
| Sarcoma | 1 | 1 | | | 1 | 1 |
| Second primary malignancy | 1 | 1 | | | 1 | 1 |
| Skin cancer | | 1 | | | | 1 |
| Thyroid cancer | 1 | 1 | | | 1 | 1 |
| Tumour perforation | 1 | 1 | | | 1 | 1 |
| | 43 | 52 | 3 | 6 | 40 | 46 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Acoustic neuritis | | 1 | | | | | | | 1 |
| Acute disseminated encephalomyelitis | | 1 | | | | | | | 1 |
| Ageusia | 114 | 228 | | | 62 | 148 | 52 | 80 | |
| Akathisia | | 1 | | | | 1 | | | |
| Alexia | 1 | 1 | | | 1 | 1 | | | |
| Allodynia | 3 | 6 | | | 3 | 5 | | | 1 |
| Altered state of consciousness | 23 | 25 | 1 | 1 | | | 23 | 25 | |
| Amnesia | 24 | 33 | | | 8 | 14 | 16 | 19 | |
| Anaesthesia | 5 | 9 | | | 2 | 6 | 3 | 3 | |
| Anosmia | 91 | 194 | | | 55 | 138 | 36 | 56 | |
| Anterograde amnesia | 2 | 2 | | | | | 2 | 2 | |
| Anticholinergic syndrome | | 1 | | | | | | | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Apallic syndrome | 1 | 1 |
| Aphasia | 38 | 51 |
| Areflexia | 2 | 2 |
| Ataxia | 7 | 8 |
| Aura | 3 | 11 |
| Autoimmune demyelinating disease | 1 | 1 |
| Autonomic nervous system imbalance | 4 | 5 |
| Axonal neuropathy | 1 | 2 |
| Balance disorder | 108 | 171 |
| Band sensation | 2 | 3 |
| Basal ganglia haemorrhage | | 2 |
| Basal ganglia infarction | 1 | 1 |
| Basal ganglia stroke | 2 | 2 |
| Basilar artery thrombosis | 1 | 1 |
| Brachial plexopathy | | 2 |
| Bradykinesia | 4 | 5 |
| Brain injury | 1 | 4 |
| Brain oedema | 3 | 5 |
| Brain stem haemorrhage | 1 | 1 |
| Brain stem stroke | 1 | 1 |
| Brain stem syndrome | 2 | 2 |
| Burning sensation | 128 | 238 |
| Burning sensation mucosal | 2 | 3 |
| Carotid artery dissection | 1 | 1 |
| Carpal tunnel syndrome | 2 | 2 |
| Cataplexy | | 1 |
| Central nervous system lesion | 3 | 4 |
| Cerebellar ataxia | 1 | 1 |
| Cerebellar haemorrhage | | 2 |
| Cerebellar infarction | | 2 |
| Cerebellar stroke | | 1 |
| Cerebellar syndrome | 3 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 13 | 18 | 25 | 33 |
| | | | | 2 | 2 |
| | | 1 | 1 | 6 | 7 |
| | | 1 | 6 | 2 | 5 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 4 |
| | | | | 1 | 2 |
| | 1 | 34 | 71 | 74 | 100 |
| | | | 1 | 2 | 2 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | 1 | 2 | 3 | 3 |
| | | | | 1 | 4 |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 68 | 142 | 60 | 96 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | | 2 |
| | | | | | 1 |
| | | | | 3 | 3 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Cerebral artery stenosis | 1 | 1 |
| Cerebral atrophy | 1 | 1 |
| Cerebral disorder | 3 | 5 |
| Cerebral haematoma | 4 | 4 |
| Cerebral haemorrhage | 18 | 25 |
| Cerebral infarction | 12 | 15 |
| Cerebral ischaemia | 2 | 3 |
| Cerebral thrombosis | 3 | 3 |
| Cerebral venous sinus thrombosis | 2 | 3 |
| Cerebrovascular accident | 111 | 160 |
| Cerebrovascular disorder | 2 | 2 |
| Cervical neuritis | 1 | 1 |
| Cervical radiculopathy | 1 | 1 |
| Cervicobrachial syndrome | 3 | 3 |
| Cholinergic syndrome | 3 | 3 |
| Chorea | 2 | 2 |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 1 | 1 |
| Clonic convulsion | 2 | 2 |
| Clonus | 6 | 6 |
| Clumsiness | 1 | 3 |
| Cluster headache | 14 | 22 |
| Cognitive disorder | 22 | 32 |
| Coma | 11 | 14 |
| Complex regional pain syndrome | 3 | 3 |
| Consciousness fluctuating | 3 | 4 |
| Coordination abnormal | 19 | 23 |
| Cranial nerve disorder | 4 | 6 |
| Cranial nerve paralysis | 1 | 1 |
| Dementia | 13 | 15 |
| Dementia Alzheimer's type | 1 | 2 |
| Dementia of the Alzheimer's type, with delirium | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 2 | 2 |
| | | | | 4 | 4 |
| | | | | 18 | 25 |
| | | | | 12 | 15 |
| | | | | 2 | 3 |
| | | | | 3 | 3 |
| | | | | 2 | 3 |
| | | | | 111 | 160 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | 5 | 5 |
| | | 1 | 2 | | 1 |
| | | 3 | 5 | 11 | 17 |
| | | 8 | 11 | 14 | 21 |
| | | | | 11 | 14 |
| | | 1 | 1 | 2 | 2 |
| | | | | 3 | 4 |
| | | 3 | 5 | 16 | 18 |
| | | 2 | 3 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 13 | 15 |
| | | | | 1 | 2 |
| | | | | | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Dementia with Lewy bodies | 1 | 1 |
| Demyelinating polyneuropathy | 1 | 2 |
| Demyelination | 1 | 3 |
| Depressed level of consciousness | 86 | 106 |
| Diplegia | 3 | 3 |
| Disturbance in attention | 112 | 166 |
| Dizziness | 2,153 | 3,672 |
| Dizziness exertional | 8 | 11 |
| Dizziness postural | 69 | 123 |
| Dreamy state | 1 | 1 |
| Drooling | 7 | 9 |
| Dysaesthesia | 22 | 30 |
| Dysarthria | 59 | 80 |
| Dysgeusia | 226 | 462 |
| Dysgraphia | 2 | 2 |
| Dyskinesia | 19 | 28 |
| Dyslexia | 1 | 2 |
| Dysmetria | 1 | 1 |
| Dysstasia | 41 | 63 |
| Dystonia | 5 | 7 |
| Encephalitis post immunisation | 1 | 2 |
| Encephalopathy | 6 | 7 |
| Epilepsy | 72 | 82 |
| Essential tremor | 2 | 2 |
| Exertional headache | 1 | 2 |
| Extensor plantar response | 3 | 3 |
| Extrapyramidal disorder | 3 | 3 |
| Facial nerve disorder | 4 | 6 |
| Facial neuralgia | 8 | 9 |
| Facial paralysis | 304 | 438 |
| Facial paresis | 55 | 72 |
| Facial spasm | 4 | 9 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 3 |
| | | 2 | 2 | 84 | 104 |
| | | | | 3 | 3 |
| | | 42 | 77 | 70 | 89 |
| 44 | 45 | 970 | 2053 | 1183 | 1619 |
| | | 1 | 4 | 7 | 7 |
| | | 14 | 35 | 55 | 88 |
| | | | | 1 | 1 |
| | | 4 | 5 | 3 | 4 |
| | | 9 | 16 | 13 | 14 |
| | | 9 | 18 | 50 | 62 |
| | | 113 | 313 | 113 | 149 |
| | | 1 | 1 | 1 | 1 |
| | | 6 | 10 | 13 | 18 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 17 | 28 | 24 | 35 |
| | | | | 5 | 7 |
| | | | | 1 | 2 |
| | | | | 6 | 7 |
| | | | | 72 | 82 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | 2 | 4 | 4 |
| | | 1 | 2 | 7 | 7 |
| 1 | 1 | 1 | 3 | 303 | 435 |
| | | 6 | 11 | 49 | 61 |
| | | | 3 | 4 | 6 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Febrile convulsion | 14 | 15 |
| Fine motor skill dysfunction | 1 | 5 |
| Formication | 14 | 25 |
| Freezing phenomenon | | 1 |
| Generalised tonic-clonic seizure | 26 | 33 |
| Gliositis | 1 | 1 |
| Guillain-Barre syndrome | 20 | 24 |
| Haemorrhage intracranial | 1 | 5 |
| Haemorrhagic stroke | 7 | 11 |
| Hand-eye coordination impaired | | 2 |
| Headache | 5,618 | 10,042 |
| Head discomfort | 73 | 132 |
| Head titubation | 2 | 3 |
| Hemianaesthesia | 14 | 14 |
| Hemianopia heteronymous | 1 | 1 |
| Hemianopia homonymous | 2 | 2 |
| Hemidysaesthesia | 4 | 4 |
| Hemihyperaesthesia | 1 | 1 |
| Hemiparaesthesia | 30 | 31 |
| Hemiparesis | 37 | 53 |
| Hemiplegia | 21 | 23 |
| Hemiplegic migraine | 2 | 2 |
| Hoffmann's sign | 1 | 1 |
| Horner's syndrome | 1 | 2 |
| Hyperaesthesia | 29 | 61 |
| Hypergeusia | 1 | 1 |
| Hyperkinesia | 1 | 1 |
| Hyperreflexia | 3 | 3 |
| Hypersomnia | 65 | 112 |
| Hypertonia | 2 | 5 |
| Hypoaesthesia | 528 | 996 |
| Hypogeusia | 5 | 11 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 3 | 11 | 12 |
| | | 1 | 5 | | |
| | | 7 | 15 | 7 | 10 |
| | | | 1 | | |
| | | | | 26 | 33 |
| | | | | 1 | 1 |
| | | 1 | 1 | 19 | 23 |
| | | | | 1 | 5 |
| | | | | 7 | 11 |
| | | | | | 2 |
| 77 | 84 | 2528 | 5819 | 3090 | 4223 |
| 1 | 1 | 43 | 88 | 30 | 44 |
| | | 2 | 3 | | |
| | | 1 | 1 | 13 | 13 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 30 | 31 |
| | | | | 37 | 53 |
| | | | | 21 | 23 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | 16 | 41 | 13 | 20 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | 31 | 66 | 34 | 46 |
| | | | 1 | 2 | 4 |
| 4 | 4 | 260 | 613 | 268 | 383 |
| | | 4 | 10 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Hypoglossal nerve disorder | 1 | 1 |
| Hypokinesia | 19 | 29 |
| Hyporeflexia | 3 | 5 |
| Hyporesponsive to stimuli | 2 | 3 |
| Hyposmia | 6 | 15 |
| Hypotonia | 16 | 21 |
| Hypotonic-hyporesponsive episode | 10 | 10 |
| Idiopathic intracranial hypertension | 1 | 2 |
| Illrd nerve paralysis | 4 | 4 |
| Incoherent | 3 | 6 |
| Infant irritability | | 3 |
| Intercostal neuralgia | 2 | 3 |
| Intracranial aneurysm | 1 | 1 |
| Intracranial haematoma | 1 | 1 |
| Intracranial pressure increased | 1 | 2 |
| Irregular sleep wake rhythm disorder | 1 | 2 |
| Ischaemic cerebral infarction | 3 | 3 |
| Ischaemic stroke | 30 | 41 |
| IVth nerve paralysis | 2 | 3 |
| IVth nerve paresis | 1 | 1 |
| Lacunar infarction | 1 | 3 |
| Lacunar stroke | | 1 |
| Language disorder | 4 | 5 |
| Lateropulsion | 1 | 1 |
| Lethargy | 275 | 513 |
| Leukoencephalopathy | 2 | 2 |
| Locked-in syndrome | | 1 |
| Long thoracic nerve palsy | 1 | 1 |
| Loss of consciousness | 269 | 356 |
| Loss of proprioception | | 1 |
| Medication overuse headache | | 1 |
| Memory impairment | 33 | 53 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 11 | 19 | 8 | 10 |
| | | | | 3 | 5 |
| | | 1 | 1 | 1 | 2 |
| | | 4 | 11 | 2 | 4 |
| | | 6 | 9 | 10 | 12 |
| | | 3 | 3 | 7 | 7 |
| | | | | 1 | 2 |
| | | | | 4 | 4 |
| | | 2 | 2 | 1 | 4 |
| | | | 3 | | |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 2 | | |
| | | | | 3 | 3 |
| | | | | 30 | 41 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| 3 | 3 | 79 | 209 | 196 | 304 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 268 | 355 |
| | | | | | 1 |
| | | | | | 1 |
| | | 12 | 24 | 21 | 29 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Meningeal disorder | 2 | 2 |
| Meningism | 2 | 3 |
| Meningitis noninfective | 1 | 1 |
| Mental impairment | 23 | 41 |
| Migraine | 310 | 570 |
| Migraine with aura | 25 | 34 |
| Mononeuropathy | 2 | 5 |
| Monoparesis | 13 | 16 |
| Monoplegia | 21 | 26 |
| Motor dysfunction | 11 | 16 |
| Movement disorder | 51 | 91 |
| Multiple sclerosis | 1 | 4 |
| Multiple sclerosis relapse | 5 | 10 |
| Muscle contractions involuntary | 13 | 22 |
| Muscle spasticity | 3 | 4 |
| Muscle tone disorder | 1 | 2 |
| Myasthenia gravis | 3 | 3 |
| Myasthenia gravis crisis | 1 | 1 |
| Myelitis transverse | 9 | 11 |
| Myoclonus | 11 | 13 |
| Narcolepsy | 3 | 4 |
| Nerve compression | 6 | 12 |
| Nerve degeneration | 1 | 2 |
| Nervous system disorder | 21 | 25 |
| Neuralgia | 76 | 114 |
| Neuralgic amyotrophy | 5 | 8 |
| Neuritis | 2 | 7 |
| Neurological symptom | 10 | 11 |
| Neurologic neglect syndrome | 2 | 2 |
| Neuromuscular pain | 1 | 1 |
| Neuromyopathy | 1 | 1 |
| Neuropathy peripheral | 35 | 49 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | | | 23 | 41 |
| | | 90 | 257 | 220 | 313 |
| | | 10 | 15 | 15 | 19 |
| | | | | 2 | 5 |
| | | 1 | 3 | 12 | 13 |
| | | | | 21 | 26 |
| | | 3 | 4 | 8 | 12 |
| | | 19 | 50 | 32 | 41 |
| | | | | 1 | 4 |
| | | | | 5 | 10 |
| | | 6 | 12 | 7 | 10 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 9 | 11 |
| | | 1 | 2 | 10 | 11 |
| | | | | 3 | 4 |
| | | 2 | 8 | 4 | 4 |
| | | | | 1 | 2 |
| | | 8 | 8 | 13 | 17 |
| | | 29 | 60 | 47 | 54 |
| 1 | 1 | 2 | 4 | 3 | 4 |
| | | | 3 | 2 | 4 |
| | | 4 | 4 | 6 | 7 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 35 | 49 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Neurotoxicity | 2 | 2 |
| Noninfective encephalitis | 3 | 4 |
| Numb chin syndrome | 1 | 1 |
| Nystagmus | 8 | 12 |
| Occipital neuralgia | 4 | 5 |
| Opisthotonus | 1 | 1 |
| Optic neuritis | 8 | 10 |
| Orthostatic intolerance | | 1 |
| Paraesthesia | 870 | 1,495 |
| Paraesthesia mucosal | | 1 |
| Paralysis | 37 | 51 |
| Paraparesis | 4 | 5 |
| Paraplegia | 1 | 2 |
| Paresis | 9 | 12 |
| Paresis cranial nerve | | 1 |
| Parkinsonism | 3 | 3 |
| Parkinson's disease | 2 | 3 |
| Parosmia | 38 | 64 |
| Partial seizures | 3 | 4 |
| Patient elopement | | 1 |
| Peripheral motor neuropathy | | 1 |
| Peripheral nerve paresis | 1 | 1 |
| Peripheral sensorimotor neuropathy | 1 | 1 |
| Peripheral sensory neuropathy | 5 | 6 |
| Peroneal nerve palsy | 4 | 7 |
| Persistent postural-perceptual dizziness | 1 | 1 |
| Petit mal epilepsy | 6 | 9 |
| Pleocytosis | 1 | 1 |
| Polyneuropathy | 1 | 3 |
| Poor quality sleep | 42 | 81 |
| Posterior reversible encephalopathy syndrome | | 1 |
| Post herpetic neuralgia | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | 2 | 4 | 6 | 8 |
| | | 2 | 3 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 8 | 10 |
| | | | | | 1 |
| 5 | 5 | 349 | 822 | 521 | 673 |
| | | | 1 | | |
| | | | | 37 | 51 |
| | | | | 4 | 5 |
| | | | | 1 | 2 |
| | | | 2 | 9 | 10 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 2 | 3 |
| | | 21 | 43 | 17 | 21 |
| | | | | 3 | 4 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 4 |
| | | 1 | 2 | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 6 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | 19 | 50 | 23 | 31 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Postictal state | 2 | 3 |
| Post-traumatic neuralgia | 1 | 1 |
| Presyncope | 244 | 381 |
| Primary cough headache | 1 | 3 |
| Primary headache associated with sexual activity | | 1 |
| Psychogenic seizure | 2 | 2 |
| Psychomotor hyperactivity | 7 | 10 |
| Psychomotor skills impaired | 2 | 2 |
| Pyramidal tract syndrome | 1 | 1 |
| Quadrantanopia | 1 | 1 |
| Quadriparesis | 2 | 2 |
| Radiculitis brachial | | 1 |
| Radiculopathy | 1 | 4 |
| Reduced facial expression | 3 | 6 |
| Repetitive speech | 1 | 1 |
| Resting tremor | 1 | 1 |
| Restless legs syndrome | 8 | 14 |
| Retinal migraine | 3 | 4 |
| Retrograde amnesia | 3 | 3 |
| Reversible cerebral vasoconstriction syndrome | 1 | 1 |
| Ruptured cerebral aneurysm | 1 | 1 |
| Sciatica | 12 | 18 |
| Sciatic nerve neuropathy | | 1 |
| Sedation | 6 | 9 |
| Seizure | 158 | 203 |
| Seizure cluster | 1 | 1 |
| Seizure like phenomena | 2 | 3 |
| Sensorimotor disorder | 1 | 2 |
| Sensory disturbance | 31 | 56 |
| Sensory loss | 25 | 42 |
| Serotonin syndrome | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | 82 | 166 | 162 | 215 |
| | | 1 | 1 | | 2 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 4 | 5 | 6 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 4 |
| | | 1 | 3 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 4 | 7 | 10 |
| | | | | 3 | 4 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 7 | 10 | 5 | 8 |
| | | | | | 1 |
| | | 3 | 6 | 3 | 3 |
| | | | | 158 | 203 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 2 |
| | | 18 | 38 | 13 | 18 |
| | | 2 | 14 | 23 | 28 |
| | | | | | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Sinus headache | 30 | 48 |
| Sleep deficit | 1 | 2 |
| Sleep paralysis | 5 | 6 |
| Slow response to stimuli | 1 | 4 |
| Slow speech | 5 | 5 |
| Somnolence | 306 | 532 |
| Speech disorder | 61 | 93 |
| Spinal cord disorder | 2 | 2 |
| Status epilepticus | 11 | 12 |
| Stiff leg syndrome | | 1 |
| Stupor | 5 | 7 |
| Subarachnoid haemorrhage | 4 | 5 |
| Sudden onset of sleep | 1 | 1 |
| Syncope | 536 | 706 |
| Tardive dyskinesia | 1 | 1 |
| Taste disorder | 62 | 114 |
| Temporal lobe epilepsy | 1 | 1 |
| Tension headache | 45 | 78 |
| Thermohypoaesthesia | 1 | 1 |
| Thoracic outlet syndrome | 1 | 1 |
| Thrombotic stroke | 2 | 2 |
| Thunderclap headache | 1 | 2 |
| Tongue biting | 3 | 3 |
| Tonic clonic movements | 6 | 7 |
| Tonic convulsion | 9 | 9 |
| Transient global amnesia | 2 | 3 |
| Transient ischaemic attack | 41 | 52 |
| Tremor | 440 | 735 |
| Trigeminal nerve disorder | 6 | 7 |
| Trigeminal neuralgia | 12 | 15 |
| Trigeminal neuritis | | 1 |
| Tunnel vision | 12 | 17 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 14 | 22 | 16 | 26 |
| | | | | 1 | 2 |
| | | 3 | 4 | 2 | 2 |
| | | | 2 | 1 | 2 |
| | | | | 5 | 5 |
| | | 149 | 316 | 157 | 216 |
| 1 | 1 | 31 | 52 | 30 | 41 |
| | | | | 2 | 2 |
| | | | | 11 | 12 |
| | | | | | 1 |
| | | | 1 | 5 | 6 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| 3 | 3 | 1 | 1 | 535 | 705 |
| | | | | 1 | 1 |
| | | 28 | 74 | 34 | 40 |
| | | | | 1 | 1 |
| | | 10 | 24 | 35 | 54 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | | 6 | 7 |
| | | | | 9 | 9 |
| | | | 1 | 2 | 2 |
| | | | | 41 | 52 |
| 3 | 3 | 147 | 318 | 293 | 417 |
| | | 1 | 2 | 5 | 5 |
| | | 4 | 5 | 8 | 10 |
| | | | 1 | | |
| | | 1 | 1 | 11 | 16 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-------|---------|-------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ulnar nerve palsy | 1 | 1 | | | 1 | 1 | | |
| Unresponsive to stimuli | 31 | 53 | | | | 1 | 31 | 52 |
| Vascular dementia | 3 | 4 | | | | | 3 | 4 |
| Vascular encephalopathy | 1 | 1 | | | | | 1 | 1 |
| Vascular headache | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Vestibular migraine | 1 | 2 | | | 1 | 1 | | 1 |
| Visual field defect | 9 | 13 | | | 4 | 7 | 5 | 6 |
| VIth nerve paralysis | 6 | 6 | | | | | 6 | 6 |
| VIth nerve paresis | 1 | 1 | | | | | 1 | 1 |
| Vocal cord paralysis | | 1 | | | | 1 | | |
| White matter lesion | 1 | 1 | | | | | 1 | 1 |
| Writer's cramp | | 1 | | | | | | 1 |
| | 15,274 | 25,774 | 145 | 154 | 5592 | 12594 | 9682 | 13180 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abortion | 2 | 2 | | | 2 | 2 |
| Abortion missed | 1 | 1 | | | 1 | 1 |
| Abortion spontaneous | 17 | 24 | | | 17 | 24 |
| Foetal death | 1 | 1 | | | 1 | 1 |
| Foetal growth restriction | 2 | 2 | | | 2 | 2 |
| Morning sickness | 2 | 3 | | | 2 | 3 |
| Premature baby | 2 | 2 | | | 2 | 2 |
| Premature rupture of membranes | | 1 | | | | 1 |
| Uterine contractions during pregnancy | | 1 | | 1 | | |
| | 27 | 37 | | 1 | 27 | 36 |

System Organ Class

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System Organ Class

Product issues

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | | |
|-------------------------------------|--|--|-------------|-----|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Device breakage | | 1 | | | | 1 | |
| Liquid product physical issue | 5 | 29 | 5 | 29 | | | |
| Needle issue | 2 | 10 | 1 | 9 | 1 | 1 | |
| Oversensing | 3 | 4 | | 1 | 3 | 3 | |
| Product colour issue | 2 | 38 | 2 | 38 | | | |
| Product complaint | 2 | 4 | 1 | 3 | 1 | 1 | |
| Product container issue | 2 | 2 | 2 | 2 | | | |
| Product deposit | | 1 | | 1 | | | |
| Product formulation issue | | 1 | | | | 1 | |
| Product leakage | 2 | 12 | 2 | 12 | | | |
| Product lot number issue | 1 | 1 | 1 | 1 | | | |
| Product packaging quantity issue | 1 | 21 | 1 | 21 | | | |
| Product quality issue | 4 | 8 | 4 | 8 | | | |
| Product supply issue | 3 | 4 | 3 | 4 | | | |
| Product taste abnormal | 1 | 1 | 1 | 1 | | | |
| Product temperature excursion issue | 165 | 280 | 164 | 279 | 1 | 1 | |
| Suspected counterfeit product | | 1 | | 1 | | | |
| Suspected product quality issue | | 5 | | 5 | | | |
| Syringe issue | 2 | 5 | 2 | 5 | | | |
| | 195 | 428 | 189 | 420 | 6 | 8 | |

System Organ Class

Psychiatric disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Non Interventional Study | | Spontaneous | | | |
|-----------------------|--|--|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal behaviour | 5 | 7 | | | 3 | 4 | 2 | 3 |
| Abnormal dreams | 15 | 37 | | | 9 | 27 | 6 | 10 |
| Affect lability | 2 | 3 | | | 2 | 3 | | |
| Aggression | 8 | 11 | | | | 2 | 8 | 9 |
| Agitation | 41 | 66 | | | 11 | 27 | 30 | 39 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Anger | 3 | 9 |
| Anorgasmia | | 1 |
| Anxiety | 165 | 306 |
| Anxiety disorder | 1 | 1 |
| Apathy | 16 | 21 |
| Automatism | 1 | 1 |
| Autoscopy | 2 | 2 |
| Behaviour disorder | 4 | 4 |
| Belligerence | 1 | 1 |
| Bipolar disorder | 1 | 1 |
| Body dysmorphic disorder | 1 | 1 |
| Bradyphrenia | 11 | 13 |
| Bruxism | 1 | 2 |
| Catatonia | 1 | 1 |
| Claustrophobia | | 1 |
| Communication disorder | 8 | 10 |
| Confusional state | 227 | 315 |
| Daydreaming | 1 | 1 |
| Decreased interest | 2 | 4 |
| Delirium | 36 | 57 |
| Delusion | 2 | 3 |
| Delusional disorder, unspecified type | 1 | 1 |
| Delusional perception | | 3 |
| Depersonalisation/derealisation disorder | | 3 |
| Depressed mood | 31 | 48 |
| Depression | 18 | 31 |
| Derealisation | 3 | 6 |
| Disinhibition | 1 | 1 |
| Disorganised speech | 4 | 5 |
| Disorientation | 76 | 103 |
| Dissociation | 6 | 10 |
| Dissociative disorder | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 7 | 1 | 2 |
| | | | | | 1 |
| | | 82 | 185 | 83 | 121 |
| | | 1 | 1 | | |
| | | 9 | 9 | 7 | 12 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 9 | 11 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 5 | 6 | 3 | 4 |
| | | 64 | 105 | 163 | 210 |
| | | 1 | 1 | | |
| | | 2 | 3 | | 1 |
| | | | | 36 | 57 |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | | 2 | | 1 |
| | | | 2 | | 1 |
| | | 8 | 21 | 23 | 27 |
| | | 7 | 14 | 11 | 17 |
| | | 3 | 5 | | 1 |
| | | | | 1 | 1 |
| | | 2 | 3 | 2 | 2 |
| | | 20 | 33 | 56 | 70 |
| | | 3 | 6 | 3 | 4 |
| | | 1 | 1 | | |

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 * AE=Adverse Event
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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Distractibility | | 1 |
| Dysphemia | 5 | 6 |
| Dysphoria | | 1 |
| Eating disorder | 16 | 28 |
| Emotional disorder | 4 | 9 |
| Emotional distress | 12 | 15 |
| Enuresis | | 3 |
| Euphoric mood | 5 | 9 |
| Fear | 7 | 24 |
| Fear of death | | 1 |
| Fear of falling | 1 | 1 |
| Fear of injection | 1 | 2 |
| Feeling of despair | 3 | 3 |
| Flashback | 1 | 1 |
| Frustration tolerance decreased | 2 | 5 |
| Hallucination | 54 | 76 |
| Hallucination, auditory | 6 | 8 |
| Hallucination, olfactory | 1 | 2 |
| Hallucinations, mixed | 5 | 5 |
| Hallucination, tactile | | 1 |
| Hallucination, visual | 7 | 15 |
| Head banging | 1 | 1 |
| Helplessness | | 1 |
| Hydrophobia | | 1 |
| Hypersexuality | 1 | 1 |
| Hypervigilance | | 1 |
| Hyposomnia | 1 | 1 |
| Illness anxiety disorder | | 1 |
| Illusion | 1 | 1 |
| Immunisation anxiety related reaction | 6 | 8 |
| Impulsive behaviour | | 1 |
| Indifference | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 2 | 4 | 4 |
| | | | | | 1 |
| | | 10 | 19 | 6 | 9 |
| | | | 5 | 4 | 4 |
| | | 2 | 4 | 10 | 11 |
| | | | 1 | | 2 |
| | | 4 | 7 | 1 | 2 |
| | | 6 | 18 | 1 | 6 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 2 | 5 | | |
| | | 1 | 1 | 53 | 75 |
| | | | | 6 | 8 |
| | | | | 1 | 2 |
| | | | | 5 | 5 |
| | | | | | 1 |
| | | | | 7 | 15 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 6 | 8 | | |
| | | | 1 | | |
| | | | | 1 | 2 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Initial insomnia | 9 | 16 |
| Insomnia | 327 | 546 |
| Intentional self-injury | | 1 |
| Intrusive thoughts | | 1 |
| Irritability | 44 | 59 |
| Lack of spontaneous speech | 2 | 2 |
| Laziness | 1 | 3 |
| L bido decreased | 1 | 1 |
| Listless | 5 | 5 |
| Logorrhoea | 3 | 3 |
| Loss of libido | 1 | 1 |
| Major depression | 1 | 1 |
| Mania | 1 | 2 |
| Mental disorder | 9 | 17 |
| Mental fatigue | 21 | 29 |
| Mental status changes | 1 | 2 |
| Middle insomnia | 29 | 54 |
| Mood altered | 8 | 11 |
| Mood disorder due to a general medical condition | 1 | 1 |
| Mood swings | 6 | 6 |
| Mutism | 2 | 3 |
| Near death experience | 4 | 4 |
| Negative thoughts | | 1 |
| Nervousness | 70 | 116 |
| Neuropsychiatric symptoms | 1 | 1 |
| Nightmare | 27 | 42 |
| Obsessive-compulsive symptom | | 1 |
| Panic attack | 18 | 31 |
| Panic disorder | 1 | 2 |
| Panic reaction | 16 | 21 |
| Paranoia | 1 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 11 | 4 | 5 |
| 1 | 1 | 153 | 323 | 174 | 223 |
| | | | 1 | | 1 |
| | | 28 | 39 | 16 | 20 |
| | | 1 | 1 | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 4 | 4 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | 8 | 15 | 1 | 2 |
| | | 4 | 8 | 17 | 21 |
| | | 1 | 1 | | 1 |
| | | 20 | 41 | 9 | 13 |
| | | 6 | 8 | 2 | 3 |
| | | | | 1 | 1 |
| | | 3 | 3 | 3 | 3 |
| | | 1 | 1 | 1 | 2 |
| | | | | 4 | 4 |
| | | | | | 1 |
| | | 42 | 80 | 28 | 36 |
| | | 1 | 1 | | |
| | | 15 | 27 | 12 | 15 |
| | | | | | 1 |
| | | 5 | 13 | 13 | 18 |
| | | 1 | 1 | | 1 |
| | | 7 | 11 | 9 | 10 |
| | | | 2 | 1 | 2 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Persistent depressive disorder | 2 | 2 |
| Personality change | 8 | 10 |
| Phonophobia | 3 | 4 |
| Post-traumatic stress disorder | | 2 |
| Posturing | | 1 |
| Pressure of speech | 1 | 2 |
| Pseudodementia | 1 | 1 |
| Psychiatric symptom | 2 | 3 |
| Psychological factor affecting medical condition | | 1 |
| Psychotic behaviour | | 1 |
| Psychotic disorder | 4 | 4 |
| Psychotic disorder due to a general medical condition | 1 | 1 |
| Psychotic symptom | 2 | 2 |
| Reading disorder | 1 | 1 |
| Restlessness | 50 | 91 |
| Self-injurious ideation | 1 | 1 |
| Sense of a foreshortened future | 2 | 2 |
| Sitophobia | | 1 |
| Sleep attacks | 1 | 3 |
| Sleep disorder | 69 | 134 |
| Sleep disorder due to a general medical condition | 4 | 11 |
| Sleep disorder due to general medical condition, hypersomnia type | 1 | 1 |
| Sleep disorder due to general medical condition, insomnia type | 11 | 17 |
| Sleep inertia | 1 | 1 |
| Sleep talking | 1 | 3 |
| Sleep terror | 2 | 3 |
| Social avoidant behaviour | 1 | 1 |
| Social fear | 1 | 1 |
| Somatic symptom disorder | 2 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 2 | 7 | 8 |
| | | 1 | 2 | 2 | 2 |
| | | | 2 | | |
| | | | | | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 21 | 50 | 29 | 41 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | 2 |
| | | 35 | 84 | 34 | 50 |
| | | | | | |
| | | 3 | 7 | 1 | 4 |
| | | 1 | 1 | | |
| | | 6 | 11 | 5 | 6 |
| | | | | 1 | 1 |
| | | 1 | 2 | | 1 |
| | | 2 | 2 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 3 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Sopor | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Staring | 4 | 6 | | | 1 | 1 | 3 | 5 |
| Stereotypy | 1 | 1 | | | | | 1 | 1 |
| Stress | 20 | 34 | | | 16 | 30 | 4 | 4 |
| Substance abuse | | 1 | | | | | | 1 |
| Suicidal ideation | 5 | 5 | | | | | 5 | 5 |
| Suicide attempt | 2 | 2 | | | | | 2 | 2 |
| Tachyphrenia | 2 | 6 | | | 1 | 5 | 1 | 1 |
| Tearfulness | 2 | 5 | | | 2 | 3 | | 2 |
| Tension | 9 | 12 | | | 7 | 9 | 2 | 3 |
| Terminal insomnia | 4 | 7 | | | 3 | 6 | 1 | 1 |
| Thinking abnormal | 14 | 22 | | | 10 | 16 | 4 | 6 |
| Tic | 1 | 3 | | | | 2 | 1 | 1 |
| Vomiting psychogenic | | 1 | | | | | | 1 |
| | 1,685 | 2,729 | 1 | 1 | 698 | 1392 | 987 | 1337 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 23 | 39 | | | 23 | 39 |
| Anuria | 3 | 4 | | | 3 | 4 |
| Azotaemia | 1 | 1 | | | 1 | 1 |
| Bladder discomfort | | 3 | | 3 | | |
| Bladder disorder | 5 | 5 | 1 | 1 | 4 | 4 |
| Bladder irritation | 1 | 1 | | | 1 | 1 |
| Bladder pain | 1 | 3 | 1 | 2 | | 1 |
| Choluria | 1 | 1 | | | 1 | 1 |
| Chromaturia | 9 | 19 | 7 | 14 | 2 | 5 |
| Chronic kidney disease | 1 | 2 | | | 1 | 2 |

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System Organ Class

Renal and urinary disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------------|--|--|
| Costovertebral angle tenderness | 1 | 3 |
| Cystitis haemorrhagic | 4 | 4 |
| Dysuria | 17 | 24 |
| Genitourinary symptom | 1 | 1 |
| Glomerulonephritis | 1 | 1 |
| Glomerulonephritis minimal lesion | 1 | 1 |
| Haematuria | 13 | 16 |
| Haemorrhage urinary tract | 3 | 4 |
| Hydronephrosis | 1 | 1 |
| Hypertonic bladder | 1 | 2 |
| Incontinence | 8 | 13 |
| Leukocyturia | 1 | 1 |
| Loss of bladder sensation | 1 | 1 |
| Micturition disorder | 3 | 4 |
| Micturition urgency | 6 | 9 |
| Nephritis | 1 | 1 |
| Nephrolithiasis | 2 | 3 |
| Nephropathy | 2 | 2 |
| Nephrotic syndrome | 2 | 3 |
| Neurogenic bladder | 1 | 1 |
| Nocturia | | 2 |
| Oliguria | 1 | 1 |
| Pollakiuria | 15 | 28 |
| Polyuria | 5 | 11 |
| Proteinuria | 3 | 3 |
| Renal atrophy | 1 | 1 |
| Renal colic | 2 | 2 |
| Renal disorder | 6 | 9 |
| Renal failure | 18 | 27 |
| Renal haemorrhage | 1 | 1 |
| Renal impairment | 6 | 7 |
| Renal pain | 32 | 54 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | 1 | 1 |
| | | 4 | 4 |
| 9 | 14 | 8 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 7 | 8 | 9 |
| | | 3 | 4 |
| | | 1 | 1 |
| 1 | 2 | | |
| 2 | 4 | 6 | 9 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 4 |
| 1 | 4 | 5 | 5 |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |
| 10 | 22 | 5 | 6 |
| 3 | 9 | 2 | 2 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 2 | 4 | 4 | 5 |
| | | 18 | 27 |
| | | 1 | 1 |
| | | 6 | 7 |
| 13 | 30 | 19 | 24 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urethral disorder | 1 | 1 | 1 | 1 | | |
| Urethral haemorrhage | 1 | 1 | | | 1 | 1 |
| Urge incontinence | | 1 | | 1 | | |
| Urinary incontinence | 19 | 28 | 5 | 9 | 14 | 19 |
| Urinary retention | 19 | 26 | 1 | 1 | 18 | 25 |
| Urinary tract disorder | 1 | 2 | 1 | 1 | | 1 |
| Urinary tract inflammation | 1 | 1 | | | 1 | 1 |
| Urinary tract pain | 1 | 1 | | | 1 | 1 |
| Urine abnormality | 2 | 2 | 2 | 2 | | |
| Urine flow decreased | 2 | 2 | | | 2 | 2 |
| Urine odour abnormal | 3 | 3 | 2 | 2 | 1 | 1 |
| | 255 | 387 | 72 | 142 | 183 | 245 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal withdrawal bleeding | 1 | 1 | | | 1 | 1 | | |
| Adnexa uteri pain | 5 | 6 | | | 1 | 2 | 4 | 4 |
| Breast cyst | 2 | 2 | | | | | 2 | 2 |
| Breast discharge | 4 | 4 | | | 4 | 4 | | |
| Breast discomfort | 2 | 6 | | | 1 | 3 | 1 | 3 |
| Breast enlargement | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Breast inflammation | 2 | 2 | | | 2 | 2 | | |
| Breast mass | 5 | 7 | | | 2 | 3 | 3 | 4 |
| Breast milk discolouration | | 1 | | | | 1 | | |
| Breast oedema | 1 | 1 | | | | | 1 | 1 |
| Breast pain | 44 | 68 | 1 | 1 | 20 | 36 | 24 | 32 |
| Breast swelling | 12 | 20 | | | 6 | 13 | 6 | 7 |
| Breast tenderness | 8 | 11 | | | 3 | 5 | 5 | 6 |

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

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Cervix oedema | | 1 |
| Dysmenorrhoea | 9 | 16 |
| Endometriosis | 1 | 1 |
| Erectile dysfunction | 10 | 12 |
| Genital lesion | 1 | 1 |
| Genital pain | 2 | 2 |
| Genital ulceration | 3 | 3 |
| Hypomenorrhoea | 1 | 1 |
| Infertility | 2 | 2 |
| Menopausal symptoms | 1 | 3 |
| Menorrhagia | 19 | 27 |
| Menstrual disorder | 15 | 23 |
| Menstruation delayed | 12 | 13 |
| Menstruation irregular | 4 | 17 |
| Metrorrhagia | 9 | 14 |
| Nipple pain | 5 | 11 |
| Nipple swelling | | 4 |
| Oligomenorrhoea | 1 | 1 |
| Ovulation pain | 1 | 1 |
| Pelvic discomfort | 1 | 1 |
| Pelvic pain | 9 | 15 |
| Penile haemorrhage | | 1 |
| Penile swelling | | 1 |
| Perineal pain | 1 | 1 |
| Polymenorrhoea | 1 | 3 |
| Postmenopausal haemorrhage | 3 | 3 |
| Premenstrual syndrome | 2 | 2 |
| Prostatitis | 1 | 1 |
| Prostatomegaly | 1 | 2 |
| Pruritus genital | | 1 |
| Scrotal disorder | 1 | 1 |
| Scrotal erythema | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 5 | 11 | 4 | 5 |
| | | | | 1 | 1 |
| | | | | 10 | 12 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 3 | | |
| | | 7 | 12 | 12 | 15 |
| | | 12 | 20 | 3 | 3 |
| | | 3 | 4 | 9 | 9 |
| | | 2 | 14 | 2 | 3 |
| | | 4 | 9 | 5 | 5 |
| | | 2 | 7 | 3 | 4 |
| | | | 4 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 9 | 6 | 6 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | 1 |
| | | | | 3 | 3 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | 1 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|--------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Scrotal exfoliation | | 1 | | | | | | | 1 |
| Scrotal inflammation | 1 | 1 | | | 1 | 1 | | | |
| Scrotal pain | 2 | 4 | | | 1 | 2 | 1 | 2 | |
| Scrotal swelling | | 1 | | | | | | | 1 |
| Suppressed lactation | | 4 | | | | 3 | | | 1 |
| Testicular pain | 3 | 3 | | | 2 | 2 | 1 | 1 | |
| Testicular swelling | | 1 | | | | 1 | | | |
| Testicular torsion | 1 | 1 | | | | | 1 | 1 | |
| Uterine haemorrhage | 2 | 3 | | | | | 2 | 3 | |
| Uterine inflammation | 1 | 1 | | | 1 | 1 | | | |
| Uterine pain | 1 | 1 | | | | | 1 | 1 | |
| Vaginal discharge | 2 | 4 | | | 2 | 4 | | | |
| Vaginal disorder | 1 | 1 | | | 1 | 1 | | | |
| Vaginal haemorrhage | 17 | 29 | | | 5 | 9 | 12 | 20 | |
| Vaginal lesion | 1 | 1 | | | 1 | 1 | | | |
| Vulval disorder | 1 | 2 | | | 1 | 1 | | | 1 |
| Vulvovaginal burning sensation | 2 | 2 | | | 1 | 1 | 1 | 1 | |
| Vulvovaginal pain | 1 | 1 | | | 1 | 1 | | | |
| Vulvovaginal pruritus | 1 | 3 | | | 1 | 2 | | | 1 |
| Vulvovaginal rash | | 1 | | | | | | | 1 |
| Vulvovaginal swelling | 1 | 2 | | | | | 1 | 2 | |
| Withdrawal bleed | 1 | 1 | | | 1 | 1 | | | |
| | 244 | 386 | 1 | 1 | 108 | 207 | 136 | 179 | |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute pulmonary oedema | 9 | 10 | | | | | 9 | 10 |
| Acute respiratory distress syndrome | 7 | 10 | | | | | 7 | 10 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Acute respiratory failure | 15 | 25 |
| Allergic cough | 1 | 3 |
| Allergic respiratory symptom | | 1 |
| Allergic sinusitis | 1 | 1 |
| Aphonia | 20 | 28 |
| Apnoea | 5 | 6 |
| Asphyxia | 6 | 8 |
| Aspiration | 7 | 10 |
| Asthma | 88 | 128 |
| Asthma exercise induced | 1 | 1 |
| Asthmatic crisis | 11 | 11 |
| Atelectasis | 6 | 7 |
| Bronchial disorder | 2 | 3 |
| Bronchial hyperreactivity | 1 | 1 |
| Bronchial obstruction | | 1 |
| Bronchial oedema | 1 | 1 |
| Bronchiectasis | 3 | 3 |
| Bronchopneumopathy | 1 | 1 |
| Bronchospasm | 79 | 94 |
| Bronchostenosis | 1 | 1 |
| Catarrh | 5 | 6 |
| Cheyne-Stokes respiration | 1 | 1 |
| Choking | 9 | 15 |
| Choking sensation | 11 | 14 |
| Chronic obstructive pulmonary disease | 23 | 27 |
| Chronic respiratory failure | 2 | 3 |
| Cough | 672 | 1,140 |
| Diaphragmalgia | 1 | 1 |
| Diaphragmatic paralysis | 1 | 1 |
| Diaphragmatic spasm | 2 | 2 |
| Dry throat | 32 | 73 |
| Dysaesthesia pharynx | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 15 | 25 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 6 | 8 | 14 | 20 |
| | | | | 5 | 6 |
| | | | | 6 | 8 |
| | | | | 7 | 10 |
| | | 19 | 40 | 69 | 88 |
| | | | | 1 | 1 |
| | | | | 11 | 11 |
| | | | | 6 | 7 |
| | | 1 | 2 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| 1 | 1 | 14 | 19 | 65 | 75 |
| | | | | 1 | 1 |
| | | 1 | 2 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 9 | 15 |
| | | 2 | 2 | 9 | 12 |
| | | 1 | 2 | 22 | 25 |
| | | | | 2 | 3 |
| 3 | 3 | 329 | 651 | 343 | 489 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 11 | 39 | 21 | 34 |
| | | 1 | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Dysphonia | 87 | 143 |
| Dyspnoea | 1,402 | 2,051 |
| Dyspnoea at rest | 9 | 10 |
| Dyspnoea exertional | 46 | 68 |
| Epiglottic oedema | 2 | 3 |
| Epistaxis | 74 | 126 |
| Grunting | 1 | 3 |
| Haemoptysis | 15 | 27 |
| Haemothorax | 1 | 1 |
| Hiccups | 4 | 7 |
| Hypercapnia | 2 | 2 |
| Hypersensitivity pneumonitis | | 1 |
| Hyperventilation | 38 | 55 |
| Hypopnoea | 18 | 23 |
| Hypoventilation | 2 | 3 |
| Hypoxia | 35 | 42 |
| Increased bronchial secretion | 5 | 7 |
| Increased upper airway secretion | 8 | 16 |
| Increased viscosity of bronchial secretion | 1 | 1 |
| Increased viscosity of upper respiratory secretion | 2 | 4 |
| Interstitial lung disease | 4 | 4 |
| Intranasal hypoaesthesia | 1 | 3 |
| Intranasal paraesthesia | 4 | 7 |
| Irregular breathing | 6 | 7 |
| Laryngeal discomfort | 3 | 3 |
| Laryngeal disorder | 1 | 1 |
| Laryngeal dyspnoea | 4 | 4 |
| Laryngeal erythema | 1 | 1 |
| Laryngeal obstruction | 3 | 3 |
| Laryngeal oedema | 60 | 82 |
| Laryngeal pain | 3 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 44 | 72 | 43 | 71 |
| 4 | 5 | 473 | 777 | 929 | 1274 |
| | | | | 9 | 10 |
| | | 24 | 38 | 22 | 30 |
| | | | | 2 | 3 |
| 1 | 1 | 26 | 64 | 48 | 62 |
| | | | 1 | 1 | 2 |
| | | 4 | 11 | 11 | 16 |
| | | | | 1 | 1 |
| | | 2 | 5 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | | 1 |
| 1 | 1 | 16 | 24 | 22 | 31 |
| | | 2 | 4 | 16 | 19 |
| | | | | 2 | 3 |
| | | 1 | 1 | 34 | 41 |
| | | 2 | 3 | 3 | 4 |
| | | 2 | 7 | 6 | 9 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | | | 4 | 4 |
| | | 1 | 2 | | 1 |
| | | 4 | 7 | | |
| | | 1 | 1 | 5 | 6 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 60 | 82 |
| | | | 2 | 3 | 3 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Laryngeal stenosis | 2 | 2 |
| Laryngospasm | 17 | 22 |
| Larynx irritation | 1 | 1 |
| Lower respiratory tract congestion | 2 | 3 |
| Lung consolidation | | 1 |
| Lung disorder | 15 | 19 |
| Lung infiltration | 6 | 9 |
| Mouth breathing | 2 | 2 |
| Nasal congestion | 111 | 267 |
| Nasal crusting | 1 | 1 |
| Nasal discharge discolouration | | 1 |
| Nasal discomfort | 14 | 25 |
| Nasal disorder | 2 | 3 |
| Nasal dryness | 3 | 7 |
| Nasal obstruction | 1 | 4 |
| Nasal odour | 1 | 2 |
| Nasal oedema | 11 | 20 |
| Nasal pruritus | 5 | 8 |
| Nocturnal dyspnoea | 1 | 1 |
| Obliterative bronchiolitis | 1 | 1 |
| Obstructive airways disorder | 10 | 17 |
| Organising pneumonia | | 1 |
| Oropharyngeal blistering | 5 | 9 |
| Oropharyngeal discomfort | 51 | 77 |
| Oropharyngeal oedema | 7 | 9 |
| Oropharyngeal pain | 548 | 944 |
| Oropharyngeal spasm | 3 | 5 |
| Oropharyngeal swelling | 1 | 2 |
| Orthopnoea | 2 | 5 |
| Painful respiration | 22 | 31 |
| Paranasal sinus discomfort | 10 | 22 |
| Paranasal sinus hypersecretion | 3 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 2 | 16 | 20 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | | | 1 |
| | | 4 | 7 | 11 | 12 |
| | | 2 | 3 | 4 | 6 |
| | | | | 2 | 2 |
| | | 73 | 214 | 38 | 53 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 8 | 16 | 6 | 9 |
| | | 2 | 3 | | |
| | | 2 | 4 | 1 | 3 |
| | | | 1 | 1 | 3 |
| | | | 1 | 1 | 1 |
| | | 3 | 9 | 8 | 11 |
| | | 2 | 5 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 4 | 7 | 13 |
| | | | | | 1 |
| | | | 1 | 5 | 8 |
| | | 20 | 33 | 31 | 44 |
| | | 1 | 2 | 6 | 7 |
| 1 | 1 | 297 | 600 | 251 | 344 |
| | | | | 3 | 5 |
| | | | | 1 | 2 |
| | | | 1 | 2 | 4 |
| | | 11 | 17 | 11 | 14 |
| | | 6 | 18 | 4 | 4 |
| | | 3 | 5 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Paranasal sinus inflammation | | 1 |
| Pharyngeal disorder | 4 | 7 |
| Pharyngeal enanthema | 1 | 1 |
| Pharyngeal erythema | 9 | 16 |
| Pharyngeal haemorrhage | 1 | 1 |
| Pharyngeal hypoaesthesia | 9 | 24 |
| Pharyngeal inflammation | 8 | 16 |
| Pharyngeal mass | 3 | 3 |
| Pharyngeal oedema | 18 | 28 |
| Pharyngeal paraesthesia | 32 | 62 |
| Pharyngeal swelling | 116 | 220 |
| Pharyngeal ulceration | 4 | 5 |
| Pleural effusion | 8 | 14 |
| Pleurisy | 7 | 10 |
| Pleuritic pain | 7 | 14 |
| Pneumonia aspiration | 21 | 28 |
| Pneumonitis | 11 | 14 |
| Productive cough | 50 | 75 |
| Prolonged expiration | | 1 |
| Pulmonary arterial hypertension | 2 | 2 |
| Pulmonary artery thrombosis | 2 | 2 |
| Pulmonary congestion | 6 | 10 |
| Pulmonary embolism | 48 | 59 |
| Pulmonary fibrosis | | 1 |
| Pulmonary infarction | 3 | 4 |
| Pulmonary oedema | 20 | 28 |
| Pulmonary pain | 26 | 34 |
| Pulmonary thrombosis | 8 | 10 |
| Rales | 12 | 17 |
| Respiration abnormal | 18 | 24 |
| Respiratory acidosis | 2 | 2 |
| Respiratory alkalosis | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 2 | 5 | 2 | 2 |
| | | 1 | 1 | | |
| | | 2 | 7 | 7 | 9 |
| | | | | 1 | 1 |
| | | 4 | 12 | 5 | 12 |
| | | 2 | 6 | 6 | 10 |
| | | 2 | 2 | 1 | 1 |
| | | 4 | 5 | 14 | 23 |
| | | 8 | 24 | 24 | 38 |
| 1 | 1 | 35 | 85 | 81 | 135 |
| | | 1 | 1 | 3 | 4 |
| | | | | 8 | 14 |
| | | 1 | 1 | 6 | 9 |
| | | 2 | 4 | 5 | 10 |
| | | | | 21 | 28 |
| | | | 1 | 11 | 13 |
| | | 21 | 33 | 29 | 42 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| 1 | 1 | | | 6 | 10 |
| | | | | 48 | 59 |
| | | | | | 1 |
| | | | | 3 | 4 |
| | | | | 20 | 28 |
| | | 10 | 14 | 16 | 20 |
| 1 | 1 | | | 8 | 10 |
| | | 4 | 4 | 8 | 13 |
| | | 2 | 4 | 16 | 20 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 3 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Respiratory arrest | 14 | 25 |
| Respiratory depression | 5 | 6 |
| Respiratory disorder | 26 | 36 |
| Respiratory distress | 363 | 393 |
| Respiratory failure | 35 | 44 |
| Respiratory fatigue | 6 | 6 |
| Respiratory symptom | 2 | 4 |
| Respiratory tract congestion | 5 | 16 |
| Respiratory tract irritation | 2 | 3 |
| Respiratory tract oedema | 7 | 10 |
| Reversible airways obstruction | 1 | 1 |
| Rhinalgia | 10 | 19 |
| Rhinitis allergic | 5 | 8 |
| Rhinorrhoea | 278 | 450 |
| Rhonchi | 3 | 5 |
| Sinonasal obstruction | | 1 |
| Sinus congestion | 13 | 32 |
| Sinus disorder | 14 | 26 |
| Sinus pain | 14 | 35 |
| Sleep apnoea syndrome | 2 | 2 |
| Sneezing | 55 | 113 |
| Snoring | 1 | 4 |
| Sputum discoloured | | 3 |
| Sputum increased | 1 | 1 |
| Status asthmaticus | | 1 |
| Stertor | 1 | 1 |
| Stridor | 15 | 22 |
| Suffocation feeling | 10 | 12 |
| Tachypnoea | 44 | 65 |
| Throat clearing | 7 | 11 |
| Throat irritation | 143 | 277 |
| Throat tightness | 127 | 286 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 1 | 1 | 13 | 24 |
| | | | | 5 | 6 |
| | | 5 | 9 | 21 | 27 |
| | | 1 | 2 | 362 | 391 |
| | | | 1 | 35 | 43 |
| | | | | 6 | 6 |
| 1 | 1 | 1 | 2 | 1 | 2 |
| | | 5 | 15 | | 1 |
| | | | 1 | 2 | 2 |
| | | | | 7 | 10 |
| | | | | 1 | 1 |
| | | 5 | 14 | 5 | 5 |
| | | 3 | 5 | 2 | 3 |
| 1 | 1 | 197 | 347 | 81 | 103 |
| | | 1 | 1 | 2 | 4 |
| | | | | | 1 |
| | | 9 | 26 | 4 | 6 |
| | | 11 | 22 | 3 | 4 |
| | | 3 | 16 | 11 | 19 |
| | | 1 | 1 | 1 | 1 |
| | | 29 | 80 | 26 | 33 |
| | | 1 | 2 | | 2 |
| | | | 2 | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 15 | 22 |
| | | 2 | 4 | 8 | 8 |
| | | 14 | 21 | 30 | 44 |
| | | 4 | 5 | 3 | 6 |
| 1 | 1 | 59 | 162 | 84 | 115 |
| 2 | 2 | 31 | 97 | 96 | 189 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------------------|--|--|
| Tonsillar disorder | 2 | 2 |
| Tonsillar erythema | 1 | 3 |
| Tonsillar hypertrophy | 11 | 20 |
| Tonsillar inflammation | | 2 |
| Tonsillar ulcer | 1 | 1 |
| Tonsillolith | | 1 |
| Tracheal oedema | 2 | 2 |
| Tracheal pain | 2 | 2 |
| Tracheomalacia | | 1 |
| Upper-airway cough syndrome | 8 | 21 |
| Upper airway obstruction | 4 | 6 |
| Upper respiratory tract congestion | 9 | 34 |
| Upper respiratory tract inflammation | 1 | 1 |
| Use of accessory respiratory muscles | 2 | 2 |
| Vasomotor rhinitis | | 1 |
| Vocal cord disorder | 3 | 4 |
| Vocal cord dysfunction | 1 | 1 |
| Wheezing | 107 | 173 |
| Yawning | 3 | 4 |
| | 5,549 | 8,812 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | 4 | 10 | 7 | 10 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | 6 | 18 | 2 | 3 |
| | | | | 4 | 6 |
| | | 9 | 32 | | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | 26 | 56 | 81 | 117 |
| | | 1 | 2 | 2 | 2 |
| 20 | 21 | 1965 | 3912 | 3584 | 4900 |

System Organ Class

Skin and subcutaneous tissue disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Acne | 8 | 14 |
| Acute febrile neutrophilic dermatosis | 2 | 2 |
| Alopecia | 8 | 14 |
| Angioedema | 153 | 209 |
| Blister | 42 | 72 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 6 | 12 | 2 | 2 |
| | | | | 2 | 2 |
| | | 4 | 9 | 4 | 5 |
| | | | | 153 | 209 |
| | | 13 | 40 | 29 | 32 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Blood blister | 2 | 2 |
| Butterfly rash | 4 | 4 |
| Chronic spontaneous urticaria | 1 | 1 |
| Circumoral oedema | 1 | 2 |
| Circumoral swelling | 1 | 3 |
| Cold sweat | 126 | 228 |
| Cutaneous symptom | 1 | 1 |
| Cutaneous vasculitis | 4 | 4 |
| Decubitus ulcer | | 1 |
| Dermatitis | 11 | 24 |
| Dermatitis acneiform | 1 | 1 |
| Dermatitis allergic | 26 | 55 |
| Dermatitis atopic | 4 | 4 |
| Dermatitis bullous | 12 | 13 |
| Dermatitis contact | | 4 |
| Dermatitis diaper | 1 | 1 |
| Dermatitis exfoliative | 2 | 3 |
| Dermatitis exfoliative generalised | 1 | 2 |
| Dermatosis | 2 | 2 |
| Diabetic wound | 1 | 1 |
| Drug eruption | 4 | 9 |
| Dry skin | 23 | 34 |
| Dyshidrotic eczema | 1 | 1 |
| Ecchymosis | 2 | 3 |
| Eczema | 31 | 41 |
| Eczema nummular | 1 | 1 |
| Eczema weeping | 1 | 1 |
| Epidermal necrosis | 1 | 1 |
| Erythema | 640 | 1,042 |
| Erythema annulare | 1 | 1 |
| Erythema multiforme | 11 | 13 |
| Erythema nodosum | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | 42 | 98 | 84 | 130 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | | 1 | | |
| | | 4 | 14 | 7 | 10 |
| | | 1 | 1 | | |
| | | 3 | 20 | 23 | 35 |
| | | 3 | 3 | 1 | 1 |
| | | | | 12 | 13 |
| | | | 4 | | |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 2 | 5 |
| | | 11 | 22 | 12 | 12 |
| | | | 1 | 2 | 2 |
| | | 13 | 19 | 18 | 22 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 2 | 2 | 300 | 593 | 340 | 449 |
| | | | | 1 | 1 |
| | | | | 11 | 13 |
| | | | 1 | 4 | 4 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Excessive granulation tissue | 1 | 1 |
| Exfoliative rash | 2 | 2 |
| Fixed eruption | | 1 |
| Fracture blisters | 1 | 1 |
| Haemorrhage subcutaneous | 2 | 3 |
| Hair colour changes | 1 | 2 |
| Hand dermatitis | 1 | 1 |
| Hidradenitis | | 2 |
| Hyperhidrosis | 526 | 897 |
| Hypersensitivity vasculitis | 2 | 2 |
| Itching scar | | 1 |
| Leukoplakia | | 1 |
| Lichen planus | 2 | 2 |
| Lipodystrophy acquired | 1 | 1 |
| Livedo reticularis | 15 | 21 |
| Lividity | 5 | 5 |
| Macule | 3 | 4 |
| Madarosis | 1 | 1 |
| Mechanical urticaria | 6 | 10 |
| Miliaria | 5 | 10 |
| Nail discolouration | 2 | 4 |
| Neurodermatitis | 3 | 3 |
| Neutrophilic dermatosis | 1 | 1 |
| Night sweats | 98 | 184 |
| Pain of skin | 55 | 88 |
| Palmar erythema | 1 | 6 |
| Palmar-plantar erythrodysesthesia syndrome | | 1 |
| Palpable purpura | 1 | 1 |
| Panniculitis | 2 | 2 |
| Papule | 5 | 12 |
| Peau d'orange | 1 | 2 |
| Pemphigoid | 5 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| 3 | 3 | 225 | 493 | 301 | 404 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 3 | 6 | 12 | 15 |
| | | 1 | 1 | 4 | 4 |
| | | 1 | 2 | 2 | 2 |
| | | 1 | 1 | | |
| 2 | 2 | 3 | 7 | 3 | 3 |
| | | 3 | 5 | 2 | 5 |
| | | | | 2 | 4 |
| | | 3 | 3 | | |
| | | | | 1 | 1 |
| 3 | 3 | 49 | 109 | 49 | 75 |
| | | 20 | 40 | 35 | 48 |
| | | | 4 | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 2 | 6 | 3 | 6 |
| | | 1 | 2 | | |
| | | | | 5 | 5 |

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* I=Interval, C=Cumulative
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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Pemphigus | 2 | 2 |
| Pernio-like erythema | 1 | 1 |
| Petechiae | 33 | 50 |
| Photosensitivity reaction | 17 | 27 |
| Pigmentation disorder | 1 | 1 |
| Piloerection | 6 | 14 |
| Pityriasis | 2 | 2 |
| Pityriasis rosea | | 1 |
| Plantar erythema | | 1 |
| Prurigo | 1 | 1 |
| Pruritus | 807 | 1,441 |
| Pruritus allergic | 1 | 2 |
| Psoriasis | 10 | 13 |
| Purpura | 12 | 16 |
| Pustular psoriasis | 1 | 1 |
| Rash | 775 | 1,395 |
| Rash erythematous | 170 | 303 |
| Rash macular | 62 | 153 |
| Rash maculo-papular | 28 | 48 |
| Rash morbilliform | 7 | 8 |
| Rash papular | 34 | 69 |
| Rash pruritic | 154 | 276 |
| Rash rubelliform | 1 | 1 |
| Rash vesicular | 19 | 32 |
| Red man syndrome | 1 | 1 |
| Rosacea | 3 | 5 |
| Scab | 3 | 4 |
| Scar pain | | 1 |
| Scleroderma associated digital ulcer | 1 | 1 |
| Sensitive skin | 163 | 178 |
| Skin burning sensation | 32 | 65 |
| Skin depigmentation | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 14 | 25 | 19 | 25 |
| | | 9 | 18 | 8 | 9 |
| | | | | 1 | 1 |
| | | | 4 | 6 | 10 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| 4 | 4 | 351 | 826 | 456 | 615 |
| | | | 1 | 1 | 1 |
| 1 | 1 | 6 | 8 | 4 | 5 |
| | | 2 | 5 | 10 | 11 |
| | | | | 1 | 1 |
| 6 | 6 | 307 | 758 | 468 | 637 |
| 1 | 1 | 63 | 147 | 107 | 156 |
| | | 28 | 96 | 34 | 57 |
| | | 14 | 31 | 14 | 17 |
| | | 3 | 3 | 4 | 5 |
| | | 15 | 44 | 19 | 25 |
| | | 58 | 141 | 96 | 135 |
| | | | | 1 | 1 |
| | | 11 | 20 | 8 | 12 |
| | | | | 1 | 1 |
| | | 2 | 3 | 1 | 2 |
| | | 2 | 3 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 133 | 143 | 30 | 35 |
| | | 13 | 33 | 19 | 32 |
| | | 1 | 1 | | |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Skin discolouration | 31 | 58 |
| Skin discomfort | 1 | 1 |
| Skin disorder | 20 | 36 |
| Skin erosion | 3 | 5 |
| Skin exfoliation | 14 | 25 |
| Skin fissures | 2 | 2 |
| Skin haemorrhage | 3 | 3 |
| Skin hypertrophy | 1 | 1 |
| Skin indentation | | 1 |
| Skin induration | | 1 |
| Skin irritation | 17 | 29 |
| Skin laxity | 2 | 2 |
| Skin lesion | 19 | 27 |
| Skin mass | 8 | 12 |
| Skin necrosis | 2 | 2 |
| Skin odour abnormal | 1 | 2 |
| Skin oedema | 2 | 2 |
| Skin plaque | 4 | 4 |
| Skin reaction | 19 | 28 |
| Skin sensitisation | | 2 |
| Skin swelling | 11 | 19 |
| Skin tightness | 8 | 18 |
| Skin ulcer | 4 | 6 |
| Skin warm | 28 | 53 |
| Skin weeping | | 1 |
| Stevens-Johnson syndrome | 5 | 7 |
| Toxic epidermal necrolysis | 2 | 3 |
| Toxic skin eruption | 1 | 2 |
| Urticaria | 435 | 862 |
| Urticaria cholinergic | | 1 |
| Urticaria chronic | 1 | 1 |
| Urticarial vasculitis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 15 | 34 | 16 | 24 |
| | | 1 | 1 | | |
| | | 10 | 25 | 10 | 11 |
| | | | 1 | 3 | 4 |
| | | 8 | 12 | 6 | 13 |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 5 | 15 | 12 | 14 |
| | | 1 | 1 | 1 | 1 |
| | | 10 | 18 | 9 | 9 |
| | | 2 | 5 | 6 | 7 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | | |
| | | 2 | 2 | 2 | 2 |
| | | 7 | 13 | 12 | 15 |
| | | | | | 2 |
| | | 6 | 12 | 5 | 7 |
| | | 2 | 6 | 6 | 12 |
| | | 1 | 1 | 3 | 5 |
| | | 8 | 19 | 20 | 34 |
| | | | | | 1 |
| | | | | 5 | 7 |
| 1 | 1 | | | 2 | 3 |
| | | | | 1 | 2 |
| 1 | 1 | 144 | 457 | 291 | 405 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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 * AE=Adverse Event
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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Urticaria papular | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Urticaria pressure | 1 | 1 | | | | | 1 | 1 |
| Urticaria thermal | 1 | 1 | | | 1 | 1 | | |
| Vascular purpura | 2 | 2 | | | | | 2 | 2 |
| Vasculitic rash | 3 | 4 | | | 2 | 2 | 1 | 2 |
| Yellow skin | 4 | 6 | | | 1 | 3 | 3 | 3 |
| | 4,889 | 8,445 | 24 | 24 | 1992 | 4494 | 2897 | 3951 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bedridden | 12 | 22 | 4 | 10 | 8 | 12 |
| Contraindication to vaccination | 1 | 2 | 1 | 2 | | |
| Exercise lack of | | 1 | | 1 | | |
| Immobile | 4 | 5 | | | 4 | 5 |
| Impaired driving ability | 11 | 17 | 7 | 12 | 4 | 5 |
| Impaired quality of life | | 1 | | 1 | | |
| Impaired work ability | 22 | 32 | 6 | 16 | 16 | 16 |
| Loss of personal independence in daily activities | 56 | 94 | 23 | 47 | 33 | 47 |
| Sitting disability | 1 | 1 | 1 | 1 | | |
| Urinary assistance device user | 1 | 1 | 1 | 1 | | |
| Walking disability | 3 | 3 | | | 3 | 3 |
| | 111 | 179 | 43 | 91 | 68 | 88 |

System Organ Class

SOC Not Yet Coded

| Interval Total # | Cumulative Total # |
|------------------|--------------------|
| | Spontaneous |
| | Nonserious |

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System Organ Class

SOC Not Yet Coded

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| | 6 | 15 | 6 | 15 |
| | 6 | 15 | 6 | 15 |

System Organ Class

Surgical and medical procedures

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma prophylaxis | | 1 | | | | 1 |
| Central nervous system stimulation | 1 | 1 | | | 1 | 1 |
| COVID-19 immunisation | | 1 | | 1 | | |
| Diabetic diet | 1 | 1 | | | 1 | 1 |
| Endodontic procedure | 1 | 1 | 1 | 1 | | |
| Hospitalisation | 1 | 1 | | | 1 | 1 |
| Limb immobilisation | 3 | 4 | 2 | 3 | 1 | 1 |
| Prophylaxis of nausea and vomiting | 1 | 1 | | | 1 | 1 |
| Spinal fusion surgery | | 1 | | | | 1 |
| Weight loss diet | | 1 | | | | 1 |
| Wound closure | 1 | 1 | 1 | 1 | | |
| | 9 | 14 | 4 | 6 | 5 | 8 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Aneurysm | 1 | 1 | | | | | 1 | 1 |
| Aneurysm ruptured | 1 | 1 | | | | | 1 | 1 |
| Angiopathy | 2 | 2 | | | 2 | 2 | | |
| Aortic aneurysm | 2 | 3 | | | | | 2 | 3 |

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* AE=Adverse Event

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Aortic aneurysm rupture | 1 | 2 |
| Aortic dissection | 1 | 3 |
| Aortic stenosis | 1 | 1 |
| Arterial occlusive disease | 2 | 2 |
| Arterial rupture | 1 | 1 |
| Arteriosclerosis | 1 | 4 |
| Arteritis | 1 | 1 |
| Axillary vein thrombosis | 1 | 1 |
| Behcet's syndrome | 2 | 2 |
| Blood pressure fluctuation | 15 | 21 |
| Blood pressure inadequately controlled | 1 | 2 |
| Blue toe syndrome | 2 | 2 |
| Capillary disorder | 1 | 1 |
| Circulatory collapse | 44 | 74 |
| CT hypotension complex | 1 | 1 |
| Cyanosis | 29 | 46 |
| Deep vein thrombosis | 23 | 35 |
| Diastolic hypertension | | 1 |
| Diastolic hypotension | 1 | 2 |
| Embolism | 1 | 3 |
| Embolism arterial | 1 | 1 |
| Femoral artery embolism | 1 | 1 |
| Flushing | 202 | 457 |
| Giant cell arteritis | 2 | 3 |
| Haematoma | 20 | 27 |
| Haemodynamic instability | 1 | 1 |
| Haemorrhage | 33 | 41 |
| Hot flush | 159 | 287 |
| Hyperaemia | 5 | 6 |
| Hypertension | 443 | 637 |
| Hypertensive crisis | 108 | 123 |
| Hypertensive emergency | 3 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 9 | 12 | 6 | 9 |
| | | 1 | 2 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| 1 | 1 | | | 44 | 74 |
| | | | | 1 | 1 |
| | | 5 | 15 | 24 | 31 |
| | | | | 23 | 35 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 82 | 254 | 120 | 203 |
| | | | 1 | 2 | 2 |
| | | 5 | 10 | 15 | 17 |
| | | 1 | 1 | | |
| 1 | 1 | | 1 | 33 | 40 |
| | | 62 | 154 | 97 | 133 |
| | | 1 | 2 | 4 | 4 |
| 4 | 4 | 132 | 227 | 311 | 410 |
| | | | | 108 | 123 |
| | | | | 3 | 7 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Hypertensive urgency | 2 | 2 |
| Hypoperfusion | 4 | 4 |
| Hypotension | 258 | 358 |
| Hypotensive crisis | 3 | 3 |
| Hypovolaemic shock | 3 | 4 |
| Infarction | 2 | 3 |
| Internal haemorrhage | 2 | 2 |
| Jugular vein distension | 1 | 1 |
| Jugular vein thrombosis | 1 | 1 |
| Labile blood pressure | 2 | 2 |
| Labile hypertension | | 1 |
| Lymphoedema | 15 | 33 |
| Malignant hypertension | 3 | 4 |
| May-Thurner syndrome | 1 | 1 |
| Microembolism | 2 | 3 |
| Neurogenic shock | 9 | 13 |
| Orthostatic hypertension | 1 | 1 |
| Orthostatic hypotension | 7 | 11 |
| Pallor | 117 | 188 |
| Peripheral artery thrombosis | 1 | 1 |
| Peripheral circulatory failure | 1 | 3 |
| Peripheral coldness | 87 | 158 |
| Peripheral embolism | | 1 |
| Peripheral ischaemia | 1 | 3 |
| Peripheral vascular disorder | 15 | 22 |
| Peripheral venous disease | 1 | 1 |
| Phlebitis | 3 | 5 |
| Poor peripheral circulation | 1 | 4 |
| Raynaud's phenomenon | 8 | 11 |
| Shock | 16 | 16 |
| Shock symptom | 3 | 5 |
| Subclavian artery thrombosis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 1 | 3 | 3 |
| 1 | 1 | 58 | 96 | 200 | 262 |
| | | | | 3 | 3 |
| | | | | 3 | 4 |
| | | | | 2 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 5 | 18 | 10 | 15 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 9 | 13 |
| | | | | 1 | 1 |
| | | 2 | 3 | 5 | 8 |
| | | 31 | 70 | 86 | 118 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| 1 | 1 | 42 | 93 | 45 | 65 |
| | | | 1 | | |
| | | | | 1 | 3 |
| 1 | 1 | 5 | 8 | 10 | 14 |
| | | 1 | 1 | | |
| | | 1 | 2 | 2 | 3 |
| | | 1 | 3 | | 1 |
| | | 4 | 6 | 4 | 5 |
| | | | | 16 | 16 |
| | | | | 3 | 5 |
| | | | | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Subclavian vein thrombosis | 1 | 1 | | | | | 1 | 1 |
| Superficial vein prominence | | 3 | | | | 3 | | |
| Systolic hypertension | 3 | 5 | | | | | 3 | 5 |
| Takayasu's arteritis | 1 | 1 | | | | | 1 | 1 |
| Thrombophlebitis | 3 | 3 | | | | | 3 | 3 |
| Thrombophlebitis superficial | 6 | 6 | | | 1 | 1 | 5 | 5 |
| Thrombosis | 27 | 38 | 1 | 1 | | | 27 | 38 |
| Varicose vein | 1 | 3 | | | 1 | 3 | | |
| Vascular pain | 1 | 2 | | | 1 | 2 | | |
| Vascular rupture | 1 | 1 | | | | | 1 | 1 |
| Vasculitis | 12 | 14 | | | 3 | 4 | 9 | 10 |
| Vasoconstriction | 4 | 5 | | | | 1 | 4 | 4 |
| Vasodilatation | 4 | 8 | | | 1 | 2 | 3 | 6 |
| Vasospasm | 1 | 1 | | | | | 1 | 1 |
| Vein discolouration | 2 | 4 | | | 2 | 4 | | |
| Vein disorder | 3 | 4 | | | 2 | 2 | 1 | 2 |
| Vein rupture | | 1 | | | | | | 1 |
| Vena cava embolism | | 1 | | | | | | 1 |
| Vena cava thrombosis | | 1 | | | | | | 1 |
| Venous haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Venous thrombosis | 3 | 3 | | | | | 3 | 3 |
| Venous thrombosis limb | 4 | 4 | | | 1 | 1 | 3 | 3 |
| White coat hypertension | 1 | 1 | | | 1 | 1 | | |
| | 1,763 | 2,780 | 10 | 10 | 465 | 1009 | 1298 | 1771 |

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APPENDIX 2.5.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by Preferred Term per Country

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval) / 42,086 (Cumulative)

Total Number of Adverse Events (PT): 91,739 (Interval) / 158,648 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

AFGHANISTAN

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Chills | | 1 | | 1 |
| Feeling of body temperature change | | 1 | | 1 |
| Swelling face | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle tightness | | 1 | | 1 |
| | | 1 | | 1 |

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

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Facial paralysis | | 1 | | | | 1 |
| Paraesthesia | | 1 | | 1 | | |
| | | 2 | | 1 | | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Erythema | | 1 | | 1 |
| Pruritus | | 1 | | 1 |
| Rash | | 1 | | 1 |
| | | 3 | | 3 |

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Country Where Event Occurred

ANDORRA

System Organ Class

Injury, poisoning and procedural complications

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous

Nonserious

I

C

Product administered to patient of inappropriate age

1

1

1

1

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANGOLA

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Swollen tongue | 1 | 1 | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Pyrexia | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Nasopharyngitis | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Antiphospholipid syndrome | 1 | 1 | | | 1 | 1 |
| Autoimmune haemolytic anaemia | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 13 | 13 | 7 | 7 | 6 | 6 |
| Lymph node pain | 4 | 4 | 4 | 4 | | |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| | 21 | 21 | 11 | 11 | 10 | 10 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute coronary syndrome | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | 4 | 4 | | | 4 | 4 |
| Bradycardia | 2 | 2 | | | 2 | 2 |
| Bundle branch block right | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 2 | 3 | | | 2 | 3 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 7 | 8 | 6 | 7 | 1 | 1 |
| Left ventricular failure | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | | 1 | | | | 1 |
| Myocarditis | 2 | 2 | | | 2 | 2 |
| Palpitations | 5 | 5 | | | 5 | 5 |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 6 | 6 | | | 6 | 6 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| | 40 | 43 | 6 | 7 | 34 | 36 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear discomfort | 2 | 2 | 2 | 2 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Vertigo | 10 | 10 | 5 | 5 | 5 | 5 |
| | 13 | 13 | 8 | 8 | 5 | 5 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blepharospasm | 1 | 1 | | | 1 | 1 |
| Diplopia | 2 | 2 | 1 | 1 | 1 | 1 |
| Eye irritation | 1 | 1 | | | 1 | 1 |
| Eye movement disorder | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye pruritus | 2 | 2 | 2 | 2 | | |
| Eye swelling | 1 | 1 | 1 | 1 | | |
| Lacrimation increased | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 2 | 2 | 2 | 2 | | |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Pupils unequal | 1 | 1 | | | 1 | 1 |
| Swelling of eyelid | 1 | 1 | | | 1 | 1 |
| Vision blurred | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual impairment | 2 | 2 | | | 2 | 2 |
| | 19 | 19 | 10 | 10 | 9 | 9 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Chapped lips | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 10 | 12 | 7 | 9 | 3 | 3 |
| Diarrhoea haemorrhagic | 1 | 1 | | | 1 | 1 |
| Dry mouth | 4 | 4 | 3 | 3 | 1 | 1 |
| Dysphagia | 3 | 3 | 2 | 2 | 1 | 1 |
| Gastrointestinal disorder | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 4 | 4 | 1 | 1 | 3 | 3 |
| Lip dry | 1 | 1 | | | 1 | 1 |
| Lip erythema | 1 | 1 | | | 1 | 1 |
| Lip pruritus | 1 | 1 | | | 1 | 1 |
| Lip swelling | 4 | 4 | | | 4 | 4 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Nausea | 28 | 32 | 16 | 20 | 12 | 12 |
| Oral discomfort | 2 | 2 | | | 2 | 2 |
| Oral mucosal erythema | 1 | 1 | | | 1 | 1 |
| Oral pruritus | 1 | 1 | | | 1 | 1 |
| Palatal swelling | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 4 | 4 | 1 | 1 | 3 | 3 |
| Retching | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 5 | 5 | 2 | 2 | 3 | 3 |
| Tongue discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Vomiting | 7 | 10 | 4 | 7 | 3 | 3 |
| | 87 | 96 | 40 | 49 | 47 | 47 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 12 | 14 | 11 | 11 | 1 | 3 |
| Chest discomfort | 3 | 3 | 2 | 2 | 1 | 1 |
| Chest pain | 4 | 4 | 2 | 2 | 2 | 2 |
| Chills | 32 | 32 | 16 | 16 | 16 | 16 |
| Complication associated with device | 1 | 1 | 1 | 1 | | |
| Concomitant disease aggravated | 1 | 1 | | | 1 | 1 |
| Death | 8 | 10 | | | 8 | 10 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disease progression | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 17 | 19 | | | 17 | 19 |
| Face oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Fatigue | 46 | 50 | 38 | 41 | 8 | 9 |
| Feeling abnormal | 2 | 2 | 2 | 2 | | |
| Feeling cold | 2 | 2 | 1 | 1 | 1 | 1 |
| Feeling drunk | 1 | 2 | 1 | 2 | | |
| Feeling hot | 3 | 3 | 1 | 1 | 2 | 2 |
| Feeling jittery | 1 | 1 | 1 | 1 | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 2 | 2 | 2 | 2 | | |
| General physical health deterioration | 4 | 4 | | | 4 | 4 |
| Hangover | | 1 | | 1 | | |
| Inflammation | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 4 | 4 | 3 | 3 | 1 | 1 |
| Injection site urticaria | 1 | 1 | 1 | 1 | | |
| Malaise | 7 | 8 | 5 | 6 | 2 | 2 |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Oedema mucosal | 1 | 1 | 1 | 1 | | |
| Pain | 5 | 5 | 4 | 4 | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pyrexia | 45 | 45 | 25 | 25 | 20 | 20 |
| Sensation of foreign body | 2 | 2 | | | 2 | 2 |
| Swelling | 3 | 3 | | | 3 | 3 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling face | 5 | 5 | 1 | 1 | 4 | 4 |
| Systemic inflammatory response syndrome | 1 | 1 | | | 1 | 1 |
| Vaccination site discolouration | 2 | 2 | | | 2 | 2 |
| Vaccination site erythema | 6 | 6 | 4 | 4 | 2 | 2 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site lymphadenopathy | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site movement impairment | 4 | 4 | 3 | 3 | 1 | 1 |
| Vaccination site pain | 41 | 46 | 35 | 40 | 6 | 6 |
| Vaccination site pruritus | 2 | 3 | | 1 | 2 | 2 |
| Vaccination site rash | 2 | 2 | 2 | 2 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 9 | 9 | 6 | 6 | 3 | 3 |
| Vaccination site warmth | 2 | 2 | 1 | 1 | 1 | 1 |
| | 299 | 318 | 178 | 190 | 121 | 128 |

System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholestasis | 1 | 1 | | | 1 | 1 |
| Hepatic pain | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 3 | 4 | | | 3 | 4 |
| Anaphylactic shock | 4 | 4 | | | 4 | 4 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 8 | 8 | 1 | 1 | 7 | 7 |
| | 16 | 17 | 1 | 1 | 15 | 16 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctivitis | 1 | 1 | | | 1 | 1 |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| COVID-19 | 19 | 20 | 4 | 4 | 15 | 16 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Ear infection | 1 | 1 | | | 1 | 1 |
| Escherichia sepsis | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | | | 1 | 1 |
| Influenza | | 1 | | 1 | | |
| Meningitis bacterial | 1 | 1 | | | 1 | 1 |
| Pneumonia | 3 | 3 | | | 3 | 3 |
| Rash pustular | 3 | 3 | 1 | 1 | 2 | 2 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Septic shock | 1 | 1 | | | 1 | 1 |
| Vaccination site pustule | 1 | 1 | 1 | 1 | | |
| Viral rash | 1 | 1 | | | 1 | 1 |
| | 36 | 38 | 7 | 8 | 29 | 30 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Incorrect route of product administration | 4 | 5 | 4 | 5 |
| Off label use | 3 | 3 | 3 | 3 |
| Poor quality product administered | | 1 | | 1 |
| Product administered at inappropriate site | 1 | 1 | 1 | 1 |
| Product preparation error | | 1 | | 1 |
| Product use issue | 3 | 3 | 3 | 3 |
| Underdose | 1 | 1 | 1 | 1 |
| Wrong technique in product usage process | 2 | 3 | 2 | 3 |
| | 14 | 18 | 14 | 18 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood creatine phosphokinase MB increased | 1 | 1 | | | 1 | 1 |
| Blood lactate dehydrogenase increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 3 | 3 | 1 | 1 | 2 | 2 |
| Blood pressure immeasurable | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 6 | 6 | 2 | 2 | 4 | 4 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 6 | 6 | 5 | 5 | 1 | 1 |
| Breath sounds | 1 | 1 | 1 | 1 | | |
| C-reactive protein increased | 2 | 2 | | | 2 | 2 |
| Electrocardiogram abnormal | 1 | 1 | 1 | 1 | | |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Interleukin level increased | 1 | 1 | | | 1 | 1 |
| Intraocular pressure increased | 1 | 1 | | | 1 | 1 |
| Lymph node palpable | 1 | 1 | 1 | 1 | | |
| Oxygen saturation | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Oxygen saturation immeasurable | 1 | 1 | | | 1 | 1 |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 2 | 3 | | | 2 | 3 |
| Serum ferritin increased | 1 | 1 | 1 | 1 | | |
| Transaminases increased | 1 | 1 | 1 | 1 | | |
| | 37 | 38 | 15 | 15 | 22 | 23 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Cachexia | 1 | 1 | 1 | 1 |
| Histamine intolerance | 1 | 1 | 1 | 1 |
| Hyperglycaemia | 1 | 1 | 1 | 1 |
| Hypernatraemia | 1 | 1 | 1 | 1 |
| Hypophagia | 1 | 1 | 1 | 1 |
| Marasmus | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 17 | 17 | 6 | 6 | 11 | 11 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Bursitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Groin pain | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 4 | 4 | 2 | 2 | 2 | 2 |
| Muscular weakness | 5 | 5 | 2 | 2 | 3 | 3 |
| Myalgia | 11 | 12 | 3 | 4 | 8 | 8 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Nuchal rigidity | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 22 | 22 | 16 | 16 | 6 | 6 |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Tendon disorder | 1 | 1 | 1 | 1 | | |
| | 68 | 69 | 36 | 37 | 32 | 32 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 2 | 2 | 2 | 2 | | |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 2 | | 1 | 1 | 1 |
| Disturbance in attention | 2 | 2 | | | 2 | 2 |
| Dizziness | 30 | 30 | 20 | 20 | 10 | 10 |
| Dizziness postural | 1 | 1 | 1 | 1 | | |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dysgraphia | 1 | 1 | 1 | 1 | | |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Facial paralysis | 4 | 4 | | | 4 | 4 |
| Facial paresis | 3 | 3 | | | 3 | 3 |
| Formication | 1 | 1 | 1 | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 62 | 64 | 46 | 48 | 16 | 16 |
| Hemiparaesthesia | 1 | 1 | | | 1 | 1 |
| Hypersomnia | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 10 | 10 | 3 | 3 | 7 | 7 |
| Hypogeusia | 1 | 1 | | | 1 | 1 |
| Hyposmia | 1 | 1 | | | 1 | 1 |
| Hypotonia | 2 | 2 | 1 | 1 | 1 | 1 |
| Loss of consciousness | 5 | 5 | | | 5 | 5 |
| Memory impairment | 1 | 1 | 1 | 1 | | |
| Migraine | 2 | 4 | 2 | 4 | | |
| Monoplegia | 1 | 1 | | | 1 | 1 |
| Movement disorder | 2 | 2 | 2 | 2 | | |
| Narcolepsy | 1 | 1 | | | 1 | 1 |
| Neuralgia | 2 | 2 | | | 2 | 2 |
| Neuralgic amyotrophy | 1 | 1 | | | 1 | 1 |
| Neuritis | 1 | 1 | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Occipital neuralgia | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 23 | 23 | 10 | 10 | 13 | 13 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Parosmia | 1 | 1 | 1 | 1 | | |
| Presyncope | 13 | 13 | 3 | 3 | 10 | 10 |
| Reduced facial expression | 1 | 1 | 1 | 1 | | |
| Seizure | 3 | 3 | | | 3 | 3 |
| Somnolence | 8 | 9 | 6 | 6 | 2 | 3 |
| Speech disorder | 3 | 3 | 1 | 1 | 2 | 2 |
| Syncope | 7 | 7 | | | 7 | 7 |
| Taste disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Tension headache | 2 | 2 | 1 | 1 | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Trigeminal neuralgia | 1 | 1 | | | 1 | 1 |
| Tunnel vision | 2 | 2 | 1 | 1 | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| | 221 | 227 | 112 | 117 | 109 | 110 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Syringe issue | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disorganised speech | 1 | 1 | 1 | 1 | | |
| Disorientation | 1 | 1 | 1 | 1 | | |
| Insomnia | 3 | 3 | 3 | 3 | | |
| Panic attack | 1 | 1 | | | 1 | 1 |
| Panic reaction | 1 | 1 | 1 | 1 | | |
| Restlessness | 3 | 3 | 2 | 2 | 1 | 1 |
| Sleep attacks | 1 | 1 | 1 | 1 | | |
| Sleep disorder due to general medical condition, hypersomnia type | 1 | 1 | 1 | 1 | | |
| Somatic symptom disorder | 1 | 1 | | | 1 | 1 |
| | 13 | 13 | 10 | 10 | 3 | 3 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Renal failure | 1 | 1 | 1 | 1 |
| Urinary retention | | 1 | | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Vaginal discharge | | 1 | | 1 | | |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 |
| | 2 | 3 | 1 | 2 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Choking | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Cough | 3 | 3 | 3 | 3 | | |
| Dry throat | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 13 | 13 | 3 | 3 | 10 | 10 |
| Dyspnoea exertional | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Laryngeal pain | 1 | 1 | | | 1 | 1 |
| Laryngospasm | 1 | 1 | | | 1 | 1 |
| Lung infiltration | 1 | 1 | | | 1 | 1 |
| Obstructive airways disorder | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Pharyngeal swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia aspiration | 2 | 2 | | | 2 | 2 |
| Pulmonary embolism | 1 | 2 | | | 1 | 2 |
| Pulmonary oedema | | 1 | | | | 1 |
| Rales | 1 | 2 | 1 | 1 | | 1 |
| Respiratory depression | | 1 | | | | 1 |
| Respiratory disorder | 1 | 1 | 1 | 1 | | |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinitis allergic | 1 | 1 | | | 1 | 1 |
| Sinus congestion | 1 | 1 | 1 | 1 | | |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Throat irritation | 3 | 3 | 1 | 1 | 2 | 2 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| | 47 | 51 | 17 | 17 | 30 | 34 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alopecia | 1 | 1 | 1 | 1 | | |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Erythema | 5 | 5 | 3 | 3 | 2 | 2 |
| Lividity | 1 | 1 | 1 | 1 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pain of skin | 1 | 1 | | | 1 | 1 |
| Palmar erythema | 1 | 1 | | | 1 | 1 |
| Pemphigus | 1 | 1 | | | 1 | 1 |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Pruritus | 19 | 21 | 3 | 5 | 16 | 16 |
| Rash | 11 | 11 | 3 | 3 | 8 | 8 |
| Rash macular | 2 | 2 | | | 2 | 2 |
| Rash morbilliform | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 3 | 3 | 1 | 1 | 2 | 2 |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Skin discolouration | 1 | 1 | | | 1 | 1 |
| Skin tightness | 1 | 1 | | | 1 | 1 |
| Urticaria | 4 | 5 | | 1 | 4 | 4 |
| Urticaria pressure | 1 | 1 | | | 1 | 1 |
| | 58 | 61 | 13 | 16 | 45 | 45 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Impaired work ability | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circulatory collapse | 9 | 9 | | | 9 | 9 |
| Flushing | 8 | 8 | 1 | 1 | 7 | 7 |
| Hot flush | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypertension | 5 | 5 | 1 | 1 | 4 | 4 |
| Hypertensive crisis | 2 | 2 | | | 2 | 2 |
| Hypertensive emergency | 1 | 1 | | | 1 | 1 |
| Hypotension | 4 | 4 | 1 | 1 | 3 | 3 |
| Pallor | 4 | 4 | 1 | 1 | 3 | 3 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Poor peripheral circulation | 1 | 1 | 1 | 1 | | |
| Shock | 1 | 1 | | | 1 | 1 |
| | 39 | 39 | 7 | 7 | 32 | 32 |

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Country Where Event Occurred

BAHRAIN

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Nausea | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Chills | 2 | 2 | 2 | 2 |
| Pain | 1 | 1 | 1 | 1 |
| Pyrexia | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Myalgia | 1 | 1 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Pruritus | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Hot flush | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

BELGIUM

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coagulopathy | 1 | 1 | | | 1 | 1 |
| Leukocytosis | | 1 | | | | 1 |
| Lymphadenopathy | 2 | 3 | | 1 | 2 | 2 |
| Lymph node pain | 1 | 1 | | | 1 | 1 |
| Neutropenia | | 1 | | | | 1 |
| Neutrophilia | 1 | 1 | | | 1 | 1 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| | 6 | 9 | | 1 | 6 | 8 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Bradycardia | | 1 | | | | 1 |
| Cardiac arrest | | 1 | | | | 1 |
| Cardiac disorder | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 2 | 2 | | | 2 | 2 |
| Cardio-respiratory arrest | 3 | 3 | | | 3 | 3 |
| Cardiovascular disorder | 8 | 12 | 1 | 1 | 7 | 11 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Palpitations | 3 | 4 | 2 | 3 | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 5 | 6 | 1 | 1 | 4 | 5 |
| | 29 | 37 | 4 | 5 | 25 | 32 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Endolymphatic hydrops | 1 | 1 | | | 1 | 1 |
| Vertigo | 7 | 7 | 1 | 1 | 6 | 6 |
| | 10 | 10 | 1 | 1 | 9 | 9 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angle closure glaucoma | 1 | 1 | | | 1 | 1 |
| Eye movement disorder | | 1 | | | | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Glaucoma | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Vision blurred | 2 | 2 | 1 | 1 | 1 | 1 |
| | 8 | 9 | 4 | 4 | 4 | 5 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 2 | | | 1 | 2 |
| Abdominal pain upper | 3 | 3 | 1 | 1 | 2 | 2 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysphagia | 2 | 3 | 2 | 3 | | |
| Intestinal dilatation | | 1 | | | | 1 |
| Intestinal ischaemia | | 2 | | | | 2 |
| Lip swelling | 2 | 2 | 2 | 2 | | |
| Nausea | 32 | 33 | 3 | 4 | 29 | 29 |
| Paraesthesia oral | 2 | 2 | 1 | 1 | 1 | 1 |
| Salivary hypersecretion | 2 | 2 | 2 | 2 | | |
| Swollen tongue | 2 | 3 | 1 | 2 | 1 | 1 |
| Tongue discomfort | 1 | 1 | 1 | 1 | | |
| Vomiting | 4 | 5 | | | 4 | 5 |
| | 53 | 61 | 13 | 16 | 40 | 45 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 4 | 4 | 1 | 1 | 3 | 3 |
| Chills | 35 | 35 | 2 | 2 | 33 | 33 |
| Death | 1 | 2 | | | 1 | 2 |
| Drug ineffective | 31 | 36 | | | 31 | 36 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 47 | 51 | 8 | 12 | 39 | 39 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | 1 | 1 | | | 1 | 1 |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Gait disturbance | 2 | 2 | | | 2 | 2 |
| General physical health deterioration | 7 | 8 | | | 7 | 8 |
| Illness | | 1 | | 1 | | |
| Influenza like illness | 3 | 3 | | | 3 | 3 |
| Malaise | 33 | 39 | 4 | 6 | 29 | 33 |
| Pain | 2 | 2 | | | 2 | 2 |
| Peripheral swelling | 7 | 7 | | | 7 | 7 |
| Pyrexia | 37 | 38 | 3 | 3 | 34 | 35 |
| Sensation of foreign body | 2 | 2 | 2 | 2 | | |
| Sense of oppression | 1 | 1 | 1 | 1 | | |
| Sudden death | 7 | 8 | | | 7 | 8 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 4 | 6 | 2 | 4 | 2 | 2 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 11 | 13 | 4 | 6 | 7 | 7 |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site reaction | 17 | 17 | 1 | 1 | 16 | 16 |
| Vaccination site swelling | 4 | 5 | 3 | 4 | 1 | 1 |
| Vaccination site warmth | 1 | 2 | 1 | 2 | | |
| | 265 | 293 | 34 | 49 | 231 | 244 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Anaphylactic reaction | 12 | 12 | 12 | 12 |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| | 13 | 13 | 13 | 13 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 35 | 40 | | | 35 | 40 |
| COVID-19 pneumonia | 2 | 2 | | | 2 | 2 |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Herpes ophthalmic | 2 | 2 | | | 2 | 2 |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Infection | 1 | 1 | | | 1 | 1 |
| Influenza | 1 | 1 | 1 | 1 | | |
| Laryngitis | 1 | 1 | | | 1 | 1 |
| Oral herpes | 2 | 2 | 1 | 1 | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 2 | 2 | | | 2 | 2 |
| Sepsis | 1 | 2 | | | 1 | 2 |
| Septic shock | | 1 | | | | 1 |
| Tonsillitis | 1 | 1 | 1 | 1 | | |
| | 51 | 58 | 4 | 4 | 47 | 54 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chillblains | 1 | 1 | | | 1 | 1 |
| Exposure via skin contact | | 1 | | 1 | | |
| Fall | 4 | 5 | 1 | 1 | 3 | 4 |
| Incorrect route of product administration | 2 | 2 | 2 | 2 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Occupational exposure to product | | 1 | | 1 | | |
| Off label use | 2 | 2 | 2 | 2 | | |
| Product use issue | 2 | 2 | 2 | 2 | | |
| | 12 | 15 | 8 | 10 | 4 | 5 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood lactic acid increased | 1 | 2 | | | 1 | 2 |
| Blood pressure decreased | 3 | 3 | 2 | 2 | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 2 | | | 2 | 2 |
| C-reactive protein increased | 2 | 2 | | | 2 | 2 |
| Fibrin D dimer increased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 2 | 2 | | | 2 | 2 |
| Heart rate irregular | 1 | 1 | 1 | 1 | | |
| Liver function test abnormal | 2 | 3 | | | 2 | 3 |
| Oxygen saturation decreased | 6 | 7 | | | 6 | 7 |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Troponin increased | 2 | 2 | | | 2 | 2 |
| | 25 | 28 | 3 | 3 | 22 | 25 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Diabetic complication | 1 | 1 | 1 | 1 |
| Hypoglycaemia | 1 | 2 | 1 | 2 |
| Hypokalaemia | 1 | 1 | 1 | 1 |
| Hyponatraemia | 1 | 1 | 1 | 1 |
| Metabolic acidosis | | 1 | | 1 |
| | 4 | 6 | 4 | 6 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 18 | 18 | 1 | 1 | 17 | 17 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Back pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 1 | 1 | | | 1 | 1 |
| Muscle tightness | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 5 | 7 | 1 | 3 | 4 | 4 |
| Myalgia | 41 | 41 | 4 | 4 | 37 | 37 |
| Neck pain | 5 | 5 | 1 | 1 | 4 | 4 |
| Pain in extremity | 8 | 9 | 1 | 2 | 7 | 7 |
| | 84 | 87 | 10 | 13 | 74 | 74 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Amnesia | | 1 | | | | 1 |
| Balance disorder | 3 | 3 | | | 3 | 3 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 2 | 2 | | | 2 | 2 |
| Coma | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 6 | 7 | | | 6 | 7 |
| Dizziness | 7 | 8 | 1 | 1 | 6 | 7 |
| Dizziness postural | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Dystonia | 1 | 1 | | | 1 | 1 |
| Epilepsy | 5 | 5 | | | 5 | 5 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 2 | 2 | | | 2 | 2 |
| Haemorrhage intracranial | | 1 | | | | 1 |
| Headache | 51 | 52 | 6 | 7 | 45 | 45 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Memory impairment | | 1 | | 1 | | |
| Nervous system disorder | 4 | 6 | | | 4 | 6 |
| Neuralgia | 1 | 1 | 1 | 1 | | |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 2 | 2 | | | 2 | 2 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Patient elopement | | 1 | | | | 1 |
| Poor quality sleep | | 1 | | 1 | | |
| Presyncope | 2 | 4 | | | 2 | 4 |
| Sedation | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sensory disturbance | 1 | 2 | 1 | 2 | | |
| Sleep deficit | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | | | 2 | 2 |
| Syncope | 11 | 11 | | | 11 | 11 |
| Thoracic outlet syndrome | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 2 | | | 2 | 2 |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| | 121 | 134 | 9 | 13 | 112 | 121 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 2 | 4 | | | 2 | 4 |
| Anxiety | 3 | 3 | | | 3 | 3 |
| Confusional state | | 2 | | | | 2 |
| Disorientation | | 1 | | | | 1 |
| Insomnia | 2 | 2 | | | 2 | 2 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 1 | 1 | | | 1 | 1 |
| Sleep disorder due to a general medical condition | 1 | 1 | 1 | 1 | | |
| Staring | | 1 | | | | 1 |
| | 10 | 16 | 2 | 2 | 8 | 14 |

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System Organ Class

Renal and urinary disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Serious | |
| | | | I | C |
| Acute kidney injury | 1 | 2 | 1 | 2 |
| Renal disorder | | 1 | | 1 |
| Renal failure | 2 | 2 | 2 | 2 |
| | 3 | 5 | 3 | 5 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | 2 | 3 | | | 2 | 3 |
| Asthma exercise induced | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 3 | 3 | | | 3 | 3 |
| Cheyne-Stokes respiration | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 1 | 1 | 1 | 1 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 8 | 9 | | | 8 | 9 |
| Hyperventilation | 1 | 1 | 1 | 1 | | |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Laryngospasm | 1 | 1 | | | 1 | 1 |
| Lung infiltration | | 1 | | | | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Pharyngeal swelling | 1 | 1 | | | 1 | 1 |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonitis | 1 | 2 | | | 1 | 2 |
| Productive cough | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 1 | 2 | | | 1 | 2 |
| Pulmonary oedema | 2 | 2 | | | 2 | 2 |
| Rales | 1 | 1 | | | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 5 | 7 | | | 5 | 7 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 3 | 3 | 2 | 2 | 1 | 1 |
| Sneezing | 1 | 1 | 1 | 1 | | |
| Tachypnoea | 1 | 2 | | | 1 | 2 |
| Upper airway obstruction | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 49 | 57 | 7 | 7 | 42 | 50 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 3 | 3 | | | 3 | 3 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Dry skin | 1 | 1 | | | 1 | 1 |
| Erythema | 5 | 5 | 2 | 2 | 3 | 3 |
| Hyperhidrosis | 2 | 2 | | | 2 | 2 |
| Livedo reticularis | 1 | 1 | | | 1 | 1 |
| Pruritus | 4 | 4 | 1 | 1 | 3 | 3 |
| Rash | 2 | 2 | | | 2 | 2 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Skin disorder | 4 | 4 | 1 | 1 | 3 | 3 |
| Urticaria | 2 | 2 | | | 2 | 2 |
| | 26 | 26 | 4 | 4 | 22 | 22 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Flushing | 1 | 1 | 1 | 1 | | |
| Hot flush | 3 | 3 | | | 3 | 3 |
| Hypertension | 7 | 7 | 2 | 2 | 5 | 5 |
| Hypotension | 5 | 6 | | | 5 | 6 |
| Hypovolaemic shock | | 1 | | | | 1 |
| Lymphoedema | 1 | 1 | | | 1 | 1 |
| Neurogenic shock | 2 | 2 | | | 2 | 2 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis | 1 | 1 | | | 1 | 1 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| | 24 | 26 | 3 | 3 | 21 | 23 |

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Country Where Event Occurred

BERMUDA

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

BULGARIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 4 | 7 | 3 | 6 | 1 | 1 |
| Lymph node pain | | 1 | | 1 | | |
| | 4 | 8 | 3 | 7 | 1 | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Extrasystoles | 1 | 1 | 1 | 1 | | |
| Palpitations | 1 | 2 | 1 | 2 | | |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| | 4 | 5 | 2 | 3 | 2 | 2 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vertigo | 3 | 4 | 2 | 2 | 1 | 2 |
| | 3 | 4 | 2 | 2 | 1 | 2 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Conjunctivitis allergic | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Dental discomfort | 1 | 1 | 1 | 1 | | |
| Diarrhoea | | 2 | | 2 | | |
| Epigastric discomfort | 1 | 1 | 1 | 1 | | |
| Gastrointestinal disorder | 1 | 1 | 1 | 1 | | |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Nausea | 3 | 6 | 3 | 5 | | 1 |
| Paraesthesia oral | | 1 | | 1 | | |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 2 | 1 | 2 | | |
| | 11 | 18 | 9 | 15 | 2 | 3 |

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 * AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Application site pain | 1 | 1 | 1 | 1 | | |
| Asthenia | 8 | 11 | 6 | 9 | 2 | 2 |
| Chills | 10 | 13 | 8 | 10 | 2 | 3 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Drug ineffective | | 4 | | | | 4 |
| Fatigue | 7 | 8 | 7 | 8 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Malaise | 3 | 3 | 3 | 3 | | |
| Pain | 1 | 2 | 1 | 2 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pyrexia | 10 | 12 | 8 | 10 | 2 | 2 |
| Swelling | | 2 | | 2 | | |
| Vaccination site erythema | 7 | 9 | 5 | 7 | 2 | 2 |
| Vaccination site extravasation | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 17 | 25 | 16 | 24 | 1 | 1 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site swelling | 10 | 12 | 8 | 10 | 2 | 2 |
| | 85 | 113 | 72 | 95 | 13 | 18 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactoid reaction | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| COVID-19 | | 4 | | 4 |
| Sweating fever | 1 | 1 | 1 | 1 |
| | 1 | 5 | 1 | 5 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anti-thyroid antibody positive | 1 | 1 | | | 1 | 1 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure increased | 4 | 4 | 3 | 3 | 1 | 1 |
| Body temperature increased | 8 | 11 | 6 | 9 | 2 | 2 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Lymphocyte count decreased | | 1 | | 1 | | |
| Rheumatoid factor positive | 1 | 1 | 1 | 1 | | |
| | 15 | 20 | 11 | 16 | 4 | 4 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 2 | 2 | 1 | 1 | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 8 | 11 | 8 | 11 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 2 | 1 | 2 | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 12 | 17 | 12 | 17 | | |
| Neck pain | | 1 | | 1 | | |
| Pain in extremity | 2 | 3 | 2 | 3 | | |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Spinal pain | 1 | 1 | 1 | 1 | | |
| | 29 | 40 | 27 | 38 | 2 | 2 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 1 | | 1 | | |
| Anosmia | | 1 | | 1 | | |
| Dizziness | 6 | 9 | 6 | 8 | | 1 |
| Dizziness postural | | 1 | | 1 | | |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Headache | 12 | 17 | 10 | 14 | 2 | 3 |
| Head discomfort | | 1 | | | | 1 |
| Meningism | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 2 | 3 | 1 | 2 | 1 | 1 |
| Peripheral sensory neuropathy | 1 | 1 | 1 | 1 | | |
| Reduced facial expression | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 2 | 2 | 2 | | |
| | 27 | 40 | 21 | 31 | 6 | 9 |

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* AE=Adverse Event

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Insomnia | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Renal pain | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Erectile dysfunction | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| | 2 | 3 | 1 | 1 | 1 | 2 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Erythema | 2 | 3 | 2 | 3 | | |
| Hyperhidrosis | 3 | 5 | 2 | 3 | 1 | 2 |
| Rash | 1 | 2 | 1 | 2 | | |
| Rash erythematous | | 1 | | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| | 8 | 14 | 6 | 11 | 2 | 3 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure inadequately controlled | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Jugular vein distension | 1 | 1 | | | 1 | 1 |
| Pallor | | 1 | | 1 | | |
| Peripheral coldness | | 1 | | 1 | | |
| Vasospasm | 1 | 1 | | | 1 | 1 |
| | 5 | 7 | 3 | 5 | 2 | 2 |

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Country Where Event Occurred

CANADA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 7 | 14 | 6 | 13 | 1 | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| | 8 | 15 | 7 | 14 | 1 | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Palpitations | 1 | 2 | 1 | 2 | | |
| Tachycardia | 2 | 7 | | 3 | 2 | 4 |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| | 6 | 12 | 1 | 5 | 5 | 7 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness | | 1 | | | | 1 |
| Ear discomfort | 1 | 2 | 1 | 2 | | |
| Hypoacusis | 2 | 2 | 2 | 2 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| | 5 | 7 | 5 | 6 | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diplopia | 1 | 1 | | | 1 | 1 |
| Eyelid function disorder | 1 | 1 | | | 1 | 1 |
| Eyelid sensory disorder | 1 | 1 | 1 | 1 | | |
| Eye pain | | 1 | | 1 | | |
| Eye pruritus | | 1 | | 1 | | |
| Eye swelling | 1 | 2 | 1 | 2 | | |
| Hypoaesthesia eye | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 1 | 1 | 1 | 1 | | |
| Vision blurred | 2 | 3 | 2 | 3 | | |
| Visual impairment | 1 | 2 | | 1 | 1 | 1 |
| | 9 | 14 | 6 | 11 | 3 | 3 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 2 | 3 | 2 | 3 | | |
| Abdominal pain lower | | 1 | | 1 | | |
| Abdominal pain upper | | 2 | | 2 | | |
| Aphthous ulcer | | 1 | | 1 | | |
| Diarrhoea | 1 | 11 | 1 | 11 | | |
| Dysphagia | 1 | 4 | 1 | 4 | | |
| Gastric disorder | 1 | 1 | 1 | 1 | | |
| Gastroesophageal reflux disease | | 1 | | 1 | | |
| Hypoaesthesia oral | 1 | 2 | | | 1 | 2 |
| Lip swelling | | 2 | | 1 | | 1 |
| Mouth swelling | | 1 | | | | 1 |
| Nausea | 10 | 24 | 10 | 24 | | |
| Odynophagia | | 1 | | 1 | | |
| Oesophageal disorder | 1 | 1 | | | 1 | 1 |
| Oral mucosal blistering | | 1 | | 1 | | |
| Paraesthesia oral | 3 | 7 | 2 | 5 | 1 | 2 |
| Swollen tongue | 1 | 4 | 1 | 3 | | 1 |
| Tongue disorder | | 1 | | | | 1 |
| Tongue pruritus | | 1 | | 1 | | |
| Vomiting | 1 | 7 | 1 | 7 | | |
| | 23 | 77 | 20 | 68 | 3 | 9 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 4 | 8 | 2 | 6 | 2 | 2 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 3 | 4 | 2 | 2 | 1 | 2 |
| Chest pain | 3 | 4 | 3 | 3 | | 1 |
| Chills | 11 | 22 | 11 | 22 | | |
| Condition aggravated | | 1 | | | | 1 |
| Disease recurrence | 2 | 3 | 1 | 2 | 1 | 1 |
| Drug ineffective | 3 | 9 | | | 3 | 9 |
| Face oedema | | 1 | | | | 1 |
| Facial pain | 3 | 3 | 3 | 3 | | |
| Fatigue | 19 | 43 | 18 | 41 | 1 | 2 |
| Feeling abnormal | 2 | 5 | 2 | 5 | | |
| Feeling cold | | 2 | | 1 | | 1 |
| Feeling drunk | 1 | 1 | 1 | 1 | | |
| Feeling hot | 2 | 3 | 2 | 3 | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Illness | | 1 | | 1 | | |
| Influenza like illness | 2 | 4 | 2 | 4 | | |
| Injection site pain | | 1 | | 1 | | |
| Malaise | 6 | 10 | 6 | 10 | | |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Oedema | | 1 | | 1 | | |
| Pain | 7 | 18 | 7 | 18 | | |
| Peripheral swelling | | 1 | | 1 | | |
| Pyrexia | 15 | 33 | 15 | 33 | | |
| Secretion discharge | 1 | 1 | 1 | 1 | | |
| Swelling | 2 | 4 | 2 | 3 | | 1 |
| Swelling face | 4 | 4 | 2 | 2 | 2 | 2 |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | |
| Thirst | | 1 | | 1 | | |
| Vaccination site erythema | 3 | 3 | 3 | 3 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site induration | 1 | 2 | 1 | 2 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 9 | 25 | 9 | 24 | | 1 |
| Vaccination site rash | | 1 | | 1 | | |
| Vaccination site reaction | 1 | 2 | 1 | 2 | | |
| Vaccination site swelling | 4 | 6 | 4 | 6 | | |
| Vaccination site urticaria | 3 | 3 | 3 | 3 | | |
| Vaccination site warmth | 1 | 2 | 1 | 2 | | |
| | 120 | 240 | 110 | 216 | 10 | 24 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | | 1 | | 1 | | |
| Anaphylactic reaction | 4 | 9 | | | 4 | 9 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 6 | 10 | 1 | 2 | 5 | 8 |
| Type I hypersensitivity | 2 | 2 | | | 2 | 2 |
| Type IV hypersensitivity reaction | | 1 | | 1 | | |
| | 13 | 24 | 1 | 4 | 12 | 20 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Beta haemolytic streptococcal infection | 1 | 1 | | | 1 | 1 |
| Cellulitis | | 1 | | | | 1 |
| COVID-19 | 3 | 9 | | 1 | 3 | 8 |
| Disseminated varicella zoster virus infection | | 1 | | | | 1 |
| Gastroenteritis | | 1 | | 1 | | |
| Herpes zoster | 1 | 3 | | 2 | 1 | 1 |
| Meningitis aseptic | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | | 1 | | 1 | | |
| Oral candidiasis | 1 | 1 | 1 | 1 | | |
| Oral herpes | | 1 | | 1 | | |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Rash pustular | | 1 | | 1 | | |
| Varicella | | 1 | | 1 | | |
| | 8 | 23 | 1 | 9 | 7 | 14 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Exposure during pregnancy | 4 | 8 | 2 | 6 | 2 | 2 |
| Exposure via breast milk | 1 | 7 | 1 | 7 | | |
| Inappropriate schedule of product administration | 10 | 14 | 10 | 14 | | |
| Incomplete course of vaccination | 1 | 2 | 1 | 2 | | |
| Incorrect dose administered | 2 | 2 | 2 | 2 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Maternal exposure during pregnancy | 2 | 13 | 2 | 13 | | |
| Maternal exposure timing unspecified | | 2 | | 2 | | |
| Off label use | 7 | 27 | 7 | 27 | | |
| Overdose | 2 | 8 | 2 | 8 | | |
| Product administered at inappropriate site | 1 | 3 | 1 | 3 | | |
| Product preparation issue | 2 | 12 | 2 | 12 | | |
| Product use issue | 6 | 24 | 6 | 24 | | |
| Skin injury | | 1 | | 1 | | |
| Underdose | 2 | 6 | 2 | 6 | | |
| | 41 | 131 | 39 | 129 | 2 | 2 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood glucose decreased | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| Grip strength decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | | 1 | | 1 | | |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Vital functions abnormal | | 1 | | | | 1 |
| | 4 | 8 | 3 | 5 | 1 | 3 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 2 | 5 | 1 | 4 | 1 | 1 |
| Dehydration | 1 | 1 | 1 | 1 | | |
| Fluid retention | 1 | 2 | 1 | 2 | | |
| Gout | | 1 | | 1 | | |
| Polydipsia | 1 | 1 | 1 | 1 | | |
| | 5 | 10 | 4 | 9 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 6 | 17 | 6 | 15 | | 2 |
| Back pain | | 1 | | 1 | | |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Fibromyalgia | | 1 | | 1 | | |
| Joint range of motion decreased | 1 | 1 | 1 | 1 | | |
| Joint swelling | | 2 | | 1 | | 1 |
| Limb discomfort | 1 | 2 | 1 | 2 | | |
| Muscle spasms | 1 | 2 | 1 | 2 | | |
| Muscle twitching | | 1 | | 1 | | |
| Muscular weakness | 1 | 2 | 1 | 2 | | |
| Musculoskeletal pain | | 1 | | 1 | | |
| Musculoskeletal stiffness | 1 | 4 | 1 | 4 | | |
| Myalgia | 10 | 27 | 10 | 25 | | 2 |
| Neck pain | 3 | 5 | 2 | 4 | 1 | 1 |
| Pain in extremity | 9 | 26 | 7 | 24 | 2 | 2 |
| Pain in jaw | 2 | 2 | 2 | 2 | | |
| Rheumatoid arthritis | | 1 | | | | 1 |
| Systemic lupus erythematosus | 1 | 1 | | | 1 | 1 |
| Temporomandibular joint syndrome | 1 | 1 | 1 | 1 | | |
| Tendonitis | 1 | 1 | 1 | 1 | | |
| | 39 | 99 | 35 | 89 | 4 | 10 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 2 | 2 | 2 | 2 | | |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Cognitive disorder | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 1 | 2 | 1 | 2 | | |
| Dizziness | 11 | 16 | 11 | 16 | | |
| Dysgeusia | 3 | 4 | 3 | 4 | | |
| Dyskinesia | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 3 | 4 | | | 3 | 4 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 17 | 49 | 17 | 49 | | |
| Head discomfort | | 1 | | 1 | | |
| Hyperaesthesia | 1 | 2 | 1 | 2 | | |
| Hypersomnia | 1 | 2 | 1 | 2 | | |
| Hypoaesthesia | 5 | 8 | 5 | 6 | | 2 |
| Hypokinesia | | 1 | | 1 | | |
| IVth nerve paralysis | 1 | 1 | | | 1 | 1 |
| Lethargy | | 3 | | 3 | | |
| Migraine | 3 | 4 | 2 | 3 | 1 | 1 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 4 | 11 | 3 | 8 | 1 | 3 |
| Presyncope | 1 | 3 | 1 | 2 | | 1 |
| Somnolence | 1 | 2 | 1 | 2 | | |
| Syncope | | 2 | | | | 2 |
| Taste disorder | | 1 | | 1 | | |
| Tremor | | 2 | | 1 | | 1 |
| | 59 | 125 | 51 | 108 | 8 | 17 |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortion spontaneous | 1 | 1 | 1 | 1 |
| Foetal growth restriction | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product supply issue | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Affect lability | | 1 | | 1 |
| Agitation | | 1 | | 1 |
| Anxiety | 1 | 3 | 1 | 3 |
| Confusional state | 1 | 1 | 1 | 1 |
| Depression | | 1 | | 1 |
| Distractibility | | 1 | | 1 |
| Fear | | 1 | | 1 |
| Insomnia | | 2 | | 2 |
| Psychotic disorder due to a general medical condition | 1 | 1 | 1 | 1 |
| Stress | | 1 | | 1 |
| | 3 | 13 | 3 | 13 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Polyuria | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Menstruation delayed | 1 | 1 | 1 | 1 | | |
| Menstruation irregular | | 1 | | 1 | | |
| Vulval disorder | | 1 | | | | 1 |
| | 1 | 3 | 1 | 2 | | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cough | 4 | 4 | 3 | 3 | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 8 | 11 | 5 | 7 | 3 | 4 |
| Lung disorder | | 1 | | | | 1 |
| Nasal congestion | | 1 | | 1 | | |
| Oropharyngeal pain | 2 | 5 | 2 | 5 | | |
| Pharyngeal hypoaesthesia | | 1 | | 1 | | |
| Pharyngeal swelling | 1 | 3 | 1 | 2 | | 1 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pulmonary infarction | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | | 1 | | | | 1 |
| Sinus pain | | 1 | | 1 | | |
| Sneezing | | 1 | | 1 | | |
| Tachypnoea | | 1 | | 1 | | |
| Throat irritation | | 2 | | 2 | | |
| Throat tightness | | 2 | | 1 | | 1 |
| Upper-airway cough syndrome | 1 | 1 | 1 | 1 | | |
| Wheezing | 4 | 4 | 3 | 3 | 1 | 1 |
| | 24 | 43 | 16 | 30 | 8 | 13 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acne | 1 | 1 | 1 | 1 | | |
| Angioedema | | 1 | | | | 1 |
| Cold sweat | 1 | 2 | 1 | 2 | | |
| Eczema | | 1 | | 1 | | |
| Erythema | 1 | 3 | 1 | 2 | | 1 |
| Erythema multiforme | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 2 | 1 | 2 | | |
| Leukoplakia | | 1 | | 1 | | |
| Pain of skin | | 1 | | 1 | | |
| Petechiae | | 1 | | 1 | | |
| Pruritus | 1 | 7 | 1 | 6 | | 1 |
| Rash | 3 | 7 | 3 | 6 | | 1 |
| Rash erythematous | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash macular | | 2 | | 2 | | |
| Rash maculo-papular | 1 | 1 | | | 1 | 1 |
| Rash papular | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Skin burning sensation | | 1 | | 1 | | |
| Skin lesion | | 1 | | 1 | | |
| Urticaria | 2 | 7 | 2 | 7 | | |
| | 16 | 44 | 11 | 35 | 5 | 9 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Impaired driving ability | 1 | 1 | 1 | 1 |
| Impaired work ability | 1 | 2 | 1 | 2 |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 |
| | 3 | 4 | 3 | 4 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Flushing | | 1 | | | | 1 |
| Hot flush | | 1 | | 1 | | |
| Hypertension | 5 | 8 | 3 | 4 | 2 | 4 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 3 | 1 | 1 | | 2 |
| Lymphoedema | | 1 | | 1 | | |
| | 7 | 15 | 4 | 7 | 3 | 8 |

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Country Where Event Occurred

CHILE

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 1 | 5 | 1 | 4 | | 1 |
| Lymph node pain | 1 | 3 | 1 | 3 | | |
| | 2 | 8 | 2 | 7 | | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Arrhythmia | 1 | 1 | 1 | 1 |
| Tachycardia | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Eye pruritus | | 1 | | 1 |
| Eye swelling | | 1 | | 1 |
| Ocular hyperaemia | | 1 | | 1 |
| Photophobia | | 1 | | 1 |
| | | 4 | | 4 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 2 | | 1 | | 1 |
| Abnormal faeces | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 6 | 1 | 6 | | |
| Dry mouth | | 1 | | | | 1 |
| Dysbiosis | | 1 | | | | 1 |
| Nausea | | 3 | | 2 | | 1 |
| Pancreatitis | | 1 | | | | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 3 | 16 | 3 | 11 | | 5 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | | 1 | | 1 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | | 3 | | 2 | | 1 |
| Crying | | 1 | | | | 1 |
| Disease recurrence | | 1 | | 1 | | |
| Face oedema | 2 | 2 | | | 2 | 2 |
| Fatigue | 3 | 5 | 3 | 5 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | | 1 | | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 4 | 1 | 4 | | |
| Pain | 2 | 4 | 1 | 3 | 1 | 1 |
| Peripheral swelling | | 1 | | 1 | | |
| Pyrexia | 1 | 6 | 1 | 5 | | 1 |
| Swelling face | | 1 | | | | 1 |
| Vaccination site pain | 2 | 5 | 1 | 3 | 1 | 2 |
| | 15 | 39 | 9 | 28 | 6 | 11 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Hypersensitivity | 1 | 2 | 1 | 2 | | |
| | 3 | 5 | 1 | 2 | 2 | 3 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | | 1 | | 1 |
| Incomplete course of vaccination | 7 | 7 | 7 | 7 |
| Incorrect route of product administration | | 1 | | 1 |
| Maternal exposure timing unspecified | | 1 | | 1 |
| Off label use | | 2 | | 2 |
| Product use issue | | 1 | | 1 |
| | 7 | 13 | 7 | 13 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Complement factor C3 decreased | 1 | 1 | 1 | 1 | | |
| C-reactive protein decreased | 1 | 1 | 1 | 1 | | |
| Monocyte count decreased | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| Urine analysis abnormal | | 1 | | | | 1 |
| | 4 | 5 | 4 | 4 | | 1 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Polydipsia | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 3 | 1 | 2 | | 1 |
| Arthritis | | 1 | | | | 1 |
| Back pain | 1 | 2 | 1 | 2 | | |
| Joint swelling | | 2 | | 1 | | 1 |
| Muscle spasms | | 1 | | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 5 | 2 | 4 | | 1 |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Rhabdomyolysis | 1 | 1 | | | 1 | 1 |
| Synovial cyst | | 1 | | 1 | | |
| | 7 | 19 | 6 | 14 | 1 | 5 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Burning sensation | | 2 | | 2 | | |
| Dizziness | 1 | 2 | | 1 | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 7 | 1 | 6 | | 1 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 2 | 3 | 1 | 1 | 1 | 2 |
| Sensory loss | | 1 | | 1 | | |
| | 9 | 20 | 2 | 11 | 7 | 9 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Mental disorder | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast pain | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Choking | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 3 | | | 2 | 3 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Nasal congestion | | 1 | | 1 | | |
| Respiratory disorder | 1 | 1 | | | 1 | 1 |
| Respiratory distress | | 1 | | | | 1 |
| | 5 | 8 | | 1 | 5 | 7 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 2 | | | 1 | 2 |
| Dermatitis allergic | | 4 | | 4 | | |
| Erythema | | 1 | | 1 | | |
| Hyperhidrosis | | 1 | | 1 | | |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| | 4 | 11 | | 6 | 4 | 5 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hypotension | 1 | 1 | 1 | 1 |
| Pallor | 1 | 1 | 1 | 1 |
| Venous thrombosis | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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Country Where Event Occurred

COLOMBIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Leukocytosis | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Stomatitis | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Chills | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| | | 2 | | 2 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Hypersensitivity | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Candida infection | | 1 | | 1 |
| Gingivitis | | 1 | | 1 |
| Oral candidiasis | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Off label use | | 1 | | 1 |
| Product use issue | | 1 | | 1 |
| | | 2 | | 2 |

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Country Where Event Occurred

COSTA RICA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymph node pain | | 1 | | 1 | | |
| Splenomegaly | | 1 | | | | 1 |
| | | 2 | | 1 | | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Tachycardia | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eye allergy | | 1 | | 1 | | |
| Eye inflammation | | 1 | | 1 | | |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Miosis | 1 | 1 | | | 1 | 1 |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| | 4 | 6 | 3 | 5 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 1 | | 1 | | |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 3 | 4 | | 1 | 3 | 3 |

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 * AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 2 | 3 | 1 | 2 | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 4 | 1 | 3 | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Energy increased | | 1 | | 1 | | |
| Fatigue | 6 | 7 | 5 | 6 | 1 | 1 |
| Feeling abnormal | 1 | 2 | 1 | 2 | | |
| Feeling cold | 2 | 2 | 2 | 2 | | |
| Feeling hot | | 1 | | 1 | | |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 4 | 2 | 3 | | 1 |
| Pain | 4 | 5 | 4 | 5 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pyrexia | 3 | 6 | 3 | 5 | | 1 |
| Sensation of foreign body | 1 | 1 | 1 | 1 | | |
| Thirst | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 6 | 10 | 6 | 10 | | |
| | 37 | 54 | 27 | 42 | 10 | 12 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Suspected COVID-19 | 1 | 1 | 1 | 1 | | |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Incorrect route of product administration | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Heart rate irregular | | 1 | | 1 | | |
| Hepatic enzyme increased | | 1 | | | | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Red blood cell sedimentation rate increased | | 1 | | 1 | | |
| | 3 | 6 | 1 | 3 | 2 | 3 |

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 * AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Joint range of motion decreased | | 1 | | | | 1 |
| Limb discomfort | 1 | 2 | 1 | 2 | | |
| Mobility decreased | | 1 | | | | 1 |
| Muscle contracture | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 8 | 5 | 6 | 1 | 2 |
| Pain in extremity | 3 | 5 | 3 | 5 | | |
| | 15 | 22 | 14 | 18 | 1 | 4 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Headache | 8 | 14 | 7 | 13 | 1 | 1 |
| Migraine | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 1 | 1 | 1 | | |
| | 13 | 19 | 10 | 16 | 3 | 3 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Communication disorder | 1 | 1 | 1 | 1 |
| Depression | 1 | 1 | 1 | 1 |
| Euphoric mood | | 1 | | 1 |
| Insomnia | | 1 | | 1 |
| Sleep disorder | | 1 | | 1 |
| | 2 | 5 | 2 | 5 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 5 | 5 | 3 | 3 | 2 | 2 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pleuritic pain | 1 | 1 | 1 | 1 | | |
| Pneumonitis | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Throat clearing | 1 | 1 | 1 | 1 | | |
| | 12 | 12 | 7 | 7 | 5 | 5 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Pruritus | | 1 | | 1 | | |
| Rash | | 1 | | 1 | | |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| | 2 | 4 | 1 | 3 | 1 | 1 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Vasculitis | | 1 | | 1 | | |
| | 2 | 3 | | 1 | 2 | 2 |

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Country Where Event Occurred

CROATIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenitis | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 4 | 4 | 4 | 4 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Lymphopenia | 1 | 1 | 1 | 1 | | |
| | 7 | 7 | 6 | 6 | 1 | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Palpitations | 6 | 6 | 3 | 3 | 3 | 3 |
| Tachycardia | 6 | 6 | 4 | 4 | 2 | 2 |
| | 13 | 13 | 7 | 7 | 6 | 6 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |
| Ear canal erythema | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Ear pruritus | 1 | 1 | | | 1 | 1 |
| Hypoacusis | 1 | 1 | 1 | 1 | | |
| Tinnitus | 3 | 3 | 2 | 2 | 1 | 1 |
| Vertigo | 3 | 3 | 2 | 2 | 1 | 1 |
| | 11 | 11 | 5 | 5 | 6 | 6 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctivitis allergic | 1 | 1 | | | 1 | 1 |
| Eye haematoma | 1 | 1 | | | 1 | 1 |
| Eye haemorrhage | 1 | 1 | | | 1 | 1 |
| Eyelid function disorder | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Eyelid ptosis | | 1 | | | | 1 |
| Eye opacity | 1 | 1 | 1 | 1 | | |
| Eye pain | | 1 | | 1 | | |
| Lacrimation increased | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vitreous detachment | 1 | 1 | | | 1 | 1 |
| | 12 | 14 | 4 | 5 | 8 | 9 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 2 | 1 | 2 | | |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dry mouth | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphagia | 2 | 2 | | | 2 | 2 |
| Gastrointestinal pain | 1 | 1 | 1 | 1 | | |
| Gingival bleeding | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | | 1 | | | | 1 |
| Lip disorder | | 1 | | | | 1 |
| Lip oedema | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Nausea | 14 | 14 | 11 | 11 | 3 | 3 |
| Oedema mouth | 1 | 1 | | | 1 | 1 |
| Oral mucosal erythema | 1 | 1 | 1 | 1 | | |
| Oral pain | 1 | 1 | 1 | 1 | | |
| Paraesthesia oral | 4 | 4 | 1 | 1 | 3 | 3 |
| Retching | 1 | 1 | 1 | 1 | | |
| Salivary hypersecretion | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 2 | | | 1 | 2 |
| Tongue oedema | 2 | 3 | | | 2 | 3 |
| Vomiting | 3 | 3 | 2 | 2 | 1 | 1 |
| | 40 | 45 | 23 | 24 | 17 | 21 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 11 | 11 | 9 | 9 | 2 | 2 |
| Chest discomfort | 4 | 4 | 1 | 1 | 3 | 3 |
| Chest pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Chills | 21 | 24 | 17 | 20 | 4 | 4 |
| Condition aggravated | 2 | 2 | | | 2 | 2 |
| Death | 2 | 2 | | | 2 | 2 |
| Discomfort | | 1 | | 1 | | |
| Extensive swelling of vaccinated limb | 14 | 14 | | | 14 | 14 |
| Fatigue | 12 | 16 | 10 | 14 | 2 | 2 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | | 1 | | 1 | | |
| Feeling hot | 6 | 7 | 3 | 4 | 3 | 3 |
| Illness | 1 | 1 | 1 | 1 | | |
| Localised oedema | 1 | 1 | 1 | 1 | | |
| Malaise | 9 | 10 | 8 | 9 | 1 | 1 |
| Multi-organ disorder | | 1 | | | | 1 |
| Pain | | 1 | | 1 | | |
| Peripheral swelling | 2 | 3 | 1 | 2 | 1 | 1 |
| Pyrexia | 34 | 42 | 25 | 33 | 9 | 9 |
| Swelling face | 1 | 2 | | | 1 | 2 |
| Vaccination site erythema | 20 | 21 | 14 | 15 | 6 | 6 |
| Vaccination site haematoma | 2 | 2 | 2 | 2 | | |
| Vaccination site hypersensitivity | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site joint erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 5 | 6 | 4 | 4 | 1 | 2 |
| Vaccination site pain | 50 | 60 | 41 | 50 | 9 | 10 |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 11 | 12 | 8 | 9 | 3 | 3 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 221 | 257 | 155 | 187 | 66 | 70 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to chemicals | | 1 | | 1 | | |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | | 1 | | | | 1 |
| Hypersensitivity | 3 | 3 | | | 3 | 3 |
| Immune system disorder | 1 | 1 | 1 | 1 | | |
| Serum sickness | 1 | 1 | | | 1 | 1 |
| Type I hypersensitivity | 17 | 18 | | | 17 | 18 |
| | 22 | 26 | 1 | 2 | 21 | 24 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| COVID-19 | 1 | 1 | 1 | 1 |
| Viral infection | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Incorrect dose administered | 1 | 1 | | | 1 | 1 |
| Underdose | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood creatine phosphokinase increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 4 | 4 | | | 4 | 4 |
| Body temperature increased | 7 | 10 | 6 | 9 | 1 | 1 |
| Rheumatoid factor positive | 1 | 1 | 1 | 1 | | |
| | 14 | 17 | 9 | 12 | 5 | 5 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Decreased appetite | 2 | 2 | 2 | 2 |
| Feeding disorder | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 9 | 9 | 9 | 9 | | |
| Back pain | 4 | 4 | 3 | 3 | 1 | 1 |
| Bone pain | 4 | 4 | 4 | 4 | | |
| Fibromyalgia | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle tightness | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 4 | 4 | 2 | 2 | 2 | 2 |
| Myalgia | 22 | 24 | 21 | 23 | 1 | 1 |
| Myosclerosis | 1 | 1 | | | 1 | 1 |
| Neck pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Pain in extremity | 10 | 11 | 8 | 9 | 2 | 2 |
| Spinal pain | 1 | 1 | 1 | 1 | | |
| | 60 | 64 | 50 | 54 | 10 | 10 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Burning sensation | 2 | 4 | | 1 | 2 | 3 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 7 | 8 | 5 | 6 | 2 | 2 |
| Dysgeusia | 1 | 2 | 1 | 1 | | 1 |
| Dyskinesia | 1 | 1 | | | 1 | 1 |
| Encephalitis post immunisation | 1 | 1 | | | 1 | 1 |
| Extrapyramidal disorder | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 3 | 4 | | | 3 | 4 |
| Headache | 43 | 51 | 30 | 37 | 13 | 14 |
| Head discomfort | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 2 | 2 | 2 | 2 | | |
| Hypogeusia | 1 | 1 | 1 | 1 | | |
| Migraine | 1 | 1 | 1 | 1 | | |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Muscle contractions involuntary | 1 | 1 | | | 1 | 1 |
| Nystagmus | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 7 | 9 | 3 | 4 | 4 | 5 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Presyncope | 2 | 2 | 1 | 1 | 1 | 1 |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Sleep paralysis | 1 | 1 | 1 | 1 | | |
| Somnolence | 2 | 2 | 1 | 1 | 1 | 1 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tremor | 7 | 8 | 6 | 6 | 1 | 2 |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| | 95 | 111 | 53 | 63 | 42 | 48 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Fear | 1 | 1 | | | 1 | 1 |
| Insomnia | 1 | 2 | 1 | 2 | | |
| Panic attack | 2 | 2 | | | 2 | 2 |
| Sleep terror | 1 | 1 | 1 | 1 | | |
| | 6 | 7 | 3 | 4 | 3 | 3 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 2 | 3 | 1 | 1 | 1 | 2 |
| Cough | 2 | 2 | | | 2 | 2 |
| Diaphragmatic spasm | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 8 | 9 | 1 | 1 | 7 | 8 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pharyngeal paraesthesia | | 1 | | | | 1 |
| Pharyngeal swelling | 1 | 1 | 1 | 1 | | |
| Pulmonary pain | 1 | 1 | 1 | 1 | | |
| Rales | 1 | 1 | | | 1 | 1 |
| Respiratory tract oedema | | 1 | | | | 1 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Tachypnoea | | 1 | | | | 1 |
| Wheezing | 1 | 2 | | | 1 | 2 |
| | 23 | 29 | 7 | 7 | 16 | 22 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 2 | | | 1 | 2 |
| Blister | 1 | 1 | | | 1 | 1 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Erythema | 13 | 16 | | 2 | 13 | 14 |
| Hyperhidrosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pain of skin | 1 | 1 | | | 1 | 1 |
| Pruritus | 5 | 6 | | | 5 | 6 |
| Psoriasis | 1 | 1 | 1 | 1 | | |
| Rash | 7 | 9 | | 1 | 7 | 8 |
| Rash erythematous | | 1 | | | | 1 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 3 | 3 | | | 3 | 3 |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Skin oedema | 1 | 1 | 1 | 1 | | |
| Urticaria | 5 | 5 | | | 5 | 5 |
| | 46 | 54 | 5 | 8 | 41 | 46 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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Country Where Event Occurred

CYPRUS

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 4 | 5 | 4 | 4 | | 1 |
| | 4 | 5 | 4 | 4 | | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 1 | 2 | | | 1 | 2 |
| Tachyarrhythmia | | 1 | | | | 1 |
| Tachycardia | 1 | 2 | 1 | 1 | | 1 |
| | 3 | 6 | 1 | 1 | 2 | 5 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear discomfort | 1 | 1 | 1 | 1 |
| Ear pain | 1 | 1 | 1 | 1 |
| Hypoacusis | 1 | 1 | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid ptosis | | 1 | | 1 | | |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia eye | | 1 | | | | 1 |
| | 1 | 3 | 1 | 2 | | 1 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 1 | 2 | | | 1 | 2 |
| Nausea | 5 | 5 | 5 | 5 | | |
| Swollen tongue | | 1 | | 1 | | |
| Vomiting | 2 | 2 | 2 | 2 | | |
| | 10 | 12 | 9 | 10 | 1 | 2 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 4 | 5 | 4 | 5 | | |
| Axillary pain | 2 | 2 | 2 | 2 | | |
| Chills | 7 | 8 | 7 | 8 | | |
| Condition aggravated | | 1 | | 1 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Face oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Fatigue | 4 | 4 | 4 | 4 | | |
| Gait disturbance | 2 | 2 | 2 | 2 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| Malaise | 5 | 5 | 5 | 5 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Pyrexia | 7 | 8 | 7 | 8 | | |
| Sluggishness | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 2 | 2 | 2 | 2 | | |
| Vaccination site pain | 9 | 11 | 9 | 11 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| | 51 | 57 | 49 | 55 | 2 | 2 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Hypersensitivity | | 1 | | 1 | | |
| | 2 | 3 | | 1 | 2 | 2 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Contusion | 1 | 1 | 1 | 1 |
| Inappropriate schedule of product administration | | 1 | | 1 |
| Off label use | 1 | 1 | 1 | 1 |
| Overdose | 1 | 1 | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 |
| | 4 | 5 | 4 | 5 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure increased | | 1 | | | | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 3 | 3 | 1 | 1 | 2 | 2 |
| SARS-CoV-2 ant body test negative | | 1 | | | | 1 |
| | 5 | 7 | 3 | 3 | 2 | 4 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Hyponatraemia | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 8 | 8 | 8 | 8 |
| Back pain | 1 | 2 | 1 | 2 |
| Bone pain | 1 | 1 | 1 | 1 |
| Muscle contracture | 1 | 1 | 1 | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 |
| Myalgia | 12 | 12 | 12 | 12 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| | 25 | 26 | 25 | 26 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Dizziness | 5 | 7 | 5 | 7 | | |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Dysgeusia | | 1 | | 1 | | |
| Facial paralysis | 1 | 2 | | | 1 | 2 |
| Facial paresis | 4 | 6 | | | 4 | 6 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 | 1 | 1 | | |
| Headache | 7 | 9 | 7 | 9 | | |
| Head titubation | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 2 | 1 | 1 | | 1 |
| Migraine | | 1 | | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Syncope | 3 | 3 | | | 3 | 3 |
| Tremor | 1 | 1 | 1 | 1 | | |
| | 28 | 38 | 18 | 24 | 10 | 14 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Confusional state | 1 | 1 | 1 | 1 |
| Insomnia | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Cervix oedema | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cough | | 1 | | 1 | | |
| Dyspnoea | 4 | 5 | 2 | 3 | 2 | 2 |
| Epistaxis | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory tract oedema | 1 | 1 | | | 1 | 1 |
| Sinus congestion | | 1 | | 1 | | |
| Upper respiratory tract congestion | | 1 | | 1 | | |
| | 11 | 16 | 4 | 9 | 7 | 7 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Dermatitis atopic | 1 | 1 | 1 | 1 |
| Eczema | 1 | 1 | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 |
| Rash | | 1 | | 1 |
| | 4 | 5 | 4 | 5 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypertension | | 1 | | | | 1 |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Pallor | 1 | 1 | 1 | 1 | | |
| Vasculitis | 1 | 1 | 1 | 1 | | |
| | 4 | 5 | 2 | 2 | 2 | 3 |

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Country Where Event Occurred

CZECH REPUBLIC

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytosis | 1 | 1 | 1 | 1 | | |
| Lymphadenitis | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 20 | 21 | 13 | 14 | 7 | 7 |
| Lymph node pain | 7 | 7 | 5 | 5 | 2 | 2 |
| | 29 | 30 | 19 | 20 | 10 | 10 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Bradycardia | 4 | 4 | | | 4 | 4 |
| Palpitations | 7 | 7 | 2 | 2 | 5 | 5 |
| Tachycardia | 7 | 8 | 5 | 6 | 2 | 2 |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| | 22 | 23 | 7 | 8 | 15 | 15 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute vestibular syndrome | 1 | 1 | | | 1 | 1 |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 3 | 3 | 1 | 1 | 2 | 2 |
| Ear swelling | 1 | 1 | | | 1 | 1 |
| Hypoacusis | 1 | 1 | 1 | 1 | | |
| Tinnitus | 1 | 1 | | | 1 | 1 |
| Vertigo | 13 | 14 | 9 | 10 | 4 | 4 |
| | 21 | 22 | 11 | 12 | 10 | 10 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blindness | 1 | 1 | | | 1 | 1 |
| Eye inflammation | 1 | 1 | 1 | 1 | | |
| Eye pain | 2 | 2 | 2 | 2 | | |
| Eye pruritus | | 1 | | 1 | | |
| Ocular hyperaemia | | 1 | | 1 | | |
| Photophobia | | 1 | | 1 | | |
| Photopsia | 1 | 1 | 1 | 1 | | |
| Vision blurred | 2 | 3 | 2 | 3 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| | 8 | 12 | 6 | 10 | 2 | 2 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Anaesthesia oral | 1 | 1 | | | 1 | 1 |
| Anal incontinence | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 8 | 9 | 7 | 8 | 1 | 1 |
| Dry mouth | 2 | 2 | 2 | 2 | | |
| Dyspepsia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 2 | | 1 | 1 | 1 |
| Frequent bowel movements | 1 | 1 | 1 | 1 | | |
| Gastrointestinal hypermotility | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 2 | | | 1 | 2 |
| Nausea | 26 | 30 | 22 | 25 | 4 | 5 |
| Oedema mouth | 1 | 1 | | | 1 | 1 |
| Oral discomfort | 1 | 1 | | | 1 | 1 |
| Oral pruritus | | 1 | | 1 | | |
| Paraesthesia oral | 5 | 5 | | | 5 | 5 |
| Retching | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 1 | 3 | | | 1 | 3 |
| Tongue discomfort | 1 | 1 | 1 | 1 | | |
| Tongue oedema | 2 | 2 | | | 2 | 2 |
| Toothache | 1 | 1 | 1 | 1 | | |
| Vomiting | 20 | 21 | 14 | 14 | 6 | 7 |
| | 78 | 89 | 52 | 58 | 26 | 31 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Application site coldness | 1 | 1 | | | 1 | 1 |
| Asthenia | 23 | 25 | 16 | 18 | 7 | 7 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chest discomfort | 5 | 5 | 2 | 2 | 3 | 3 |
| Chest pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Chills | 49 | 52 | 44 | 46 | 5 | 6 |
| Condition aggravated | 1 | 1 | 1 | 1 | | |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 4 | 7 | | | 4 | 7 |
| Facial pain | 1 | 1 | | | 1 | 1 |
| Fatigue | 49 | 58 | 42 | 51 | 7 | 7 |
| Feeling abnormal | 3 | 3 | 3 | 3 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | 6 | 6 | 4 | 4 | 2 | 2 |
| Generalised oedema | 1 | 1 | 1 | 1 | | |
| General physical health deterioration | 2 | 2 | | | 2 | 2 |
| Illness | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 7 | 7 | 5 | 5 | 2 | 2 |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 | | |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Malaise | 6 | 7 | 5 | 6 | 1 | 1 |
| Mucosal disorder | 1 | 1 | | | 1 | 1 |
| Mucosal dryness | 1 | 1 | 1 | 1 | | |
| Multiple organ dysfunction syndrome | 2 | 2 | | | 2 | 2 |
| Oedema | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Pain | 7 | 8 | 6 | 7 | 1 | 1 |
| Peripheral swelling | 4 | 5 | 1 | 1 | 3 | 4 |
| Pyrexia | 71 | 75 | 51 | 55 | 20 | 20 |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Swelling | 1 | 2 | 1 | 1 | | 1 |
| Swelling face | 6 | 7 | 1 | 1 | 5 | 6 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site atrophy | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 25 | 25 | 17 | 17 | 8 | 8 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 2 | 1 | 2 | | |
| Vaccination site oedema | 11 | 11 | 7 | 7 | 4 | 4 |
| Vaccination site pain | 41 | 44 | 35 | 38 | 6 | 6 |
| Vaccination site papule | 1 | 1 | | | 1 | 1 |
| Vaccination site paraesthesia | 2 | 2 | 2 | 2 | | |
| Vaccination site pruritus | 6 | 6 | 6 | 6 | | |
| Vaccination site reaction | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 8 | 8 | 6 | 6 | 2 | 2 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 5 | 5 | 5 | 5 | | |
| | 372 | 402 | 274 | 297 | 98 | 105 |

System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Jaundice | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 1 | 3 | | | 1 | 3 |
| Anaphylactic reaction | 5 | 7 | | | 5 | 7 |
| Drug hypersensitivity | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | 12 | 14 | 4 | 5 | 8 | 9 |
| | 19 | 25 | 5 | 6 | 14 | 19 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacterial rhinitis | 1 | 1 | | | 1 | 1 |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| COVID-19 | 10 | 12 | 4 | 4 | 6 | 8 |
| COVID-19 pneumonia | 3 | 3 | | | 3 | 3 |
| Gastroenteritis | 1 | 1 | 1 | 1 | | |
| Influenza | 1 | 1 | 1 | 1 | | |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Rash pustular | 1 | 1 | 1 | 1 | | |
| Rhinitis | | 1 | | 1 | | |
| Sepsis | 1 | 1 | | | 1 | 1 |
| | 20 | 23 | 7 | 8 | 13 | 15 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Fall | 1 | 1 | 1 | 1 | | |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 3 | 3 | 3 | 3 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Off label use | 4 | 4 | 4 | 4 | | |
| Poor quality product administered | 83 | 83 | 83 | 83 | | |
| Product preparation error | 82 | 82 | 82 | 82 | | |
| Product preparation issue | 1 | 1 | 1 | 1 | | |
| Product use issue | 4 | 4 | 4 | 4 | | |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| | 183 | 183 | 182 | 182 | 1 | 1 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure increased | 3 | 4 | 3 | 3 | | 1 |
| Blood pressure systolic increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Body temperature increased | 2 | 3 | 2 | 3 | | |
| C-reactive protein increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 2 | 3 | 2 | 2 | | 1 |
| | 13 | 16 | 11 | 12 | 2 | 4 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 6 | 6 | 4 | 4 | 2 | 2 |
| Hyperglycaemia | 1 | 1 | 1 | 1 | | |
| Hyperphagia | 1 | 1 | 1 | 1 | | |
| Hypoglycaemia | 1 | 1 | 1 | 1 | | |
| Hypokalaemia | 2 | 2 | | | 2 | 2 |
| | 11 | 11 | 7 | 7 | 4 | 4 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 30 | 32 | 25 | 27 | 5 | 5 |
| Back pain | 3 | 4 | 3 | 4 | | |
| Joint effusion | 1 | 1 | | | 1 | 1 |
| Joint instability | 1 | 1 | | | 1 | 1 |
| Joint range of motion decreased | 1 | 1 | 1 | 1 | | |
| Joint stiffness | | 1 | | 1 | | |
| Joint warmth | 1 | 1 | 1 | 1 | | |
| Mobility decreased | | 1 | | 1 | | |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 3 | 3 | 3 | 3 | | |
| Musculoskeletal chest pain | | 1 | | 1 | | |
| Musculoskeletal disorder | 1 | 1 | 1 | 1 | | |
| Musculoskeletal pain | | 1 | | 1 | | |
| Musculoskeletal stiffness | 2 | 4 | 2 | 4 | | |
| Myalgia | 26 | 29 | 20 | 23 | 6 | 6 |
| Myosclerosis | 1 | 1 | | | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 18 | 20 | 15 | 17 | 3 | 3 |
| Polyarthritits | 1 | 1 | | | 1 | 1 |
| Spinal pain | 1 | 1 | | | 1 | 1 |
| | 92 | 106 | 72 | 86 | 20 | 20 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anosmia | 2 | 2 | 2 | 2 | | |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Burning sensation mucosal | 2 | 2 | 2 | 2 | | |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 9 | 11 | 6 | 7 | 3 | 4 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 2 | | | 1 | 2 |
| Formication | 1 | 1 | 1 | 1 | | |
| Headache | 53 | 57 | 44 | 48 | 9 | 9 |
| Head discomfort | 1 | 1 | | | 1 | 1 |
| Hypersomnia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 5 | 6 | 3 | 4 | 2 | 2 |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Language disorder | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 5 | 5 | | | 5 | 5 |
| Memory impairment | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 1 | 1 | 1 | | |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 17 | 20 | 11 | 12 | 6 | 8 |
| Presyncope | 9 | 9 | 2 | 2 | 7 | 7 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 4 | 1 | 3 | 1 | 1 |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Syncope | 4 | 4 | | | 4 | 4 |
| Tension headache | 2 | 2 | 1 | 1 | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 6 | 6 | 4 | 4 | 2 | 2 |
| Visual field defect | 1 | 1 | | | 1 | 1 |
| | 138 | 151 | 83 | 92 | 55 | 59 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | 3 | 4 | 2 | 3 | 1 | 1 |
| Apathy | 3 | 3 | 1 | 1 | 2 | 2 |
| Communication disorder | 1 | 1 | | | 1 | 1 |
| Confusional state | 3 | 3 | 1 | 1 | 2 | 2 |
| Decreased interest | 1 | 1 | 1 | 1 | | |
| Delirium | 1 | 1 | | | 1 | 1 |
| Depression | 1 | 1 | 1 | 1 | | |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Eating disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Hallucination | 2 | 2 | | | 2 | 2 |
| Illusion | 1 | 1 | 1 | 1 | | |
| Insomnia | 3 | 3 | 2 | 2 | 1 | 1 |
| Irritability | 1 | 1 | 1 | 1 | | |
| Logorrhoea | 1 | 1 | 1 | 1 | | |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| | 28 | 29 | 15 | 16 | 13 | 13 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Breast pain | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Asthma | | 1 | | | | 1 | |
| Choking sensation | 1 | 1 | | | 1 | 1 | |
| Cough | 5 | 6 | 4 | 5 | 1 | 1 | |
| Dyspnoea | 12 | 16 | 4 | 5 | 8 | 11 | |
| Grunting | 1 | 1 | | | 1 | 1 | |
| Hyperventilation | | 1 | | 1 | | | |
| Hypoxia | 2 | 2 | | | 2 | 2 | |
| Laryngeal oedema | 1 | 1 | | | 1 | 1 | |
| Nasal discomfort | 1 | 1 | | | 1 | 1 | |
| Oropharyngeal discomfort | 2 | 2 | 1 | 1 | 1 | 1 | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | | |
| Pharyngeal oedema | 1 | 2 | | 1 | 1 | 1 | |
| Pharyngeal swelling | 1 | 2 | | | 1 | 2 | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 | |
| Pulmonary pain | 1 | 1 | 1 | 1 | | | |
| Respiration abnormal | 1 | 1 | | | 1 | 1 | |
| Respiratory acidosis | 1 | 1 | 1 | 1 | | | |
| Respiratory depression | 1 | 1 | | | 1 | 1 | |
| Respiratory disorder | 1 | 1 | | | 1 | 1 | |
| Respiratory failure | 1 | 1 | | | 1 | 1 | |
| Respiratory tract oedema | 1 | 1 | | | 1 | 1 | |
| Rhinorrhoea | 1 | 2 | 1 | 2 | | | |
| Tachypnoea | 1 | 2 | 1 | 1 | | 1 | |
| Throat tightness | 1 | 2 | | | 1 | 2 | |
| Wheezing | 1 | 1 | 1 | 1 | | | |
| | 40 | 52 | 15 | 20 | 25 | 32 | |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | | 1 | | | | 1 |
| Cold sweat | 2 | 2 | 2 | 2 | | |
| Dermatitis | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | 1 | 1 | | |
| Erythema | 13 | 15 | 7 | 9 | 6 | 6 |
| Hyperhidrosis | 5 | 5 | 5 | 5 | | |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Photosensitivity reaction | 1 | 1 | 1 | 1 | | |
| Pruritus | 14 | 15 | 4 | 5 | 10 | 10 |
| Rash | 13 | 14 | 5 | 6 | 8 | 8 |
| Rash macular | 3 | 3 | 1 | 1 | 2 | 2 |
| Rash pruritic | 3 | 3 | | | 3 | 3 |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Skin disorder | 1 | 1 | | | 1 | 1 |
| Skin reaction | 1 | 1 | 1 | 1 | | |
| Urticaria | 2 | 2 | 2 | 2 | | |
| | 62 | 67 | 31 | 35 | 31 | 32 |

System Organ Class

Surgical and medical procedures

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Limb immobilisation | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circulatory collapse | 3 | 4 | | | 3 | 4 |
| Flushing | 2 | 2 | | | 2 | 2 |
| Hot flush | 3 | 3 | 2 | 2 | 1 | 1 |
| Hypertension | 4 | 5 | 1 | 2 | 3 | 3 |
| Hypotension | 8 | 9 | 3 | 3 | 5 | 6 |
| Lymphoedema | 1 | 1 | 1 | 1 | | |
| Pallor | 3 | 3 | 2 | 2 | 1 | 1 |
| Peripheral coldness | 5 | 5 | 5 | 5 | | |
| Shock | 2 | 2 | | | 2 | 2 |
| | 31 | 34 | 14 | 15 | 17 | 19 |

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Country Where Event Occurred

DENMARK

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemia | 2 | 2 | 1 | 1 | 1 | 1 |
| Leukopenia | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Lymphadenopathy | 14 | 17 | 8 | 11 | 6 | 6 |
| Lymph node pain | 2 | 3 | 2 | 3 | | |
| Lymphopenia | 1 | 1 | | | 1 | 1 |
| | 22 | 26 | 12 | 16 | 10 | 10 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Atrial flutter | | 1 | | | | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | | 1 | | | | 1 |
| Cardiogenic shock | 1 | 1 | | | 1 | 1 |
| Palpitations | 7 | 17 | 5 | 10 | 2 | 7 |
| Sinus tachycardia | 1 | 2 | 1 | 2 | | |
| Tachycardia | 1 | 5 | | 1 | 1 | 4 |
| | 15 | 32 | 6 | 13 | 9 | 19 |

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* AE=Adverse Event

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Auricular swelling | 1 | 1 | 1 | 1 | | |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear pruritus | 1 | 1 | | | 1 | 1 |
| Hyperacusis | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypoacusis | 2 | 2 | 2 | 2 | | |
| Tinnitus | 2 | 2 | 2 | 2 | | |
| Vertigo | 1 | 2 | | | 1 | 2 |
| | 10 | 11 | 7 | 7 | 3 | 4 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Dry eye | | 1 | | 1 | | |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Eye pain | 2 | 5 | 2 | 5 | | |
| Eye pruritus | 1 | 3 | | 2 | 1 | 1 |
| Lacrimation increased | 2 | 2 | 2 | 2 | | |
| Periorbital swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Photophobia | 2 | 2 | 1 | 1 | 1 | 1 |
| Photopsia | 2 | 3 | | 1 | 2 | 2 |
| Swelling of eyelid | | 2 | | 1 | | 1 |
| Vision blurred | 1 | 2 | | | 1 | 2 |
| Visual impairment | | 1 | | 1 | | |
| | 14 | 25 | 7 | 16 | 7 | 9 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 5 | 7 | 2 | 4 | 3 | 3 |
| Abdominal pain upper | 2 | 2 | 1 | 1 | 1 | 1 |
| Diarrhoea | 11 | 16 | 4 | 9 | 7 | 7 |
| Dry mouth | 3 | 3 | 3 | 3 | | |
| Dysphagia | 2 | 4 | | 1 | 2 | 3 |
| Gastrooesophageal reflux disease | | 1 | | 1 | | |
| Glossodynia | | 1 | | 1 | | |
| Hypoaesthesia oral | 2 | 2 | | | 2 | 2 |
| Lip swelling | 2 | 2 | | | 2 | 2 |
| Nausea | 57 | 79 | 33 | 47 | 24 | 32 |
| Odynophagia | 2 | 3 | 1 | 2 | 1 | 1 |
| Oral mucosal blistering | 1 | 1 | 1 | 1 | | |
| Oral mucosal eruption | 1 | 1 | 1 | 1 | | |
| Oral pruritus | 2 | 2 | 2 | 2 | | |
| Paraesthesia oral | 6 | 7 | 4 | 4 | 2 | 3 |
| Salivary hypersecretion | 1 | 1 | | | 1 | 1 |
| Stomatitis | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 3 | 6 | 1 | 1 | 2 | 5 |
| Tongue pruritus | 2 | 2 | | | 2 | 2 |
| Vomiting | 18 | 26 | 9 | 12 | 9 | 14 |
| | 123 | 169 | 65 | 93 | 58 | 76 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 5 | 9 | 1 | 3 | 4 | 6 |
| Axillary pain | 3 | 5 | 3 | 5 | | |
| Chest discomfort | 8 | 14 | 3 | 5 | 5 | 9 |
| Chest pain | 8 | 8 | 4 | 4 | 4 | 4 |
| Chills | 27 | 41 | 19 | 30 | 8 | 11 |
| Condition aggravated | 6 | 8 | | | 6 | 8 |
| Crying | 1 | 1 | | | 1 | 1 |
| Death | 5 | 6 | | | 5 | 6 |
| Discomfort | 3 | 6 | 1 | 1 | 2 | 5 |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 9 | 10 | | | 9 | 10 |
| Drug interaction | | 1 | | | | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial pain | | 1 | | 1 | | |
| Fatigue | 64 | 84 | 50 | 65 | 14 | 19 |
| Feeling abnormal | 2 | 2 | 2 | 2 | | |
| Feeling cold | 8 | 9 | 6 | 7 | 2 | 2 |
| Feeling drunk | | 1 | | 1 | | |
| Feeling hot | 12 | 20 | 8 | 12 | 4 | 8 |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Foaming at mouth | 1 | 2 | | 1 | 1 | 1 |
| General physical health deterioration | 4 | 7 | | | 4 | 7 |
| Illness | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 8 | 11 | 7 | 10 | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 | | |
| Injection site pain | | 1 | | 1 | | |
| Loss of control of legs | 1 | 1 | | | 1 | 1 |
| Malaise | 55 | 85 | 33 | 51 | 22 | 34 |
| Oedema peripheral | 1 | 2 | | 1 | 1 | 1 |
| Pain | 9 | 14 | 7 | 11 | 2 | 3 |
| Peripheral swelling | 5 | 6 | 3 | 4 | 2 | 2 |
| Pyrexia | 91 | 126 | 62 | 90 | 29 | 36 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Sudden cardiac death | 1 | 1 | | | 1 | 1 |
| Sudden death | 2 | 3 | | | 2 | 3 |
| Swelling | 1 | 2 | 1 | 2 | | |
| Swelling face | 7 | 13 | 2 | 4 | 5 | 9 |
| Tenderness | 3 | 3 | 3 | 3 | | |
| Vaccination site discolouration | 1 | 1 | | | 1 | 1 |
| Vaccination site discomfort | 1 | 2 | 1 | 2 | | |
| Vaccination site erythema | 12 | 20 | 10 | 17 | 2 | 3 |
| Vaccination site haematoma | 1 | 2 | 1 | 2 | | |
| Vaccination site haemorrhage | | 1 | | 1 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site irritation | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site lymphadenopathy | | 1 | | 1 | | |
| Vaccination site mass | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 2 | 2 | 2 | 2 | | |
| Vaccination site necrosis | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 70 | 115 | 64 | 107 | 6 | 8 |
| Vaccination site paraesthesia | 1 | 2 | 1 | 2 | | |
| Vaccination site pruritus | 3 | 5 | 3 | 5 | | |
| Vaccination site rash | 2 | 3 | 2 | 2 | | 1 |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 18 | 28 | 15 | 24 | 3 | 4 |
| Vaccination site thrombosis | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 6 | 8 | 5 | 7 | 1 | 1 |
| | 481 | 708 | 328 | 495 | 153 | 213 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 5 | 12 | | | 5 | 12 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Hypersensitivity | 10 | 16 | 1 | 2 | 9 | 14 |
| Seasonal allergy | 1 | 1 | 1 | 1 | | |
| | 17 | 31 | 2 | 3 | 15 | 28 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacteraemia | | 1 | | | | 1 |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| Chorioretinitis | 1 | 1 | | | 1 | 1 |
| COVID-19 | 14 | 15 | | | 14 | 15 |
| Cystitis | 1 | 1 | 1 | 1 | | |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Infection | 1 | 2 | 1 | 1 | | 1 |
| Influenza | 5 | 5 | 4 | 4 | 1 | 1 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 1 | 2 | 1 | 2 | | |
| Oral fungal infection | 1 | 1 | 1 | 1 | | |
| Pharyngitis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 6 | 7 | | | 6 | 7 |
| Pneumonia bacterial | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Sepsis | | 1 | | | | 1 |
| Severe acute respiratory syndrome | | 1 | | | | 1 |
| Upper respiratory tract infection | 1 | 1 | 1 | 1 | | |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Vaccination site abscess | 1 | 1 | | | 1 | 1 |
| | 42 | 49 | 11 | 12 | 31 | 37 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accidental exposure to product | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Exposure via skin contact | 1 | 1 | 1 | 1 | | |
| Fall | 2 | 2 | | | 2 | 2 |
| Head injury | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 2 | 2 | 2 | | |
| Incorrect route of product administration | 2 | 4 | 1 | 3 | 1 | 1 |
| Off label use | 7 | 7 | 7 | 7 | | |
| Product administration error | | 1 | | 1 | | |
| Product use issue | 6 | 6 | 6 | 6 | | |
| Underdose | 1 | 2 | 1 | 2 | | |
| Vaccination complication | 1 | 2 | 1 | 1 | | 1 |
| Wound complication | 1 | 1 | 1 | 1 | | |
| | 26 | 31 | 22 | 26 | 4 | 5 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Blood albumin decreased | 1 | 1 | 1 | 1 | | |
| Blood chloride increased | 1 | 1 | 1 | 1 | | |
| Blood creatine phosphokinase increased | 1 | 1 | | | 1 | 1 |
| Blood creatinine increased | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | | 1 | | 1 | | |
| Blood lactate dehydrogenase abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | | 1 | | | | 1 |
| Blood pressure decreased | 1 | 3 | 1 | 1 | | 2 |
| Blood pressure increased | 3 | 4 | 1 | 1 | 2 | 3 |
| Blood pressure systolic increased | 1 | 2 | | 1 | 1 | 1 |
| Body temperature increased | 2 | 4 | 2 | 4 | | |
| Calcium ionised increased | 1 | 1 | 1 | 1 | | |
| C-reactive protein increased | 5 | 5 | 1 | 1 | 4 | 4 |
| Electrocardiogram QT prolonged | 1 | 1 | | | 1 | 1 |
| Electrocardiogram ST segment depression | 1 | 1 | | | 1 | 1 |
| Glomerular filtration rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate abnormal | 1 | 1 | 1 | 1 | | |
| Heart rate decreased | 2 | 2 | 2 | 2 | | |
| Heart rate increased | 2 | 5 | 1 | 3 | 1 | 2 |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 2 | | | 1 | 2 |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 2 | 2 | 1 | 1 | 1 | 1 |
| Troponin I increased | 1 | 1 | | | 1 | 1 |
| Weight increased | | 1 | | 1 | | |
| | 33 | 46 | 16 | 23 | 17 | 23 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Fluid intake reduced | | 1 | | 1 | | |
| Hypoglycaemia | 1 | 1 | 1 | 1 | | |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypophagia | 1 | 2 | 1 | 2 | | |
| | 4 | 6 | 3 | 5 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 13 | 23 | 8 | 18 | 5 | 5 |
| Back pain | 3 | 4 | 2 | 3 | 1 | 1 |
| Groin pain | 1 | 1 | 1 | 1 | | |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Joint swelling | 2 | 3 | | 1 | 2 | 2 |
| Limb discomfort | 6 | 6 | 4 | 4 | 2 | 2 |
| Mobility decreased | 1 | 2 | 1 | 1 | | 1 |
| Muscle discomfort | 1 | 2 | | 1 | 1 | 1 |
| Muscle fatigue | 1 | 2 | 1 | 2 | | |
| Muscle spasms | 3 | 3 | 2 | 2 | 1 | 1 |
| Muscle tightness | 1 | 2 | | 1 | 1 | 1 |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 4 | 4 | 1 | 1 | 3 | 3 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 40 | 62 | 32 | 53 | 8 | 9 |
| Neck pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Pain in extremity | 16 | 24 | 15 | 23 | 1 | 1 |
| Periarthritis | 2 | 2 | 2 | 2 | | |
| Temporomandibular joint syndrome | 1 | 1 | | | 1 | 1 |
| | 101 | 148 | 71 | 116 | 30 | 32 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Acute leukaemia | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Altered state of consciousness | 2 | 2 | | | 2 | 2 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Burning sensation | 3 | 3 | 2 | 2 | 1 | 1 |
| Cerebral thrombosis | 1 | 1 | | | 1 | 1 |
| Coma | | 1 | | | | 1 |
| Coordination abnormal | 2 | 2 | | | 2 | 2 |
| Depressed level of consciousness | 4 | 5 | | | 4 | 5 |
| Disturbance in attention | 1 | 3 | 1 | 2 | | 1 |
| Dizziness | 57 | 83 | 31 | 45 | 26 | 38 |
| Dizziness exertional | 1 | 1 | 1 | 1 | | |
| Dizziness postural | | 1 | | | | 1 |
| Dysaesthesia | 1 | 2 | | 1 | 1 | 1 |
| Dysgeusia | | 1 | | 1 | | |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Haemorrhage intracranial | 1 | 1 | | | 1 | 1 |
| Headache | 115 | 159 | 84 | 120 | 31 | 39 |
| Head discomfort | 3 | 3 | 2 | 2 | 1 | 1 |
| Hemiparesis | | 1 | | | | 1 |
| Hypersomnia | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 2 | 1 | 2 | | |
| Lethargy | 2 | 2 | 2 | 2 | | |
| Loss of consciousness | 3 | 4 | | | 3 | 4 |
| Migraine | 2 | 3 | 1 | 2 | 1 | 1 |
| Motor dysfunction | 1 | 1 | | | 1 | 1 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 20 | 27 | 14 | 17 | 6 | 10 |
| Presyncope | 7 | 18 | 2 | 5 | 5 | 13 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sensory disturbance | 4 | 5 | 4 | 5 | | |
| Sensory loss | 2 | 2 | | | 2 | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Somnolence | 5 | 6 | 4 | 4 | 1 | 2 |
| Syncope | 6 | 10 | | | 6 | 10 |
| Taste disorder | 1 | 1 | | | 1 | 1 |
| Tonic convulsion | 1 | 1 | | | 1 | 1 |
| Tremor | 6 | 9 | 3 | 3 | 3 | 6 |
| Tunnel vision | 1 | 1 | | | 1 | 1 |
| | 260 | 368 | 155 | 217 | 105 | 151 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aggression | | 1 | | | | 1 |
| Anxiety | 2 | 3 | 1 | 1 | 1 | 2 |
| Confusional state | 3 | 4 | 1 | 1 | 2 | 3 |
| Delirium | 1 | 1 | | | 1 | 1 |
| Delusion | 1 | 1 | | | 1 | 1 |
| Derealisation | 2 | 3 | 2 | 3 | | |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Hallucination, visual | 1 | 1 | | | 1 | 1 |
| Insomnia | 3 | 4 | 3 | 4 | | |
| Panic attack | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 5 | 1 | 5 | | |
| Thinking abnormal | | 1 | | | | 1 |
| | 16 | 26 | 8 | 14 | 8 | 12 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Micturition urgency | 1 | 1 | | | 1 | 1 |
| Renal colic | 1 | 1 | 1 | 1 | | |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Renal pain | 1 | 1 | | | 1 | 1 |
| Urinary incontinence | | 1 | | | | 1 |
| | 4 | 5 | 1 | 1 | 3 | 4 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Postmenopausal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vaginal discharge | 1 | 1 | 1 | 1 | | |
| Vaginal haemorrhage | 1 | 1 | 1 | 1 | | |
| Vulvovaginal pain | 1 | 1 | 1 | 1 | | |
| Vulvovaginal pruritus | 1 | 1 | 1 | 1 | | |
| | 6 | 6 | 5 | 5 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Aspiration | | 1 | | | | 1 |
| Asthma | 2 | 2 | 1 | 1 | 1 | 1 |
| Bronchospasm | | 1 | | | | 1 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 2 | 3 | | | 2 | 3 |
| Cough | 8 | 16 | 6 | 9 | 2 | 7 |
| Dry throat | | 1 | | 1 | | |
| Dysphonia | 4 | 6 | 4 | 4 | | 2 |
| Dyspnoea | 26 | 43 | 7 | 14 | 19 | 29 |
| Dyspnoea at rest | | 1 | | | | 1 |
| Dyspnoea exertional | 4 | 4 | 3 | 3 | 1 | 1 |
| Hyperventilation | 2 | 4 | | | 2 | 4 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 3 | 4 | 3 | 4 | | |
| Nasal obstruction | | 1 | | 1 | | |
| Nasal pruritus | 1 | 2 | | 1 | 1 | 1 |
| Obliterative bronchiolitis | 1 | 1 | | | 1 | 1 |
| Obstructive airways disorder | | 1 | | | | 1 |
| Oropharyngeal discomfort | 1 | 2 | 1 | 2 | | |
| Oropharyngeal pain | 11 | 14 | 10 | 13 | 1 | 1 |
| Painful respiration | 2 | 2 | 2 | 2 | | |
| Pharyngeal oedema | | 1 | | | | 1 |
| Pharyngeal paraesthesia | 1 | 1 | 1 | 1 | | |
| Pharyngeal swelling | 5 | 9 | 2 | 2 | 3 | 7 |
| Pleural effusion | 1 | 2 | | | 1 | 2 |
| Pneumonia aspiration | | 1 | | | | 1 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Prolonged expiration | | 1 | | | | 1 |
| Pulmonary arterial hypertension | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 3 | 3 | | | 3 | 3 |
| Pulmonary fibrosis | | 1 | | | | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pulmonary oedema | 2 | 3 | | | 2 | 3 |
| Rales | | 1 | | | | 1 |
| Respiratory acidosis | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | | 1 | | | | 1 |
| Respiratory failure | 6 | 8 | | | 6 | 8 |
| Rhinalgia | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 4 | 4 | 4 | 4 | | |
| Sneezing | 5 | 5 | 5 | 5 | | |
| Stridor | | 1 | | | | 1 |
| Tachypnoea | 1 | 2 | | | 1 | 2 |
| Throat irritation | 3 | 6 | 1 | 4 | 2 | 2 |
| Throat tightness | 2 | 5 | 1 | 2 | 1 | 3 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 108 | 172 | 53 | 75 | 55 | 97 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 5 | | | 1 | 5 |
| Cold sweat | | 1 | | 1 | | |
| Dermatitis allergic | 1 | 2 | | | 1 | 2 |
| Dry skin | 1 | 1 | 1 | 1 | | |
| Erythema | 21 | 27 | 12 | 16 | 9 | 11 |
| Hand dermatitis | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 7 | 9 | 4 | 5 | 3 | 4 |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pruritus | 23 | 32 | 15 | 23 | 8 | 9 |
| Rash | 11 | 19 | 8 | 12 | 3 | 7 |
| Rash erythematous | 6 | 13 | 5 | 9 | 1 | 4 |
| Rash morbilliform | 1 | 1 | 1 | 1 | | |
| Rash papular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 4 | 7 | 4 | 6 | | 1 |
| Rash vesicular | 1 | 1 | 1 | 1 | | |
| Skin lesion | | 1 | | 1 | | |
| Urticaria | 10 | 20 | 7 | 14 | 3 | 6 |
| | 90 | 142 | 61 | 93 | 29 | 49 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Flushing | 2 | 9 | 2 | 5 | | 4 |
| Hot flush | 4 | 5 | 4 | 5 | | |
| Hypertension | 9 | 11 | 4 | 5 | 5 | 6 |
| Hypotension | 4 | 6 | 1 | 1 | 3 | 5 |
| Pallor | 2 | 8 | | 3 | 2 | 5 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Vasodilatation | | 1 | | | | 1 |
| | 25 | 44 | 12 | 20 | 13 | 24 |

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Country Where Event Occurred

ECUADOR

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Laryngitis | 1 | 1 | 1 | 1 |
| Tracheitis | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Blood pressure increased | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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 * AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Musculoskeletal disorder | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

ESTONIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Palpitations | | 1 | | 1 | | |
| Tachycardia | 1 | 2 | 1 | 2 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | 1 | 3 | 2 | 2 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Visual impairment | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Nausea | 9 | 9 | 5 | 5 | 4 | 4 |
| Paraesthesia oral | 3 | 3 | 3 | 3 | | |
| Retching | 1 | 1 | | | 1 | 1 |
| | 14 | 14 | 9 | 9 | 5 | 5 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 10 | 11 | 5 | 6 | 5 | 5 |
| Chills | 7 | 7 | 6 | 6 | 1 | 1 |
| Drug ineffective | | 1 | | | | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Fatigue | 6 | 6 | 5 | 5 | 1 | 1 |
| Feeling hot | | 1 | | 1 | | |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Malaise | 7 | 8 | 4 | 5 | 3 | 3 |
| Pain | 1 | 1 | | | 1 | 1 |
| Pyrexia | 14 | 14 | 12 | 12 | 2 | 2 |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site oedema | 2 | 2 | 2 | 2 | | |
| Vaccination site pain | 22 | 23 | 22 | 23 | | |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| | 77 | 82 | 63 | 67 | 14 | 15 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 3 | 3 | 1 | 1 | 2 | 2 |
| Immunisation reaction | 1 | 1 | | | 1 | 1 |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| | 6 | 6 | 1 | 1 | 5 | 5 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asymptomatic COVID-19 | | 1 | | | | 1 |
| Oral herpes | 2 | 2 | 2 | 2 | | |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| | 3 | 4 | 2 | 2 | 1 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Fall | 1 | 1 | 1 | 1 | | |
| Fracture | | 1 | | | | 1 |
| Maternal exposure during pregnancy | | 4 | | 4 | | |
| Off label use | 1 | 2 | 1 | 2 | | |
| Product use issue | 1 | 2 | 1 | 2 | | |
| Underdose | | 1 | | 1 | | |
| | 4 | 12 | 4 | 11 | | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Blood creatine phosphokinase increased | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Decreased appetite | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 5 | 6 | 5 | 6 | | |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 7 | 5 | 6 | 1 | 1 |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 3 | 4 | 3 | 4 | | |
| | 20 | 23 | 16 | 19 | 4 | 4 |

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 * AE=Adverse Event
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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Dizziness | 4 | 4 | 1 | 1 | 3 | 3 |
| Dysgeusia | 5 | 5 | 4 | 4 | 1 | 1 |
| Facial nerve disorder | | 1 | | 1 | | |
| Headache | 18 | 20 | 14 | 16 | 4 | 4 |
| Hypoaesthesia | 1 | 3 | 1 | 3 | | |
| Migraine with aura | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 10 | 14 | 8 | 12 | 2 | 2 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Somnolence | 5 | 5 | 4 | 4 | 1 | 1 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| | 50 | 59 | 33 | 42 | 17 | 17 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Syringe issue | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Immunisation anxiety related reaction | 5 | 7 | 5 | 7 |
| Insomnia | 1 | 1 | 1 | 1 |
| Restlessness | | 1 | | 1 |
| | 6 | 9 | 6 | 9 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cough | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 2 | 2 | 2 | 2 | | |
| Hypopnoea | 1 | 1 | | | 1 | 1 |
| Intranasal paraesthesia | 1 | 1 | 1 | 1 | | |
| Laryngeal oedema | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pharyngeal paraesthesia | 1 | 1 | 1 | 1 | | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| | 12 | 12 | 7 | 7 | 5 | 5 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Cold sweat | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Flushing | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 2 | 1 | 2 | | |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Pallor | 1 | 1 | | | 1 | 1 |
| | 5 | 6 | 2 | 3 | 3 | 3 |

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Country Where Event Occurred

FINLAND

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 18 | 22 | 7 | 11 | 11 | 11 |
| Lymph node pain | 2 | 2 | 1 | 1 | 1 | 1 |
| | 20 | 24 | 8 | 12 | 12 | 12 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 4 | 4 | | | 4 | 4 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Congestive cardiomyopathy | 1 | 1 | | | 1 | 1 |
| Extrasystoles | 2 | 3 | 1 | 2 | 1 | 1 |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Palpitations | 9 | 10 | 2 | 3 | 7 | 7 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 4 | 6 | | 1 | 4 | 5 |
| | 24 | 28 | 3 | 6 | 21 | 22 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear canal erythema | 1 | 1 | 1 | 1 | | |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Ear pruritus | 1 | 1 | 1 | 1 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tympanic membrane hyperaemia | 1 | 1 | 1 | 1 | | |
| Vertigo | 3 | 3 | | | 3 | 3 |
| | 9 | 9 | 6 | 6 | 3 | 3 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Dry eye | 1 | 1 | | | 1 | 1 |
| Erythema of eyelid | 1 | 1 | | | 1 | 1 |
| Eye haematoma | 1 | 1 | | | 1 | 1 |
| Eyelid irritation | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Eyelid ptosis | 1 | 1 | | | 1 | 1 |
| Eye pain | 5 | 5 | 2 | 2 | 3 | 3 |
| Gaze palsy | 2 | 2 | | | 2 | 2 |
| Mydriasis | 1 | 1 | 1 | 1 | | |
| Photophobia | 1 | 1 | | | 1 | 1 |
| Swelling of eyelid | 1 | 1 | | | 1 | 1 |
| Vision blurred | 2 | 2 | | | 2 | 2 |
| Visual impairment | 2 | 2 | | | 2 | 2 |
| | 23 | 23 | 4 | 4 | 19 | 19 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 3 | 3 | | | 3 | 3 |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 5 | 5 | 2 | 2 | 3 | 3 |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 4 | 4 | | | 4 | 4 |
| Diarrhoea | 4 | 4 | 2 | 2 | 2 | 2 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysphagia | 5 | 5 | | | 5 | 5 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Gastric disorder | 1 | 1 | 1 | 1 | | |
| Gingival swelling | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 6 | 7 | 1 | 2 | 5 | 5 |
| Hypoaesthesia teeth | 1 | 1 | 1 | 1 | | |
| Lip oedema | 1 | 1 | 1 | 1 | | |
| Lip pain | 2 | 2 | 2 | 2 | | |
| Lip pruritus | 1 | 1 | | | 1 | 1 |
| Lip swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Mouth swelling | 2 | 2 | | | 2 | 2 |
| Nausea | 29 | 31 | 8 | 9 | 21 | 22 |
| Oral discomfort | 1 | 1 | 1 | 1 | | |
| Oral disorder | 1 | 1 | | | 1 | 1 |
| Oral mucosal blistering | | 1 | | 1 | | |
| Oral pruritus | 3 | 4 | | | 3 | 4 |
| Paraesthesia oral | 9 | 10 | 2 | 3 | 7 | 7 |
| Stiff tongue | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Toothache | 1 | 1 | 1 | 1 | | |
| Vomiting | 8 | 9 | 4 | 4 | 4 | 5 |
| | 97 | 104 | 31 | 35 | 66 | 69 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 20 | 22 | 4 | 6 | 16 | 16 |
| Axillary pain | 6 | 7 | 3 | 4 | 3 | 3 |
| Chest discomfort | 5 | 7 | 2 | 2 | 3 | 5 |
| Chest pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Chills | 10 | 10 | 4 | 4 | 6 | 6 |
| Condition aggravated | 2 | 2 | | | 2 | 2 |
| Death | 3 | 3 | | | 3 | 3 |
| Discomfort | 3 | 3 | 1 | 1 | 2 | 2 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Face oedema | 6 | 6 | 1 | 1 | 5 | 5 |
| Facial pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Fatigue | 40 | 42 | 16 | 17 | 24 | 25 |
| Feeling abnormal | 5 | 5 | 1 | 1 | 4 | 4 |
| Feeling cold | 4 | 5 | 1 | 2 | 3 | 3 |
| Feeling hot | 8 | 9 | 1 | 2 | 7 | 7 |
| Foaming at mouth | 1 | 1 | | | 1 | 1 |
| Gait disturbance | 1 | 2 | | 1 | 1 | 1 |
| General physical health deterioration | 7 | 7 | | | 7 | 7 |
| Irritability postvaccinal | | 1 | | 1 | | |
| Localised oedema | 2 | 2 | | | 2 | 2 |
| Loss of control of legs | 2 | 2 | | | 2 | 2 |
| Malaise | 23 | 27 | 5 | 8 | 18 | 19 |
| Nodule | | 1 | | 1 | | |
| Obstruction | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain | 5 | 5 | 1 | 1 | 4 | 4 |
| Pyrexia | 45 | 48 | 6 | 9 | 39 | 39 |
| Sensation of foreign body | 5 | 5 | 1 | 1 | 4 | 4 |
| Sudden death | 2 | 2 | | | 2 | 2 |
| Swelling | 3 | 3 | 1 | 1 | 2 | 2 |
| Swelling face | 2 | 2 | | | 2 | 2 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site erythema | 16 | 18 | 9 | 11 | 7 | 7 |
| Vaccination site haematoma | 3 | 4 | 3 | 4 | | |
| Vaccination site hyperaesthesia | 2 | 2 | | | 2 | 2 |
| Vaccination site hypoaesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site induration | 2 | 2 | 2 | 2 | | |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site macule | | 1 | | 1 | | |
| Vaccination site movement impairment | 6 | 6 | | | 6 | 6 |
| Vaccination site oedema | 10 | 12 | 8 | 10 | 2 | 2 |
| Vaccination site pain | 33 | 36 | 13 | 16 | 20 | 20 |
| Vaccination site plaque | | 1 | | 1 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 6 | 6 | 2 | 2 | 4 | 4 |
| Vaccination site warmth | 5 | 8 | 2 | 5 | 3 | 3 |
| | 310 | 342 | 96 | 124 | 214 | 218 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 8 | 10 | | | 8 | 10 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Hypersensitivity | 7 | 8 | 1 | 1 | 6 | 7 |
| Type IV hypersensitivity reaction | | 1 | | 1 | | |
| | 17 | 22 | 1 | 2 | 16 | 20 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appendicitis | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 2 | 2 | 1 | 1 | 1 | 1 |
| Herpes zoster cutaneous disseminated | 1 | 1 | | | 1 | 1 |
| Oral herpes | 1 | 1 | 1 | 1 | | |
| Pneumonia | 2 | 2 | | | 2 | 2 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | | | 1 | 1 |
| Subcutaneous abscess | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Vaccination site abscess | 1 | 1 | | | 1 | 1 |
| Viral infection | 2 | 2 | | | 2 | 2 |
| | 15 | 15 | 2 | 2 | 13 | 13 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fall | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | 8 | 8 | 8 | 8 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | 12 | 12 | 12 | 12 | | |
| Product preparation error | 12 | 12 | 12 | 12 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 37 | 37 | 36 | 36 | 1 | 1 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Preferred Term | | | | | | |
| Blood pressure decreased | 3 | 3 | | | 3 | 3 |
| Blood pressure diastolic increased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 10 | 10 | 1 | 1 | 9 | 9 |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| C-reactive protein increased | 7 | 8 | | 1 | 7 | 7 |
| Grip strength decreased | 1 | 1 | | | 1 | 1 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 12 | 13 | 1 | 1 | 11 | 12 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Inflammatory marker increased | 1 | 1 | | | 1 | 1 |
| Lymph nodes scan abnormal | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| Rinne tuning fork test abnormal | 1 | 1 | 1 | 1 | | |
| Synovial fluid white blood cells positive | 1 | 1 | | | 1 | 1 |
| Weber tuning fork test abnormal | 1 | 1 | 1 | 1 | | |
| | 46 | 48 | 5 | 6 | 41 | 42 |

System Organ Class

| Metabolism and nutrition disorders | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Preferred Term | | | | |
| Decreased appetite | 1 | 1 | 1 | 1 |
| Feeding disorder | 1 | 1 | 1 | 1 |
| Hypokalaemia | 3 | 5 | 3 | 5 |
| | 5 | 7 | 5 | 7 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ankylosing spondylitis | 1 | 1 | | | 1 | 1 |
| Arthralgia | 17 | 18 | 5 | 6 | 12 | 12 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Arthritis reactive | 1 | 1 | | | 1 | 1 |
| Back pain | 4 | 5 | 1 | 2 | 3 | 3 |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Flank pain | 1 | 1 | | | 1 | 1 |
| Joint range of motion decreased | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 1 | 1 | | | 1 | 1 |
| Muscle fatigue | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 2 | 2 | | | 2 | 2 |
| Muscle twitching | 3 | 3 | 1 | 1 | 2 | 2 |
| Muscular weakness | 11 | 11 | 2 | 2 | 9 | 9 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal stiffness | 2 | 3 | | 1 | 2 | 2 |
| Myalgia | 27 | 30 | 3 | 6 | 24 | 24 |
| Neck pain | 3 | 3 | | | 3 | 3 |
| Nuchal rigidity | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 34 | 37 | 12 | 15 | 22 | 22 |
| Tendon pain | 1 | 1 | | | 1 | 1 |
| | 117 | 127 | 27 | 37 | 90 | 90 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Malignant lymphoid neoplasm | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 2 | 2 | | | 2 | 2 |
| Cognitive disorder | 1 | 1 | 1 | 1 | | |
| Dementia Alzheimer's type | 1 | 2 | | | 1 | 2 |
| Dizziness | 15 | 16 | | | 15 | 16 |
| Dysarthria | 3 | 3 | | | 3 | 3 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Facial paralysis | 7 | 7 | | | 7 | 7 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Headache | 47 | 50 | 11 | 12 | 36 | 38 |
| Head discomfort | 2 | 2 | | | 2 | 2 |
| Hemianaesthesia | 7 | 7 | | | 7 | 7 |
| Hemiparaesthesia | 1 | 1 | | | 1 | 1 |
| Hyperaesthesia | 3 | 3 | | | 3 | 3 |
| Hypoaesthesia | 13 | 14 | 2 | 3 | 11 | 11 |
| Hypotonia | 2 | 2 | | | 2 | 2 |
| Loss of consciousness | 2 | 2 | | | 2 | 2 |
| Memory impairment | 1 | 1 | 1 | 1 | | |
| Migraine | 2 | 3 | | | 2 | 3 |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Movement disorder | 1 | 1 | | | 1 | 1 |
| Muscle spasticity | 1 | 1 | | | 1 | 1 |
| Neuralgia | 3 | 3 | | | 3 | 3 |
| Neurological symptom | 1 | 1 | | | 1 | 1 |
| Opisthotonus | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 17 | 18 | 5 | 5 | 12 | 13 |
| Presyncope | 1 | 2 | | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Seizure | 1 | 2 | | | 1 | 2 |
| Sensory disturbance | 1 | 1 | 1 | 1 | | |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Slow speech | 1 | 1 | | | 1 | 1 |
| Somnolence | 3 | 4 | | 1 | 3 | 3 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Syncope | 3 | 4 | | | 3 | 4 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 4 | 5 | | | 4 | 5 |
| | 160 | 173 | 22 | 26 | 138 | 147 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusional state | 3 | 3 | 1 | 1 | 2 | 2 |
| Derealisation | | 1 | | 1 | | |
| Hallucination, auditory | 1 | 1 | | | 1 | 1 |
| Insomnia | 3 | 3 | 1 | 1 | 2 | 2 |
| Middle insomnia | 2 | 2 | 1 | 1 | 1 | 1 |
| Self-injurious ideation | 1 | 1 | | | 1 | 1 |
| | 10 | 11 | 3 | 4 | 7 | 7 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Breast cyst | 1 | 1 | 1 | 1 |
| Menstrual disorder | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphonia | 3 | 3 | 1 | 1 | 2 | 2 |
| Apnoea | 1 | 1 | | | 1 | 1 |
| Cough | 7 | 8 | | | 7 | 8 |
| Dysphonia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dyspnoea | 32 | 35 | 4 | 4 | 28 | 31 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Increased upper airway secretion | 4 | 4 | | | 4 | 4 |
| Laryngeal pain | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 2 | 2 | | | 2 | 2 |
| Nasal oedema | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Oropharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 7 | 7 | 3 | 3 | 4 | 4 |
| Pharyngeal hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Pharyngeal oedema | 4 | 5 | 1 | 1 | 3 | 4 |
| Pharyngeal paraesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Pharyngeal swelling | 2 | 3 | | | 2 | 3 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 1 | | | 1 | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory tract irritation | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Rhonchi | 1 | 1 | | | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Throat irritation | 8 | 9 | 2 | 2 | 6 | 7 |
| Throat tightness | 2 | 2 | | | 2 | 2 |
| Wheezing | 4 | 4 | 1 | 1 | 3 | 3 |
| | 98 | 105 | 18 | 18 | 80 | 87 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Eczema | 2 | 2 | | | 2 | 2 |
| Erythema | 19 | 22 | 4 | 5 | 15 | 17 |
| Erythema multiforme | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 5 | 5 | 1 | 1 | 4 | 4 |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pain of skin | 3 | 3 | 1 | 1 | 2 | 2 |
| Papule | 1 | 1 | 1 | 1 | | |
| Pruritus | 7 | 7 | 5 | 5 | 2 | 2 |
| Rash | 3 | 5 | 1 | 1 | 2 | 4 |
| Rash erythematous | 1 | 2 | | 1 | 1 | 1 |
| Rash macular | 3 | 3 | 1 | 1 | 2 | 2 |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Urticaria | 15 | 16 | 6 | 6 | 9 | 10 |
| | 63 | 70 | 22 | 24 | 41 | 46 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Impaired work ability | 1 | 1 | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Flushing | 5 | 5 | | | 5 | 5 |
| Haematoma | 2 | 2 | 2 | 2 | | |
| Hot flush | 2 | 2 | | | 2 | 2 |
| Hypotension | | 1 | | | | 1 |
| Pallor | 4 | 4 | | | 4 | 4 |
| Thrombophlebitis superficial | 1 | 1 | | | 1 | 1 |
| | 15 | 16 | 2 | 2 | 13 | 14 |

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Country Where Event Occurred

FRANCE

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemia | 2 | 2 | | | 2 | 2 |
| Eosinophilia | 1 | 1 | | | 1 | 1 |
| Hyperleukocytosis | 5 | 6 | | | 5 | 6 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Iron deficiency anaemia | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Leukopenia | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 2 | 2 | 2 | 2 | | |
| Lymphadenopathy | 29 | 31 | 19 | 21 | 10 | 10 |
| Lymph node pain | 1 | 1 | | | 1 | 1 |
| Lymphopenia | 4 | 5 | | 1 | 4 | 4 |
| Neutropenia | 3 | 3 | | | 3 | 3 |
| Pancytopenia | 2 | 2 | | | 2 | 2 |
| Thrombocytopenia | 3 | 4 | | | 3 | 4 |
| Thrombocytopenic purpura | 1 | 1 | | | 1 | 1 |
| | 57 | 62 | 21 | 24 | 36 | 38 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute coronary syndrome | 5 | 5 | | | 5 | 5 |
| Acute myocardial infarction | 2 | 2 | | | 2 | 2 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 11 | 13 | | | 11 | 13 |
| Arrhythmia supraventricular | 1 | 2 | | | 1 | 2 |
| Atrial fibrillation | 14 | 16 | | | 14 | 16 |
| Atrial flutter | 3 | 3 | | | 3 | 3 |
| Atrioventricular block | 2 | 2 | | | 2 | 2 |
| Atrioventricular block complete | 2 | 2 | | | 2 | 2 |
| Bradycardia | 11 | 11 | | | 11 | 11 |
| Bundle branch block | 1 | 1 | | | 1 | 1 |
| Bundle branch block left | 1 | 1 | | | 1 | 1 |
| Bundle branch block right | 2 | 2 | | | 2 | 2 |
| Cardiac arrest | 6 | 7 | | | 6 | 7 |
| Cardiac disorder | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 19 | 21 | | | 19 | 21 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cardiac failure congestive | 1 | 1 | | | 1 | 1 |
| Cardiac fibrillation | 1 | 1 | | | 1 | 1 |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Cardiogenic shock | 3 | 3 | | | 3 | 3 |
| Cardiomegaly | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 6 | 8 | | | 6 | 8 |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Coronary artery disease | 1 | 1 | | | 1 | 1 |
| Coronary artery stenosis | 1 | 1 | | | 1 | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Intracardiac thrombus | 1 | 1 | | | 1 | 1 |
| Ischaemic cardiomyopathy | 1 | 1 | | | 1 | 1 |
| Left ventricular failure | 1 | 1 | | | 1 | 1 |
| Left ventricular hypertrophy | 1 | 1 | | | 1 | 1 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Mitral valve disease | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 15 | 15 | | | 15 | 15 |
| Myocardial ischaemia | 1 | 1 | | | 1 | 1 |
| Myocardial necrosis | 1 | 1 | | | 1 | 1 |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Palpitations | 12 | 13 | 5 | 6 | 7 | 7 |
| Pericardial effusion | 1 | 1 | | | 1 | 1 |
| Pericarditis | 6 | 6 | | | 6 | 6 |
| Sinus arrest | 1 | 1 | | | 1 | 1 |
| Sinus bradycardia | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 5 | 5 | 1 | 1 | 4 | 4 |
| Supraventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Supraventricular tachycardia | 5 | 5 | | | 5 | 5 |
| Tachyarrhythmia | 4 | 4 | 1 | 1 | 3 | 3 |
| Tachycardia | 76 | 79 | 18 | 20 | 58 | 59 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Ventricular fibrillation | 1 | 1 | | | 1 | 1 |
| Ventricular tachycardia | 2 | 2 | | | 2 | 2 |
| | 242 | 256 | 25 | 28 | 217 | 228 |

System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hyperglycinaemia | 1 | 1 | 1 | 1 |
| Macroglossia | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute vestibular syndrome | 2 | 2 | | | 2 | 2 |
| Deafness unilateral | 2 | 2 | | | 2 | 2 |
| Ear discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Ear disorder | 1 | 1 | 1 | 1 | | |
| Ear pain | 4 | 4 | 3 | 3 | 1 | 1 |
| Hypoacusis | 2 | 2 | | | 2 | 2 |
| Tinnitus | 5 | 5 | 2 | 2 | 3 | 3 |
| Vertigo | 31 | 31 | 10 | 10 | 21 | 21 |
| Vertigo positional | 2 | 2 | | | 2 | 2 |
| Vestibular disorder | 2 | 2 | | | 2 | 2 |
| | 53 | 53 | 17 | 17 | 36 | 36 |

System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autoimmune thyroiditis | 1 | 1 | | | 1 | 1 |
| Hyperthyroidism | 1 | 1 | | | 1 | 1 |
| Thyroid mass | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 1 | 1 | 2 | 2 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Amaurosis fugax | 1 | 1 | | | 1 | 1 |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Conjunctival haemorrhage | 6 | 6 | | | 6 | 6 |
| Diplopia | 3 | 3 | | | 3 | 3 |
| Erythema of eyelid | 1 | 1 | | | 1 | 1 |
| Eye disorder | 1 | 1 | | | 1 | 1 |
| Eye irritation | 1 | 1 | 1 | 1 | | |
| Eyelid function disorder | 1 | 1 | | | 1 | 1 |
| Eyelid haematoma | 1 | 1 | 1 | 1 | | |
| Eyelid irritation | | 1 | | 1 | | |
| Eyelid oedema | 5 | 5 | 3 | 3 | 2 | 2 |
| Eyelid ptosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Eye pain | 2 | 2 | | | 2 | 2 |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Gaze palsy | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | 3 | 3 | 1 | 1 | 2 | 2 |
| Metamorphopsia | 1 | 1 | 1 | 1 | | |
| Miosis | 1 | 1 | | | 1 | 1 |
| Mydriasis | 2 | 2 | | | 2 | 2 |
| Noninfective chorioretinitis | 1 | 1 | | | 1 | 1 |
| Ocular discomfort | 2 | 3 | 2 | 3 | | |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Optic ischaemic neuropathy | 1 | 1 | | | 1 | 1 |
| Periorbital oedema | 1 | 1 | | | 1 | 1 |
| Photophobia | 4 | 4 | | | 4 | 4 |
| Photopsia | 1 | 1 | | | 1 | 1 |
| Retinal artery occlusion | 1 | 1 | | | 1 | 1 |
| Vision blurred | 6 | 6 | 2 | 2 | 4 | 4 |
| Visual acuity reduced | 1 | 1 | | | 1 | 1 |
| Visual impairment | 3 | 3 | 1 | 1 | 2 | 2 |
| | 56 | 58 | 13 | 15 | 43 | 43 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal distension | 2 | 2 | 1 | 1 | 1 | 1 |
| Abdominal pain | 25 | 27 | 13 | 14 | 12 | 13 |
| Abdominal pain upper | 10 | 10 | 3 | 3 | 7 | 7 |
| Abdominal rigidity | 1 | 1 | | | 1 | 1 |
| Acute abdomen | 1 | 1 | | | 1 | 1 |
| Anaesthesia oral | 2 | 2 | | | 2 | 2 |
| Aphthous ulcer | 2 | 3 | 1 | 2 | 1 | 1 |
| Colitis | 1 | 1 | 1 | 1 | | |
| Constipation | 1 | 2 | 1 | 2 | | |
| Diarrhoea | 50 | 54 | 19 | 21 | 31 | 33 |
| Diarrhoea haemorrhagic | 2 | 2 | | | 2 | 2 |
| Dry mouth | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphagia | 9 | 11 | 2 | 2 | 7 | 9 |
| Eructation | 3 | 3 | | | 3 | 3 |
| Faecal vomiting | 2 | 2 | | | 2 | 2 |
| Faeces soft | 1 | 1 | 1 | 1 | | |
| Gastric volvulus | 1 | 1 | | | 1 | 1 |
| Gastrointestinal disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 | 1 | 1 | | |
| Gastrointestinal motility disorder | 1 | 1 | | | 1 | 1 |
| Gastrointestinal pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Gastrooesophageal reflux disease | 1 | 1 | 1 | 1 | | |
| Gingival discomfort | 1 | 1 | | | 1 | 1 |
| Haematemesis | 2 | 2 | | | 2 | 2 |
| Haematochezia | 2 | 2 | | | 2 | 2 |
| Hypoaesthesia oral | 4 | 4 | | | 4 | 4 |
| Lip oedema | 4 | 5 | 1 | 1 | 3 | 4 |
| Lip pruritus | 1 | 1 | | | 1 | 1 |
| Lip swelling | 4 | 4 | 1 | 1 | 3 | 3 |
| Melaena | 1 | 1 | | | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Mouth haemorrhage | 1 | 1 | 1 | 1 | | |
| Mucous stools | 1 | 1 | 1 | 1 | | |
| Nausea | 92 | 101 | 36 | 43 | 56 | 58 |
| Obstruction gastric | 1 | 1 | | | 1 | 1 |
| Odynophagia | 1 | 1 | | | 1 | 1 |
| Oesophageal pain | 1 | 1 | | | 1 | 1 |
| Oral discomfort | | 1 | | 1 | | |
| Oral dysaesthesia | 1 | 1 | 1 | 1 | | |
| Oral pain | 2 | 2 | 2 | 2 | | |
| Oral pruritus | 2 | 2 | | | 2 | 2 |
| Palatal oedema | 2 | 2 | | | 2 | 2 |
| Pancreatitis acute | 3 | 3 | | | 3 | 3 |
| Paraesthesia oral | 8 | 9 | 3 | 4 | 5 | 5 |
| Pneumoperitoneum | 1 | 1 | | | 1 | 1 |
| Salivary hypersecretion | 3 | 3 | 1 | 1 | 2 | 2 |
| Stomatitis | 1 | 1 | | | 1 | 1 |
| Subileus | 2 | 2 | | | 2 | 2 |
| Swollen tongue | 3 | 4 | 1 | 2 | 2 | 2 |
| Tongue coated | 1 | 1 | | | 1 | 1 |
| Tongue discolouration | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tongue dry | 1 | 1 | | | 1 | 1 |
| Tongue haematoma | | 2 | | 2 | | |
| Tongue movement disturbance | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Toothache | 1 | 1 | | | 1 | 1 |
| Vomiting | 57 | 59 | 19 | 19 | 38 | 40 |
| | 335 | 362 | 116 | 133 | 219 | 229 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 163 | 165 | 72 | 74 | 91 | 91 |
| Axillary pain | 5 | 5 | 3 | 3 | 2 | 2 |
| Chest discomfort | 20 | 20 | 12 | 12 | 8 | 8 |
| Chest pain | 19 | 20 | 5 | 5 | 14 | 15 |
| Chills | 71 | 75 | 26 | 30 | 45 | 45 |
| Condition aggravated | 5 | 6 | 1 | 1 | 4 | 5 |
| Crepitations | 1 | 1 | | | 1 | 1 |
| Death | 40 | 49 | | | 40 | 49 |
| Discomfort | 18 | 18 | 3 | 3 | 15 | 15 |
| Disease progression | 1 | 1 | | | 1 | 1 |
| Disease recurrence | 14 | 14 | 1 | 1 | 13 | 13 |
| Drug ineffective | 100 | 107 | 1 | 1 | 99 | 106 |
| Extensive swelling of vaccinated limb | 3 | 3 | 2 | 2 | 1 | 1 |
| Face oedema | 11 | 11 | 1 | 1 | 10 | 10 |
| Facial pain | 4 | 4 | | | 4 | 4 |
| Fatigue | 93 | 98 | 51 | 56 | 42 | 42 |
| Fat tissue increased | 1 | 1 | 1 | 1 | | |
| Feeling abnormal | 4 | 4 | 3 | 3 | 1 | 1 |
| Feeling cold | 9 | 9 | 5 | 5 | 4 | 4 |
| Feeling drunk | 4 | 4 | 3 | 3 | 1 | 1 |
| Feeling hot | 8 | 8 | 3 | 3 | 5 | 5 |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Foaming at mouth | 1 | 1 | | | 1 | 1 |
| Gait disturbance | 10 | 10 | 4 | 4 | 6 | 6 |
| Gait inability | 3 | 3 | 1 | 1 | 2 | 2 |
| Generalised oedema | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 12 | 12 | 1 | 1 | 11 | 11 |
| High-pitched crying | 1 | 1 | 1 | 1 | | |
| Hyperthermia | 15 | 15 | 6 | 6 | 9 | 9 |
| Hypothermia | 7 | 7 | | | 7 | 7 |
| Ill-defined disorder | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------------|--|--|
| Inflammation | 8 | 8 |
| Inflammatory pain | 1 | 1 |
| Influenza like illness | 36 | 36 |
| Injected limb mobility decreased | 9 | 9 |
| Injection site erythema | | 2 |
| Injection site pain | 1 | 2 |
| Injection site rash | 1 | 1 |
| Localised oedema | 3 | 3 |
| Malaise | 103 | 113 |
| Mass | 1 | 1 |
| Mucosal pain | 1 | 1 |
| Oedema | 2 | 2 |
| Oedema peripheral | 9 | 10 |
| Pain | 52 | 53 |
| Peripheral swelling | 4 | 4 |
| Pyrexia | 153 | 162 |
| Sluggishness | 1 | 1 |
| Sudden death | 21 | 27 |
| Swelling | 1 | 1 |
| Swelling face | 2 | 2 |
| Thirst | 3 | 3 |
| Vaccination site bruising | 1 | 1 |
| Vaccination site coldness | 1 | 1 |
| Vaccination site discolouration | 1 | 1 |
| Vaccination site discomfort | 1 | 1 |
| Vaccination site dysaesthesia | 1 | 1 |
| Vaccination site erythema | 18 | 20 |
| Vaccination site exfoliation | 1 | 1 |
| Vaccination site haematoma | 6 | 6 |
| Vaccination site haemorrhage | 3 | 3 |
| Vaccination site hypersensitivity | 18 | 18 |
| Vaccination site hypoaesthesia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | 6 | 6 |
| | | 1 | 1 |
| 11 | 11 | 25 | 25 |
| 2 | 2 | 7 | 7 |
| | 2 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 31 | 36 | 72 | 77 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | 8 | 9 |
| 28 | 29 | 24 | 24 |
| 2 | 2 | 2 | 2 |
| 55 | 63 | 98 | 99 |
| 1 | 1 | | |
| | | 21 | 27 |
| 1 | 1 | | |
| | | 2 | 2 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 17 | 19 | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 3 | 3 |
| 2 | 2 | 1 | 1 |
| 18 | 18 | | |
| | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site induration | 4 | 6 | 4 | 6 | | |
| Vaccination site inflammation | 8 | 8 | 4 | 4 | 4 | 4 |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 8 | 8 | 6 | 6 | 2 | 2 |
| Vaccination site nodule | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site oedema | 5 | 5 | 2 | 2 | 3 | 3 |
| Vaccination site pain | 132 | 139 | 86 | 93 | 46 | 46 |
| Vaccination site papule | 1 | 1 | 1 | 1 | | |
| Vaccination site paraesthesia | 8 | 8 | 5 | 5 | 3 | 3 |
| Vaccination site pruritus | 7 | 9 | 4 | 6 | 3 | 3 |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 2 | 3 | 2 | 3 | | |
| Vaccination site recall reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 9 | 10 | 6 | 7 | 3 | 3 |
| Vaccination site thrombosis | 1 | 1 | | | 1 | 1 |
| Vaccination site urticaria | | 1 | | 1 | | |
| Vaccination site warmth | 5 | 5 | 4 | 4 | 1 | 1 |
| | 1,306 | 1,381 | 516 | 560 | 790 | 821 |

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System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholecystitis | 1 | 1 | | | 1 | 1 |
| Cholestatic liver injury | 1 | 1 | | | 1 | 1 |
| Hepatic function abnormal | 1 | 1 | 1 | 1 | | |
| Hepatitis cholestatic | 1 | 1 | | | 1 | 1 |
| Hepatocellular injury | 3 | 3 | | | 3 | 3 |
| Jaundice | 2 | 2 | | | 2 | 2 |
| Liver injury | 1 | 1 | | | 1 | 1 |
| | 10 | 10 | 1 | 1 | 9 | 9 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 3 | 3 | 1 | 1 | 2 | 2 |
| Anaphylactic reaction | 16 | 17 | | | 16 | 17 |
| Anaphylactic shock | 5 | 6 | | | 5 | 6 |
| Anaphylactoid reaction | 2 | 2 | | | 2 | 2 |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 36 | 37 | 16 | 16 | 20 | 21 |
| Type I hypersensitivity | 2 | 2 | | | 2 | 2 |
| Type II hypersensitivity | 1 | 1 | | | 1 | 1 |
| | 66 | 69 | 17 | 17 | 49 | 52 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aerococcus urinae infection | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 3 | 3 | | | 3 | 3 |
| Bacterial infection | 1 | 1 | | | 1 | 1 |
| Bronchiolitis | 1 | 1 | | | 1 | 1 |
| Bronchitis | 1 | 2 | | | 1 | 2 |
| Cellulitis | 1 | 1 | | | 1 | 1 |
| Conjunctivitis | 1 | 1 | | | 1 | 1 |
| Coronavirus infection | 2 | 2 | 1 | 1 | 1 | 1 |
| COVID-19 | 130 | 135 | 17 | 17 | 113 | 118 |
| COVID-19 pneumonia | 3 | 3 | | | 3 | 3 |
| Cystitis klebsiella | 1 | 1 | | | 1 | 1 |
| Cytomegalovirus infection | 1 | 1 | | | 1 | 1 |
| Dermo-hypodermatitis | 2 | 2 | | | 2 | 2 |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Epstein-Barr virus infection | 1 | 1 | | | 1 | 1 |
| Erysipelas | 3 | 3 | | | 3 | 3 |
| Escherichia urinary tract infection | 1 | 1 | | | 1 | 1 |
| Hepatitis infectious mononucleosis | 1 | 1 | | | 1 | 1 |
| Herpes ophthalmic | 1 | 1 | | | 1 | 1 |
| Herpes simplex | 1 | 1 | 1 | 1 | | |
| Herpes zoster | 13 | 14 | 2 | 3 | 11 | 11 |
| Infection | 3 | 3 | | | 3 | 3 |
| Influenza | 6 | 6 | | | 6 | 6 |
| Laryngitis | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Lung abscess | 1 | 1 | | | 1 | 1 |
| Mononucleosis syndrome | 1 | 1 | | | 1 | 1 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 2 | 2 | 2 | 2 | | |
| Ophthalmic herpes zoster | 4 | 4 | | | 4 | 4 |
| Otitis externa | | 1 | | 1 | | |
| Pneumonia | 8 | 8 | | | 8 | 8 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pneumonia bacterial | 1 | 1 | | | 1 | 1 |
| Pneumonia moraxella | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Rhinitis | 5 | 5 | 3 | 3 | 2 | 2 |
| Septic shock | 3 | 3 | | | 3 | 3 |
| Suspected COVID-19 | 2 | 4 | | | 2 | 4 |
| Tooth infection | 1 | 1 | 1 | 1 | | |
| Urinary tract candidiasis | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Urosepsis | 1 | 1 | | | 1 | 1 |
| Vaccination site abscess | 1 | 1 | 1 | 1 | | |
| Vestibular neuronitis | 3 | 3 | | | 3 | 3 |
| | 220 | 230 | 28 | 30 | 192 | 200 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accidental overdose | 1 | 2 | 1 | 2 | | |
| Cerebral hyperperfusion syndrome | 1 | 1 | | | 1 | 1 |
| Chest injury | 1 | 1 | | | 1 | 1 |
| Chillblains | 2 | 2 | 1 | 1 | 1 | 1 |
| Exposure via breast milk | | 2 | | 2 | | |
| Extradural haematoma | 1 | 1 | | | 1 | 1 |
| Eye injury | 1 | 1 | | | 1 | 1 |
| Fall | 20 | 21 | 4 | 4 | 16 | 17 |
| Frostbite | 1 | 1 | 1 | 1 | | |
| Head injury | 4 | 4 | | | 4 | 4 |
| Inappropriate schedule of product administration | 3 | 6 | 2 | 5 | 1 | 1 |
| Incorrect dose administered | 3 | 3 | 3 | 3 | | |
| Incorrect route of product administration | 9 | 13 | 9 | 13 | | |
| Intercepted product preparation error | | 1 | | 1 | | |
| Medication error | 1 | 1 | 1 | 1 | | |
| Occupational exposure to product | 1 | 2 | 1 | 2 | | |
| Off label use | 10 | 11 | 10 | 11 | | |
| Overdose | 2 | 8 | 2 | 8 | | |
| Poor quality product administered | 119 | 121 | 119 | 121 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product administration error | 1 | 1 | | | 1 | 1 |
| Product preparation error | 1 | 2 | 1 | 2 | | |
| Product preparation issue | 2 | 19 | 2 | 19 | | |
| Product use issue | 9 | 10 | 9 | 10 | | |
| Rib fracture | 1 | 1 | | | 1 | 1 |
| Transcription medication error | 1 | 1 | 1 | 1 | | |
| Underdose | 2 | 16 | 2 | 16 | | |
| Vaccination complication | 2 | 3 | 1 | 2 | 1 | 1 |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | 1 | 3 | 1 | 3 | | |
| | 201 | 260 | 171 | 229 | 30 | 31 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alanine aminotransferase increased | 2 | 2 | 2 | 2 | | |
| Aspartate aminotransferase increased | 2 | 2 | 2 | 2 | | |
| Blood alkaline phosphatase increased | 2 | 2 | 2 | 2 | | |
| Blood glucose increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure decreased | 8 | 8 | 1 | 1 | 7 | 7 |
| Blood pressure increased | 12 | 12 | 2 | 2 | 10 | 10 |
| Blood pressure systolic decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure systolic increased | 1 | 2 | | | 1 | 2 |
| Blood thyroid stimulating hormone increased | 1 | 1 | 1 | 1 | | |
| Blood uric acid increased | | 1 | | 1 | | |
| Body temperature decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Brain natriuretic peptide increased | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 14 | 16 | 7 | 8 | 7 | 8 |
| Creatinine renal clearance decreased | 1 | 1 | | | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | 1 | | | 1 | 1 |
| Electrocardiogram T wave inversion | 1 | 1 | | | 1 | 1 |
| Electroencephalogram abnormal | 1 | 1 | | | 1 | 1 |
| Eosinophil count increased | 1 | 1 | 1 | 1 | | |
| Epstein-Barr virus test positive | 1 | 1 | 1 | 1 | | |
| Gamma-glutamyltransferase increased | 2 | 2 | 2 | 2 | | |
| Glomerular filtration rate decreased | 2 | 2 | | | 2 | 2 |
| Glycosylated haemoglobin increased | | 1 | | 1 | | |
| Haemoglobin decreased | 2 | 2 | 2 | 2 | | |
| Heart rate increased | 9 | 9 | 4 | 4 | 5 | 5 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Heart sounds abnormal | 1 | 1 | | | 1 | 1 |
| International normalised ratio abnormal | 1 | 2 | 1 | 1 | | 1 |
| Lymphocyte count decreased | 1 | 1 | | | 1 | 1 |
| Myocardial necrosis marker increased | 1 | 1 | | | 1 | 1 |
| Neutrophil count abnormal | 1 | 1 | | | 1 | 1 |
| Neutrophil count decreased | 1 | 1 | | | 1 | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| N-terminal prohormone brain natriuretic peptide increased | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 41 | 42 | 4 | 4 | 37 | 38 |
| Platelet count decreased | 1 | 1 | 1 | 1 | | |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 | | |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test negative | 8 | 8 | 7 | 7 | 1 | 1 |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 8 | 8 | 3 | 3 | 5 | 5 |
| Serum ferritin increased | 1 | 1 | 1 | 1 | | |
| Transaminases increased | 1 | 1 | | | 1 | 1 |
| Troponin increased | 1 | 1 | | | 1 | 1 |
| Venous oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 2 | 2 | 1 | 1 | 1 | 1 |
| | 146 | 153 | 51 | 54 | 95 | 99 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adult failure to thrive | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 16 | 17 | 8 | 9 | 8 | 8 |
| Dehydration | 6 | 6 | 1 | 1 | 5 | 5 |
| Diabetes mellitus | 2 | 2 | | | 2 | 2 |
| Diabetic ketoacidosis | 3 | 3 | | | 3 | 3 |
| Diabetic ketosis | 1 | 1 | | | 1 | 1 |
| Diabetic metabolic decompensation | 1 | 1 | | | 1 | 1 |
| Dyslipidaemia | 1 | 1 | 1 | 1 | | |
| Food aversion | 1 | 1 | 1 | 1 | | |
| Gout | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperkalaemia | 3 | 3 | | | 3 | 3 |
| Hypernatraemia | 2 | 2 | 2 | 2 | | |
| Hypervitaminosis B12 | 1 | 1 | | | 1 | 1 |
| Hypocalcaemia | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 4 | 4 | 1 | 1 | 3 | 3 |
| Hypokalaemia | 2 | 2 | | | 2 | 2 |
| Insulin-requiring type 2 diabetes mellitus | 1 | 1 | | | 1 | 1 |
| Lactic acidosis | 1 | 1 | | | 1 | 1 |
| Malnutrition | 1 | 1 | 1 | 1 | | |
| Polydipsia | 2 | 2 | 1 | 1 | 1 | 1 |
| Type 2 diabetes mellitus | 1 | 1 | | | 1 | 1 |
| | 54 | 55 | 17 | 18 | 37 | 37 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ankylosing spondylitis | 2 | 2 | | | 2 | 2 |
| Arthralgia | 44 | 46 | 21 | 23 | 23 | 23 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Back pain | 9 | 9 | 5 | 5 | 4 | 4 |
| Bursal fluid accumulation | 1 | 1 | 1 | 1 | | |
| Bursitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Haemarthrosis | 1 | 1 | | | 1 | 1 |
| Joint effusion | 1 | 1 | 1 | 1 | | |
| Joint stiffness | 2 | 2 | | | 2 | 2 |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 3 | 3 | 3 | 3 | | |
| Mobility decreased | 3 | 3 | | | 3 | 3 |
| Muscle contracture | 3 | 3 | 1 | 1 | 2 | 2 |
| Muscle fatigue | 1 | 1 | 1 | 1 | | |
| Muscle rigidity | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 6 | 6 | 2 | 2 | 4 | 4 |
| Muscle tightness | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 3 | 3 | 2 | 2 | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 | | | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 | 1 | 1 | | |
| Musculoskeletal disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 29 | 30 | 7 | 8 | 22 | 22 |
| Myalgia | 92 | 94 | 42 | 44 | 50 | 50 |
| Myalgia intercostal | 1 | 1 | | | 1 | 1 |
| Myokymia | 1 | 1 | 1 | 1 | | |
| Myositis | 1 | 1 | 1 | 1 | | |
| Neck pain | 9 | 10 | 2 | 3 | 7 | 7 |
| Pain in extremity | 27 | 29 | 11 | 13 | 16 | 16 |
| Pain in jaw | 2 | 2 | 2 | 2 | | |
| Periarthritis | 1 | 1 | | | 1 | 1 |
| Polyarthritis | 1 | 1 | | | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rhabdomyolysis | 1 | 1 | | | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Spinal osteoarthritis | 1 | 1 | 1 | 1 | | |
| Spinal pain | 1 | 1 | | | 1 | 1 |
| Spondylitis | 1 | 1 | | | 1 | 1 |
| Synovial cyst | 1 | 1 | | | 1 | 1 |
| Systemic lupus erythematosus | 1 | 1 | | | 1 | 1 |
| Tendonitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Tendon pain | 2 | 2 | 2 | 2 | | |
| Trismus | 1 | 1 | 1 | 1 | | |
| | 266 | 274 | 115 | 123 | 151 | 151 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Benign breast neoplasm | 1 | 1 | 1 | 1 | | |
| Metastases to peritoneum | 1 | 1 | | | 1 | 1 |
| Phaeochromocytoma | 1 | 1 | | | 1 | 1 |
| Tumour perforation | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 2 | | 1 | 1 | 1 |
| Altered state of consciousness | 5 | 5 | | | 5 | 5 |
| Anosmia | 2 | 3 | | 1 | 2 | 2 |
| Aphasia | 6 | 6 | 1 | 1 | 5 | 5 |
| Aura | 1 | 1 | | | 1 | 1 |
| Balance disorder | 7 | 7 | 1 | 1 | 6 | 6 |
| Burning sensation | 5 | 6 | 2 | 3 | 3 | 3 |
| Central nervous system lesion | 1 | 1 | | | 1 | 1 |
| Cerebellar syndrome | 1 | 1 | | | 1 | 1 |
| Cerebral artery stenosis | 1 | 1 | | | 1 | 1 |
| Cerebral haematoma | 2 | 2 | | | 2 | 2 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 8 | 10 | | | 8 | 10 |
| Clonus | 1 | 1 | | | 1 | 1 |
| Cognitive disorder | 2 | 3 | 2 | 2 | | 1 |
| Coma | 4 | 4 | | | 4 | 4 |
| Coordination abnormal | 1 | 1 | 1 | 1 | | |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 7 | 8 | | | 7 | 8 |
| Disturbance in attention | 6 | 6 | 2 | 2 | 4 | 4 |
| Dizziness | 43 | 45 | 15 | 16 | 28 | 29 |
| Dizziness postural | 1 | 1 | | | 1 | 1 |
| Drooling | 2 | 2 | 2 | 2 | | |
| Dysaesthesia | 5 | 5 | 3 | 3 | 2 | 2 |
| Dysarthria | 5 | 6 | 1 | 1 | 4 | 5 |
| Dysgeusia | 10 | 10 | 5 | 5 | 5 | 5 |
| Dysstasia | 2 | 2 | 1 | 1 | 1 | 1 |
| Epilepsy | 8 | 8 | | | 8 | 8 |
| Extensor plantar response | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 28 | 28 | | | 28 | 28 |
| Facial paresis | 3 | 3 | | | 3 | 3 |
| Formication | 3 | 4 | 2 | 2 | 1 | 2 |

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System Organ Class

Nervous system disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|----------------------------------|--|--|
| Generalised tonic-clonic seizure | 1 | 1 |
| Haemorrhagic stroke | 3 | 4 |
| Headache | 174 | 183 |
| Head discomfort | 3 | 3 |
| Hemianopia homonymous | 2 | 2 |
| Hemiparaesthesia | 1 | 1 |
| Hemiparesis | 5 | 5 |
| Hemiplegia | 6 | 6 |
| Hoffmann's sign | 1 | 1 |
| Horner's syndrome | 1 | 1 |
| Hyperaesthesia | 1 | 1 |
| Hypersomnia | 3 | 3 |
| Hypertonia | | 1 |
| Hypoaesthesia | 9 | 9 |
| Hypokinesia | 2 | 2 |
| Hypotonia | 1 | 1 |
| Illrd nerve paralysis | 1 | 1 |
| Intercostal neuralgia | 1 | 1 |
| Intracranial haematoma | 1 | 1 |
| Ischaemic stroke | 13 | 14 |
| Language disorder | 2 | 2 |
| Leukoencephalopathy | 1 | 1 |
| Loss of consciousness | 20 | 22 |
| Memory impairment | 2 | 2 |
| Migraine | 12 | 12 |
| Migraine with aura | 4 | 4 |
| Monoparesis | 1 | 1 |
| Monoplegia | 1 | 1 |
| Motor dysfunction | 2 | 2 |
| Movement disorder | 1 | 1 |
| Myoclonus | 3 | 3 |
| Nervous system disorder | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 3 | 4 |
| 76 | 85 | 98 | 98 |
| 2 | 2 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 6 | 6 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | | 1 |
| 6 | 6 | 3 | 3 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 13 | 14 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 20 | 22 |
| | | 2 | 2 |
| 6 | 6 | 6 | 6 |
| 3 | 3 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 2 | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neuralgia | 13 | 13 | 5 | 5 | 8 | 8 |
| Neuromuscular pain | 1 | 1 | 1 | 1 | | |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Nystagmus | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 49 | 50 | 15 | 16 | 34 | 34 |
| Paralysis | 3 | 3 | | | 3 | 3 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Parkinsonism | 1 | 1 | | | 1 | 1 |
| Parosmia | 3 | 3 | 3 | 3 | | |
| Partial seizures | 1 | 1 | | | 1 | 1 |
| Petit mal epilepsy | | 1 | | | | 1 |
| Presyncope | 14 | 14 | 8 | 8 | 6 | 6 |
| Psychomotor hyperactivity | 1 | 1 | | | 1 | 1 |
| Psychomotor skills impaired | 2 | 2 | 1 | 1 | 1 | 1 |
| Seizure | 9 | 9 | | | 9 | 9 |
| Sensorimotor disorder | 1 | 1 | | | 1 | 1 |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Sensory loss | 2 | 2 | | | 2 | 2 |
| Somnolence | 11 | 11 | 5 | 5 | 6 | 6 |
| Speech disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Status epilepticus | 2 | 2 | | | 2 | 2 |
| Syncope | 14 | 14 | | | 14 | 14 |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Tension headache | 1 | 1 | | | 1 | 1 |
| Thermohypoaesthesia | 1 | 1 | 1 | 1 | | |
| Tongue biting | 1 | 1 | | | 1 | 1 |
| Tonic clonic movements | 3 | 3 | | | 3 | 3 |
| Transient ischaemic attack | 8 | 8 | | | 8 | 8 |
| Tremor | 16 | 17 | 5 | 6 | 11 | 11 |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| | 620 | 648 | 181 | 196 | 439 | 452 |

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System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|-----|
| | | | Nonserious | |
| | | | I | C |
| Needle issue | | 1 | | 1 |
| Product packaging quantity issue | 1 | 1 | 1 | 1 |
| Product temperature excursion issue | 115 | 116 | 115 | 116 |
| | 116 | 118 | 116 | 118 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal behaviour | 1 | 1 | | | 1 | 1 |
| Aggression | 2 | 2 | | | 2 | 2 |
| Agitation | 9 | 9 | 3 | 3 | 6 | 6 |
| Anxiety | 4 | 6 | 1 | 1 | 3 | 5 |
| Anxiety disorder | 1 | 1 | 1 | 1 | | |
| Apathy | 3 | 3 | 2 | 2 | 1 | 1 |
| Behaviour disorder | 2 | 2 | | | 2 | 2 |
| Bipolar disorder | 1 | 1 | | | 1 | 1 |
| Bradyphrenia | 1 | 1 | | | 1 | 1 |
| Confusional state | 9 | 10 | 2 | 2 | 7 | 8 |
| Delirium | 1 | 1 | | | 1 | 1 |
| Depression | 1 | 1 | 1 | 1 | | |
| Disinhibition | 1 | 1 | | | 1 | 1 |
| Disorientation | 4 | 4 | 2 | 2 | 2 | 2 |
| Dysphemia | 3 | 3 | | | 3 | 3 |
| Eating disorder | 1 | 1 | | | 1 | 1 |
| Fear | | 1 | | | | 1 |
| Hallucination, auditory | 1 | 1 | | | 1 | 1 |
| Hallucinations, mixed | 1 | 1 | | | 1 | 1 |
| Initial insomnia | 1 | 1 | | | 1 | 1 |
| Insomnia | 15 | 17 | 7 | 9 | 8 | 8 |
| Irritability | 1 | 1 | 1 | 1 | | |
| Listless | 1 | 1 | | | 1 | 1 |
| Logorrhoea | 1 | 1 | | | 1 | 1 |
| Mental fatigue | 1 | 1 | | | 1 | 1 |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Nightmare | 1 | 1 | 1 | 1 | | |
| Persistent depressive disorder | 1 | 1 | | | 1 | 1 |
| Phonophobia | 2 | 2 | 1 | 1 | 1 | 1 |
| Pseudodementia | 1 | 1 | | | 1 | 1 |
| Restlessness | 4 | 4 | 2 | 2 | 2 | 2 |
| Sleep disorder | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sleep disorder due to general medical condition, insomnia type | 1 | 1 | 1 | 1 | | |
| Sleep talking | 1 | 1 | 1 | 1 | | |
| Staring | 1 | 1 | | | 1 | 1 |
| Stress | 2 | 2 | 1 | 1 | 1 | 1 |
| Suicidal ideation | 1 | 1 | | | 1 | 1 |
| Tension | 3 | 3 | 2 | 2 | 1 | 1 |
| | 89 | 95 | 31 | 33 | 58 | 62 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 7 | 7 | | | 7 | 7 |
| Anuria | 1 | 1 | | | 1 | 1 |
| Costovertebral angle tenderness | 1 | 1 | | | 1 | 1 |
| Dysuria | 2 | 2 | 1 | 1 | 1 | 1 |
| Glomerulonephritis | 1 | 1 | | | 1 | 1 |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Renal failure | 4 | 5 | | | 4 | 5 |
| Renal impairment | 2 | 2 | | | 2 | 2 |
| | 19 | 20 | 1 | 1 | 18 | 19 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast swelling | 1 | 1 | 1 | 1 | | |
| Erectile dysfunction | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute pulmonary oedema | 7 | 7 | | | 7 | 7 |
| Acute respiratory distress syndrome | 5 | 6 | | | 5 | 6 |
| Acute respiratory failure | 4 | 5 | | | 4 | 5 |
| Aphonia | 2 | 2 | | | 2 | 2 |
| Asthma | 4 | 4 | | | 4 | 4 |
| Asthmatic crisis | 2 | 2 | | | 2 | 2 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Bronchial obstruction | | 1 | | | | 1 |
| Bronchopneumopathy | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 4 | 4 | | | 4 | 4 |
| Choking | 1 | 1 | | | 1 | 1 |
| Choking sensation | 1 | 1 | 1 | 1 | | |
| Chronic obstructive pulmonary disease | 3 | 3 | | | 3 | 3 |
| Cough | 23 | 24 | 10 | 11 | 13 | 13 |
| Dry throat | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphonia | 3 | 3 | 1 | 1 | 2 | 2 |
| Dyspnoea | 53 | 56 | 10 | 10 | 43 | 46 |
| Dyspnoea at rest | 1 | 1 | | | 1 | 1 |
| Dyspnoea exertional | 4 | 4 | 1 | 1 | 3 | 3 |
| Epistaxis | 2 | 2 | 2 | 2 | | |
| Haemoptysis | | 1 | | | | 1 |
| Haemothorax | 1 | 1 | | | 1 | 1 |
| Hyperventilation | 3 | 3 | 2 | 2 | 1 | 1 |
| Hypoventilation | 1 | 1 | | | 1 | 1 |
| Hypoxia | 7 | 7 | | | 7 | 7 |
| Increased bronchial secretion | 1 | 2 | | | 1 | 2 |
| Interstitial lung disease | 1 | 1 | | | 1 | 1 |
| Laryngeal discomfort | 3 | 3 | 1 | 1 | 2 | 2 |
| Laryngeal dyspnoea | 2 | 2 | | | 2 | 2 |
| Laryngeal oedema | 4 | 4 | | | 4 | 4 |
| Larynx irritation | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract congestion | 1 | 1 | | | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Lung disorder | 5 | 5 |
| Nasal congestion | 2 | 3 |
| Obstructive airways disorder | 1 | 1 |
| Oropharyngeal discomfort | 1 | 2 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 7 | 7 |
| Oropharyngeal swelling | 1 | 1 |
| Painful respiration | 1 | 1 |
| Pharyngeal disorder | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 2 |
| Pleural effusion | 1 | 1 |
| Pneumonia aspiration | 12 | 12 |
| Pneumonitis | 1 | 1 |
| Productive cough | 3 | 4 |
| Pulmonary arterial hypertension | 1 | 1 |
| Pulmonary congestion | 1 | 1 |
| Pulmonary embolism | 13 | 13 |
| Pulmonary infarction | 1 | 1 |
| Pulmonary oedema | 2 | 2 |
| Rales | 2 | 3 |
| Respiration abnormal | 1 | 1 |
| Respiratory alkalosis | 2 | 2 |
| Respiratory arrest | 1 | 1 |
| Respiratory depression | 1 | 1 |
| Respiratory disorder | 3 | 3 |
| Respiratory distress | 12 | 12 |
| Respiratory failure | 3 | 3 |
| Respiratory tract oedema | 1 | 1 |
| Rhinorrhoea | 5 | 5 |
| Rhonchi | 1 | 1 |
| Sinus disorder | 1 | 1 |
| Sleep apnoea syndrome | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 4 | 4 |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| 7 | 7 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 12 | 12 |
| | | 1 | 1 |
| 2 | 2 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 13 | 13 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 12 | 12 |
| | | 3 | 3 |
| | | 1 | 1 |
| 2 | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Suffocation feeling | 2 | 2 | | | 2 | 2 |
| Tachypnoea | 9 | 9 | | | 9 | 9 |
| Throat irritation | 2 | 2 | 1 | 1 | 1 | 1 |
| Tonsillar hypertrophy | 1 | 1 | 1 | 1 | | |
| Wheezing | 2 | 2 | | | 2 | 2 |
| | 255 | 268 | 48 | 50 | 207 | 218 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute febrile neutrophilic dermatosis | 1 | 1 | | | 1 | 1 |
| Angioedema | 10 | 11 | | | 10 | 11 |
| Blister | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 | | | 1 | 1 |
| Dermatitis bullous | 1 | 1 | | | 1 | 1 |
| Eczema | 2 | 2 | 1 | 1 | 1 | 1 |
| Erythema | 37 | 40 | 15 | 18 | 22 | 22 |
| Hair colour changes | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 23 | 24 | 6 | 7 | 17 | 17 |
| Hypersensitivity vasculitis | 1 | 1 | | | 1 | 1 |
| Lichen planus | 1 | 1 | | | 1 | 1 |
| Livedo reticularis | 4 | 4 | 1 | 1 | 3 | 3 |
| Lividity | 1 | 1 | | | 1 | 1 |
| Neutrophilic dermatosis | 1 | 1 | | | 1 | 1 |
| Papule | 1 | 2 | | 1 | 1 | 1 |
| Peau d'orange | 1 | 1 | 1 | 1 | | |
| Pernio-like erythema | 1 | 1 | 1 | 1 | | |
| Petechiae | 2 | 2 | 2 | 2 | | |
| Photosensitivity reaction | 1 | 1 | 1 | 1 | | |
| Piloerection | 1 | 1 | | | 1 | 1 |
| Pruritus | 25 | 28 | 12 | 15 | 13 | 13 |
| Purpura | 2 | 2 | | | 2 | 2 |
| Rash | 22 | 23 | 12 | 13 | 10 | 10 |
| Rash erythematous | 6 | 6 | 2 | 2 | 4 | 4 |
| Rash macular | 3 | 3 | | | 3 | 3 |
| Rash maculo-papular | 3 | 4 | 3 | 4 | | |
| Rash papular | 4 | 4 | 3 | 3 | 1 | 1 |
| Rash pruritic | 5 | 5 | 3 | 3 | 2 | 2 |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Skin lesion | 1 | 1 | | | 1 | 1 |
| Skin mass | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Skin plaque | 3 | 3 | 2 | 2 | 1 | 1 |
| Skin warm | 2 | 2 | 2 | 2 | | |
| Urticaria | 24 | 26 | 10 | 10 | 14 | 16 |
| Vascular purpura | 2 | 2 | | | 2 | 2 |
| Yellow skin | | 1 | | 1 | | |
| | 198 | 212 | 80 | 91 | 118 | 121 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Impaired work ability | 2 | 2 | | | 2 | 2 |
| Walking disability | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aortic dissection | | 2 | | | | 2 |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 3 | 3 | | | 3 | 3 |
| Cyanosis | 5 | 5 | | | 5 | 5 |
| Deep vein thrombosis | 2 | 2 | | | 2 | 2 |
| Flushing | 9 | 9 | 3 | 3 | 6 | 6 |
| Haematoma | 3 | 3 | | | 3 | 3 |
| Haemodynamic instability | 1 | 1 | 1 | 1 | | |
| Hot flush | 17 | 18 | 9 | 10 | 8 | 8 |
| Hypertension | 89 | 91 | 15 | 17 | 74 | 74 |
| Hypertensive crisis | 9 | 10 | | | 9 | 10 |
| Hypertensive urgency | 1 | 1 | | | 1 | 1 |
| Hypoperfusion | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypotension | 44 | 45 | 12 | 12 | 32 | 33 |
| Infarction | 1 | 1 | | | 1 | 1 |
| Jugular vein thrombosis | 1 | 1 | | | 1 | 1 |
| Malignant hypertension | 1 | 1 | | | 1 | 1 |
| Microembolism | 1 | 1 | | | 1 | 1 |
| Pallor | 9 | 9 | | | 9 | 9 |
| Peripheral coldness | 3 | 3 | 2 | 2 | 1 | 1 |
| Shock | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis superficial | 3 | 3 | 1 | 1 | 2 | 2 |
| Thrombosis | 2 | 2 | | | 2 | 2 |
| Vasculitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Vasodilatation | 1 | 1 | 1 | 1 | | |
| Venous thrombosis | 2 | 2 | | | 2 | 2 |
| | 213 | 220 | 46 | 49 | 167 | 171 |

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Country Where Event Occurred

FRENCH POLYNESIA

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dermatitis bullous | 1 | 1 | 1 | 1 |
| Dermatosis | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

GERMANY

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|--------------------------|----------|-------------|-----------|-----------|-----------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Agranulocytosis | 1 | 1 | | | | | 1 | 1 |
| Immune thrombocytopenia | 2 | 2 | | | | | 2 | 2 |
| Leukocytosis | 1 | 1 | | | | | 1 | 1 |
| Leukopenia | | 1 | | | | | | 1 |
| Lymphadenopathy | 20 | 33 | 1 | 1 | 20 | 33 | | |
| Lymph node pain | 8 | 12 | | | 8 | 12 | | |
| Lymphopenia | 1 | 1 | | | | | 1 | 1 |
| Microcytic anaemia | 1 | 1 | | | | | 1 | 1 |
| Monocytosis | 1 | 1 | | | | | 1 | 1 |
| Neutropenia | 1 | 1 | | | | | 1 | 1 |
| Thrombocytopenia | 2 | 2 | | | | | 2 | 2 |
| | 38 | 56 | 1 | 1 | 28 | 45 | 10 | 11 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute coronary syndrome | 3 | 3 | | | | | 3 | 3 |
| Acute myocardial infarction | 2 | 8 | | | | | 2 | 8 |
| Angina pectoris | 6 | 8 | | | | | 6 | 8 |
| Arrhythmia | 12 | 16 | 1 | 1 | | | 12 | 16 |
| Atrial fibrillation | 5 | 7 | | | | | 5 | 7 |
| Atrial flutter | 1 | 1 | | | 1 | 1 | | |
| Atrioventricular block complete | 1 | 1 | | | | | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 | | | 1 | 1 | | |
| Bradycardia | 2 | 4 | | | | | 2 | 4 |
| Cardiac aneurysm | 1 | 1 | | | | | 1 | 1 |
| Cardiac arrest | 4 | 5 | | | | | 4 | 5 |
| Cardiac failure | 10 | 17 | | | | | 10 | 17 |
| Cardiac failure acute | 1 | 1 | | | | | 1 | 1 |
| Cardiac failure congestive | 1 | 2 | | | | | 1 | 2 |
| Cardiac fibrillation | | 1 | | | | | | 1 |
| Cardiogenic shock | 2 | 3 | | | | | 2 | 3 |
| Cardiopulmonary failure | | 1 | | | | | | 1 |
| Cardio-respiratory arrest | 1 | 1 | | | | | 1 | 1 |
| Cardiovascular disorder | 13 | 19 | | | 8 | 13 | 5 | 6 |
| Cardiovascular insufficiency | 2 | 3 | | | | | 2 | 3 |
| Cor pulmonale | 1 | 1 | | | | | 1 | 1 |
| Left ventricular failure | 1 | 1 | | | | | 1 | 1 |
| Myocardial infarction | 3 | 4 | | | | | 3 | 4 |
| Myocarditis | 5 | 5 | | | | | 5 | 5 |
| Palpitations | 16 | 34 | 4 | 4 | 9 | 24 | 7 | 10 |
| Pericarditis | 1 | 1 | | | | | 1 | 1 |
| Sinus tachycardia | 1 | 2 | | | | | 1 | 2 |
| Supraventricular extrasystoles | 2 | 2 | | | 2 | 2 | | |
| Supraventricular tachycardia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Tachyarrhythmia | 1 | 4 | | | 1 | 1 | | 3 |
| Tachycardia | 32 | 50 | 6 | 6 | 9 | 17 | 23 | 33 |
| Ventricular fibrillation | 1 | 3 | | | | | 1 | 3 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ventricular tachycardia | 1 | 1 | | | | | 1 | 1 |
| | 135 | 213 | 11 | 11 | 32 | 60 | 103 | 153 |

System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Huntington's disease | | 3 | | 3 |
| | | 3 | | 3 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness | 1 | 1 | | | 1 | 1 |
| Deafness transitory | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear pain | 2 | 5 | 2 | 5 | | |
| Sudden hearing loss | 3 | 4 | | | 3 | 4 |
| Tinnitus | 2 | 2 | 2 | 2 | | |
| Vertigo | 4 | 8 | 3 | 7 | 1 | 1 |
| | 15 | 23 | 8 | 15 | 7 | 8 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Amaurosis fugax | 1 | 1 | | | 1 | 1 |
| Asthenopia | | 1 | | 1 | | |
| Blepharitis | 1 | 1 | 1 | 1 | | |
| Conjunctival haemorrhage | 2 | 2 | | | 2 | 2 |
| Diplopia | | 1 | | | | 1 |
| Dry eye | | 1 | | 1 | | |
| Episcleritis | | 1 | | 1 | | |
| Eye haemorrhage | 2 | 3 | | | 2 | 3 |
| Eye irritation | | 3 | | 3 | | |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |
| Eye pain | 3 | 4 | 3 | 4 | | |
| Eye pruritus | 4 | 6 | 1 | 2 | 3 | 4 |
| Eye swelling | 3 | 5 | 3 | 4 | | 1 |
| Lacrimation increased | 5 | 6 | 3 | 4 | 2 | 2 |
| Ocular discomfort | 2 | 2 | 2 | 2 | | |
| Ocular hyperaemia | 3 | 4 | 2 | 3 | 1 | 1 |
| Optic neuropathy | 1 | 1 | | | 1 | 1 |
| Photopsia | 2 | 2 | 2 | 2 | | |
| Retinal tear | 2 | 2 | | | 2 | 2 |
| Retinopathy | 1 | 1 | | | 1 | 1 |
| Sudden visual loss | 1 | 1 | | | 1 | 1 |
| Swelling of eyelid | 1 | 1 | 1 | 1 | | |
| Vision blurred | 5 | 7 | 3 | 4 | 2 | 3 |
| Visual acuity reduced | 1 | 1 | | | 1 | 1 |
| Visual impairment | 7 | 9 | 4 | 5 | 3 | 4 |
| Vitreous disorder | 1 | 1 | | | 1 | 1 |
| | 49 | 68 | 25 | 38 | 24 | 30 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | 6 | 11 | 1 | 1 | 3 | 8 | 3 | 3 |
| Abdominal pain lower | 2 | 6 | | | 1 | 5 | 1 | 1 |
| Abdominal pain upper | 7 | 10 | | | 5 | 8 | 2 | 2 |
| Abnormal faeces | 2 | 7 | | | 2 | 7 | | |
| Acute abdomen | 1 | 1 | | | | | 1 | 1 |
| Constipation | | 1 | | | | 1 | | |
| Diarrhoea | 29 | 50 | 11 | 11 | 21 | 41 | 8 | 9 |
| Dry mouth | 4 | 5 | | | 2 | 3 | 2 | 2 |
| Dyspepsia | | 1 | | | | 1 | | |
| Dysphagia | 10 | 14 | | | 7 | 7 | 3 | 7 |
| Enteritis | 1 | 1 | | | | | 1 | 1 |
| Flatulence | 1 | 3 | 1 | 1 | 1 | 3 | | |
| Gastrointestinal disorder | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal pain | | | 1 | 1 | | | | |
| Gingival swelling | 1 | 1 | | | 1 | 1 | | |
| Haematemesis | 3 | 3 | | | | | 3 | 3 |
| Haematochezia | 1 | 1 | | | | | 1 | 1 |
| Hypoaesthesia oral | 3 | 6 | | | 3 | 5 | | 1 |
| Ileus paralytic | 1 | 1 | | | | | 1 | 1 |
| Intestinal ischaemia | 1 | 1 | | | | | 1 | 1 |
| Lip oedema | 1 | 2 | | | | 1 | 1 | 1 |
| Lip swelling | 2 | 4 | | | | | 2 | 4 |
| Mesenteric vein thrombosis | | 1 | | | | | | 1 |
| Mouth swelling | 2 | 2 | | | | | 2 | 2 |
| Nausea | 55 | 94 | 35 | 35 | 42 | 77 | 13 | 17 |
| Odynophagia | | | 1 | 1 | | | | |
| Oral discomfort | 1 | 1 | | | 1 | 1 | | |
| Oral mucosa erosion | | 1 | | | | 1 | | |
| Palatal swelling | 1 | 1 | | | | | 1 | 1 |
| Pancreatitis acute | 1 | 1 | | | | | 1 | 1 |
| Paraesthesia oral | 4 | 7 | | | 2 | 4 | 2 | 3 |
| Retching | 2 | 3 | | | 1 | 2 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------------|--|--|
| Stomatitis | 1 | 1 |
| Swollen tongue | 6 | 9 |
| Tongue discomfort | 1 | 2 |
| Tongue disorder | | 1 |
| Tongue oedema | 1 | 1 |
| Tongue pruritus | 1 | 1 |
| Trichoglossia | 1 | 1 |
| Upper gastrointestinal haemorrhage | 2 | 2 |
| Vomiting | 34 | 49 |
| | 190 | 308 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 7 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| 8 | 8 | 19 | 29 | 15 | 20 |
| 58 | 58 | 114 | 211 | 76 | 97 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Application site vesicles | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 37 | 73 | | | 27 | 58 | 10 | 15 |
| Axillary pain | 3 | 3 | | | 3 | 3 | | |
| Chest discomfort | 2 | 6 | | | 1 | 5 | 1 | 1 |
| Chest pain | 7 | 7 | | | 5 | 5 | 2 | 2 |
| Chills | 62 | 100 | 25 | 25 | 54 | 90 | 8 | 10 |
| Condition aggravated | 2 | 4 | | | 2 | 2 | | 2 |
| Crepitations | | 1 | | | | | | 1 |
| Death | 46 | 77 | | | | | 46 | 77 |
| Discomfort | | | 3 | 3 | | | | |
| Disease recurrence | 3 | 5 | | | 2 | 3 | 1 | 2 |
| Drug ineffective | 146 | 251 | | | 1 | 1 | 145 | 250 |
| Drug interaction | | 1 | | | | 1 | | |
| Enanthema | 1 | 1 | | | | | 1 | 1 |
| Exercise tolerance decreased | | | 1 | 1 | | | | |
| Face oedema | | 1 | | | | | | 1 |
| Facial pain | | 1 | | | | 1 | | |
| Fatigue | 103 | 226 | 54 | 55 | 97 | 216 | 6 | 10 |
| Feeling abnormal | 4 | 4 | | | 4 | 4 | | |
| Feeling cold | 7 | 15 | | | 5 | 12 | 2 | 3 |
| Feeling hot | 16 | 20 | | | 10 | 14 | 6 | 6 |
| Feeling jittery | | | 1 | 1 | | | | |
| Feeling of body temperature change | 1 | 2 | | | 1 | 2 | | |
| Gait disturbance | 6 | 8 | | | 1 | 3 | 5 | 5 |
| General physical health deterioration | 18 | 29 | | | 2 | 4 | 16 | 25 |
| Hunger | | 1 | | | | 1 | | |
| Hyperpyrexia | | 1 | | | | | | 1 |
| Illness | 1 | 2 | | | 1 | 2 | | |
| Induration | | 1 | | | | 1 | | |
| Influenza like illness | 14 | 35 | | | 12 | 32 | 2 | 3 |
| Injection site discomfort | | 1 | | | | 1 | | |
| Injection site pain | 1 | 3 | | | 1 | 2 | | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Local reaction | 4 | 8 |
| Malaise | 25 | 44 |
| Multimorbidity | | 1 |
| Multi-organ disorder | 1 | 1 |
| Multiple organ dysfunction syndrome | 3 | 5 |
| Necrosis | 1 | 1 |
| No adverse event | 2 | 3 |
| Nodule | 1 | 1 |
| Oedema | 1 | 2 |
| Oedema peripheral | 1 | 1 |
| Pain | 12 | 29 |
| Performance status decreased | 1 | 2 |
| Peripheral swelling | 6 | 10 |
| Pyrexia | 93 | 148 |
| Sensation of foreign body | 7 | 10 |
| Sense of oppression | | 1 |
| Sudden cardiac death | | 1 |
| Sudden death | 15 | 22 |
| Swelling | 4 | 12 |
| Swelling face | 7 | 11 |
| Systemic inflammatory response syndrome | 1 | 1 |
| Therapeutic response unexpected | 4 | 4 |
| Thirst | | 1 |
| Vaccination site bruising | 1 | 3 |
| Vaccination site dermatitis | | 1 |
| Vaccination site discomfort | 2 | 4 |
| Vaccination site dysaesthesia | 1 | 1 |
| Vaccination site erythema | 10 | 21 |
| Vaccination site haematoma | 3 | 5 |
| Vaccination site haemorrhage | 2 | 2 |
| Vaccination site hyperaesthesia | 1 | 4 |
| Vaccination site induration | 1 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 6 | 2 | 2 |
| 49 | 50 | 18 | 31 | 7 | 13 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | 2 | 3 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | 10 | 24 | 2 | 5 |
| | | | 1 | 1 | 1 |
| | | 5 | 7 | 1 | 3 |
| 25 | 26 | 69 | 114 | 24 | 34 |
| | | 1 | 1 | 6 | 9 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 15 | 22 |
| | | 3 | 10 | 1 | 2 |
| 3 | 3 | 4 | 4 | 3 | 7 |
| | | | | 1 | 1 |
| | | 4 | 4 | | |
| 1 | 1 | | 1 | | |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 2 | 4 | | |
| | | 1 | 1 | | |
| 1 | 1 | 8 | 19 | 2 | 2 |
| | | 2 | 4 | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 4 | | |
| | | 1 | 4 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | | |
|--|------------------------------------|--------------------------------------|--------------------------|-----|-------------|------|---------|---|-----|---|
| | | | Serious | | Nonserious | | Serious | | | |
| | | | I | C | I | C | I | C | | |
| Vaccination site inflammation | | | 1 | 1 | | | | | | |
| Vaccination site irritation | | 1 | | | | 1 | | | | |
| Vaccination site joint movement impairment | 1 | 3 | | | 1 | 2 | | | | 1 |
| Vaccination site joint pain | 2 | 2 | | | 2 | 2 | | | | |
| Vaccination site lymphadenopathy | 1 | 1 | | | 1 | 1 | | | | |
| Vaccination site movement impairment | 2 | 8 | | | 2 | 8 | | | | |
| Vaccination site pain | 128 | 304 | 53 | 53 | 124 | 298 | 4 | | 6 | |
| Vaccination site paraesthesia | 2 | 3 | | | 2 | 3 | | | | |
| Vaccination site pruritus | 5 | 9 | | | 5 | 9 | | | | |
| Vaccination site rash | 1 | 2 | | | 1 | 2 | | | | |
| Vaccination site reaction | 2 | 5 | | | 2 | 5 | | | | |
| Vaccination site swelling | 12 | 36 | 12 | 12 | 9 | 33 | 3 | | 3 | |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 | | | | |
| Vaccination site warmth | 12 | 18 | 1 | 1 | 11 | 17 | 1 | | 1 | |
| | 860 | 1,637 | 230 | 233 | 528 | 1096 | 332 | | 541 | |

System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Cholelithiasis | | 1 | | 1 | | | |
| Hepatic pain | 1 | 1 | 1 | 1 | | | |
| Hepatitis cholestatic | 1 | 1 | | | 1 | 1 | |
| Jaundice | | 1 | | 1 | | | |
| | 2 | 4 | 1 | 3 | 1 | 1 | |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|-----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|--|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Allergic oedema | | 1 | | | | 1 | | | |
| Allergy to vaccine | 3 | 4 | | | 1 | 1 | 2 | 3 | |
| Anaphylactic reaction | 46 | 57 | | | | | 46 | 57 | |
| Anaphylactic shock | 7 | 10 | 1 | 1 | | | 7 | 10 | |
| Anaphylactoid reaction | | 1 | | | | | | 1 | |
| Hypersensitivity | 31 | 47 | 4 | 4 | 8 | 14 | 23 | 33 | |
| Reaction to excipient | | 1 | | | | 1 | | | |
| Type IV hypersensitivity reaction | 4 | 4 | | | 4 | 4 | | | |
| | 91 | 125 | 5 | 5 | 13 | 21 | 78 | 104 | |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abscess | | 1 | | | | | | 1 |
| Appendicitis | | | 1 | 1 | | | | |
| Asymptomatic COVID-19 | 1 | 1 | | | | | 1 | 1 |
| Atypical pneumonia | | 1 | | | | | | 1 |
| Bronchitis | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Bronchitis bacterial | | 1 | | | | | | 1 |
| Cellulitis | 1 | 1 | | | | | 1 | 1 |
| Conjunctivitis | 1 | 2 | | | 1 | 1 | | 1 |
| Coronavirus infection | 5 | 6 | | | 1 | 1 | 4 | 5 |
| COVID-19 | 167 | 246 | 1 | 1 | 25 | 26 | 142 | 220 |
| COVID-19 pneumonia | 6 | 11 | | | | | 6 | 11 |
| Encephalitis | 1 | 1 | | | | | 1 | 1 |
| Erysipelas | 1 | 1 | | | | | 1 | 1 |
| Escherichia infection | 1 | 1 | | | | | 1 | 1 |
| Febrile infection | | 2 | | | | | | 2 |
| Genital herpes | | 1 | | | | 1 | | |
| Herpes simplex | 1 | 1 | | | | | 1 | 1 |
| Herpes zoster | 11 | 14 | | | 6 | 9 | 5 | 5 |
| Herpes zoster infection neurological | 1 | 1 | | | | | 1 | 1 |
| Herpes zoster meningitis | 1 | 1 | | | | | 1 | 1 |
| Herpes zoster oticus | 1 | 1 | | | | | 1 | 1 |
| Herpes zoster reactivation | 1 | 1 | | | 1 | 1 | | |
| Hordeolum | | 1 | | | | 1 | | |
| Infection | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 |
| Infective exacerbation of chronic obstructive airways disease | 1 | 2 | | | | | 1 | 2 |
| Localised infection | 1 | 1 | | | 1 | 1 | | |
| Myelitis | 1 | 1 | | | | | 1 | 1 |
| Myocarditis infectious | 1 | 1 | | | | | 1 | 1 |
| Nasopharyngitis | 11 | 18 | 1 | 1 | 9 | 16 | 2 | 2 |
| Ophthalmic herpes zoster | 2 | 2 | | | | | 2 | 2 |
| Oral herpes | 2 | 2 | | | 1 | 1 | 1 | 1 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|-----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|-----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Otitis media | | 1 | | | | 1 | | | |
| Pathogen resistance | | 1 | | | | | | | 1 |
| Pharyngitis | 1 | 1 | | | 1 | 1 | | | |
| Pneumonia | 15 | 19 | | | | | 15 | | 19 |
| Pulmonary sepsis | 1 | 2 | | | | | 1 | | 2 |
| Pustule | 3 | 3 | 1 | 1 | 1 | 1 | 2 | | 2 |
| Respiratory tract infection | 2 | 4 | | | | | 2 | | 4 |
| Rhinitis | | 1 | | | | | 1 | | |
| SARS-CoV-2 sepsis | 1 | 1 | | | | | 1 | | 1 |
| Sepsis | 1 | 2 | | | | | 1 | | 2 |
| Septic shock | 1 | 2 | | | | | 1 | | 2 |
| Sialoadenitis | 1 | 1 | | | | | 1 | | 1 |
| Sinusitis | 1 | 2 | | | 1 | 2 | | | |
| Soft tissue infection | 1 | 1 | | | | | 1 | | 1 |
| Staphylococcal sepsis | | 1 | | | | | | | 1 |
| Superinfection bacterial | 1 | 1 | | | | | 1 | | 1 |
| Suspected COVID-19 | | 5 | | | | | | | 5 |
| Upper respiratory tract infection | 2 | 2 | | | | | 2 | | 2 |
| Urinary tract infection | 1 | 1 | | | | | 1 | | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | | | 1 | | 1 |
| Urosepsis | 1 | 1 | | | | | 1 | | 1 |
| Varicella zoster virus infection | 1 | 1 | | | 1 | 1 | | | |
| | 258 | 382 | 5 | 5 | 51 | 67 | 207 | | 315 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Accidental overdose | | 13 | | | | 10 | | 3 |
| Circumstance or information capable of leading to medication error | | 1 | | | | 1 | | |
| Contusion | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Exposure during pregnancy | | 1 | | | | 1 | | |
| Exposure via breast milk | 2 | 3 | | | 2 | 3 | | |
| Fall | 5 | 9 | | | 1 | 1 | 4 | 8 |
| Femoral neck fracture | | 1 | | | | | | 1 |
| Femur fracture | 1 | 1 | | | | | 1 | 1 |
| Fracture | 1 | 1 | | | | | 1 | 1 |
| Head injury | | 1 | | | | | | 1 |
| Inappropriate schedule of product administration | 7 | 10 | | | 7 | 10 | | |
| Incorrect route of product administration | 7 | 16 | | | 7 | 15 | | 1 |
| Maternal exposure during pregnancy | 11 | 24 | | | 10 | 23 | 1 | 1 |
| Muscle strain | | | 1 | 1 | | | | |
| Occupational exposure to product | | 1 | | | | 1 | | |
| Off label use | 11 | 18 | | | 11 | 18 | | |
| Poor quality product administered | 26 | 27 | | | 25 | 26 | 1 | 1 |
| Product administered at inappropriate site | | 1 | | | | 1 | | |
| Product administered to patient of inappropriate age | 1 | 1 | | | 1 | 1 | | |
| Product preparation error | | 2 | | | | 2 | | |
| Product preparation issue | 8 | 9 | | | 8 | 9 | | |
| Product storage error | 1 | 1 | | | 1 | 1 | | |
| Product use issue | 10 | 18 | | | 10 | 18 | | |
| Scratch | | 1 | | | | 1 | | |
| Skin abrasion | 1 | 1 | | | | | 1 | 1 |
| Toxicity to various agents | 1 | 1 | | | | | 1 | 1 |
| Underdose | 9 | 18 | | | 9 | 18 | | |
| Vaccination failure | 2 | 2 | 1 | 1 | | | 2 | 2 |
| Wound | 1 | 1 | | | 1 | 1 | | |
| Wrong technique in product usage process | | 1 | | | | 1 | | |

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 2 | 2 | 94 | 163 | 13 | 23 |

107

186

2

2

94

163

13

23

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Alanine aminotransferase increased | 1 | 1 | | | | | 1 | 1 |
| Aspartate aminotransferase increased | 1 | 1 | | | | | 1 | 1 |
| Blood calcium decreased | | 1 | | | | 1 | | |
| Blood cholesterol increased | 1 | 1 | | | 1 | 1 | | |
| Blood creatine phosphokinase increased | | 1 | | | | 1 | | |
| Blood creatine phosphokinase MB increased | | 1 | | | | 1 | | |
| Blood creatinine increased | | 1 | | | | 1 | | |
| Blood glucose fluctuation | | 1 | | | | 1 | | |
| Blood lactate dehydrogenase increased | 2 | 2 | | | | | 2 | 2 |
| Blood potassium decreased | | 1 | | | | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 | | |
| Blood pressure decreased | 5 | 8 | 1 | 1 | | 1 | 5 | 7 |
| Blood pressure immeasurable | 1 | 1 | | | | | 1 | 1 |
| Blood pressure increased | 6 | 9 | 2 | 2 | 3 | 5 | 3 | 4 |
| Blood urine present | | 1 | | | | | | 1 |
| Body temperature increased | 20 | 31 | | | 18 | 27 | 2 | 4 |
| Capillary nail refill test abnormal | 1 | 1 | | | 1 | 1 | | |
| Chest X-ray abnormal | 1 | 1 | | | | | 1 | 1 |
| Coronavirus test positive | 3 | 3 | | | 1 | 1 | 2 | 2 |
| C-reactive protein increased | 3 | 3 | | | 1 | 1 | 2 | 2 |
| General physical condition abnormal | 7 | 8 | | | | | 7 | 8 |
| Glomerular filtration rate decreased | 1 | 1 | | | 1 | 1 | | |
| Haematocrit decreased | | 1 | | | | 1 | | |
| Haemoglobin decreased | | 1 | | | | 1 | | |
| Heart rate decreased | 1 | 1 | | | | | 1 | 1 |
| Heart rate increased | 5 | 7 | | | 2 | 3 | 3 | 4 |
| Inflammatory marker increased | 1 | 1 | | | | | 1 | 1 |
| Lipase increased | 1 | 1 | | | | | 1 | 1 |
| Liver function test increased | 2 | 2 | | | | | 2 | 2 |
| Low density lipoprotein increased | 1 | 1 | | | 1 | 1 | | |
| Oxygen saturation decreased | 4 | 8 | | | | | 4 | 8 |
| Platelet count decreased | 1 | 1 | | | | | 1 | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|---|----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Protein urine present | | 1 | | | | 1 | | | |
| Pulse waveform abnormal | 1 | 1 | | | 1 | 1 | | | |
| Red blood cell count decreased | | 1 | | | | 1 | | | |
| Red blood cell sedimentation rate increased | 1 | 1 | | | 1 | 1 | | | |
| SARS-CoV-2 ant body test negative | 9 | 9 | | | 9 | 9 | | | |
| SARS-CoV-2 ant body test positive | 22 | 26 | | | 22 | 25 | | | 1 |
| SARS-CoV-2 test false positive | 1 | 4 | | | 1 | 4 | | | |
| SARS-CoV-2 test positive | 19 | 50 | | | 8 | 14 | 11 | | 36 |
| Transaminases increased | 1 | 1 | | | | | 1 | | 1 |
| White blood cell count increased | 2 | 2 | | | | | 2 | | 2 |
| | 126 | 199 | 3 | 3 | 72 | 107 | 54 | | 92 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acidosis | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 3 | 5 | 2 | 3 | 1 | 2 |
| Dehydration | 2 | 2 | 1 | 1 | 1 | 1 |
| Diabetes mellitus | | 2 | | | | 2 |
| Diet refusal | 3 | 5 | | | 3 | 5 |
| Food refusal | | 2 | | | | 2 |
| Gout | 1 | 1 | 1 | 1 | | |
| Hypercalcaemia | 1 | 2 | | | 1 | 2 |
| Hyperkalaemia | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 1 | 1 | 1 | 1 | | |
| Hyponatraemia | 2 | 2 | | | 2 | 2 |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Tetany | 1 | 1 | | | 1 | 1 |
| | 17 | 26 | 5 | 6 | 12 | 20 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Arthralgia | 24 | 42 | 22 | 22 | 22 | 40 | 2 | 2 |
| Arthritis reactive | 1 | 1 | | | | | 1 | 1 |
| Arthropathy | 1 | 1 | | | | | 1 | 1 |
| Back pain | 4 | 7 | | | 4 | 7 | | |
| Bone pain | 8 | 9 | | | 6 | 7 | 2 | 2 |
| Bursitis | | | 1 | 1 | | | | |
| Flank pain | 1 | 1 | | | 1 | 1 | | |
| Jaw clicking | | 1 | | | | | | 1 |
| Joint range of motion decreased | 2 | 2 | | | 2 | 2 | | |
| Joint swelling | 1 | 1 | | | | | 1 | 1 |
| Limb discomfort | 6 | 14 | | | 6 | 14 | | |
| Mobility decreased | 5 | 9 | | | 4 | 7 | 1 | 2 |
| Muscle discomfort | 1 | 1 | | | 1 | 1 | | |
| Muscle spasms | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Muscle swelling | | 1 | | | | 1 | | |
| Muscle tightness | | 1 | 1 | 1 | | 1 | | |
| Muscle twitching | 1 | 2 | | | 1 | 2 | | |
| Muscular weakness | 6 | 12 | | | 4 | 10 | 2 | 2 |
| Musculoskeletal chest pain | 1 | 1 | | | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 2 | | | 1 | 2 | | |
| Myalgia | 55 | 110 | 34 | 35 | 47 | 102 | 8 | 8 |
| Myosclerosis | 1 | 1 | | | | | 1 | 1 |
| Neck pain | 2 | 11 | | | 2 | 11 | | |
| Oligoarthritis | 1 | 1 | | | | | 1 | 1 |
| Pain in extremity | 89 | 153 | | | 85 | 147 | 4 | 6 |
| Pain in jaw | 2 | 2 | | | 2 | 2 | | |
| Polyarthritis | 1 | 1 | | | | | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 | | | | | 1 | 1 |
| Spinal pain | 1 | 1 | | | 1 | 1 | | |
| Temporomandibular joint syndrome | 1 | 1 | | | 1 | 1 | | |
| Tenosynovitis | 1 | 1 | | | 1 | 1 | | |
| Weight bearing difficulty | | 1 | | | | | | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| | 222 | 396 | 58 | 59 | 192 | 361 | 30 | 35 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ageusia | 3 | 6 | | | 3 | 6 | | |
| Altered state of consciousness | | | 1 | 1 | | | | |
| Amnesia | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Anosmia | 2 | 4 | | | 2 | 4 | | |
| Aphasia | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Ataxia | 5 | 5 | | | | | 5 | 5 |
| Autonomic nervous system imbalance | 1 | 1 | | | | | 1 | 1 |
| Basal ganglia infarction | 1 | 1 | | | | | 1 | 1 |
| Burning sensation | 3 | 5 | | | 2 | 3 | 1 | 2 |
| Cerebellar ataxia | 1 | 1 | | | | | 1 | 1 |
| Cerebellar syndrome | 2 | 2 | | | | | 2 | 2 |
| Cerebral atrophy | 1 | 1 | | | | | 1 | 1 |
| Cerebral haemorrhage | 1 | 2 | | | | | 1 | 2 |
| Cerebral infarction | 3 | 4 | | | | | 3 | 4 |
| Cerebral ischaemia | 1 | 1 | | | | | 1 | 1 |
| Cerebrovascular accident | 11 | 13 | | | | | 11 | 13 |
| Cerebrovascular disorder | 1 | 1 | | | | | 1 | 1 |
| Cranial nerve disorder | 1 | 2 | | | 1 | 2 | | |
| Dementia | | 1 | | | | | | 1 |
| Dementia of the Alzheimer's type, with delirium | | 1 | | | | | | 1 |
| Depressed level of consciousness | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Disturbance in attention | 13 | 18 | | | 8 | 12 | 5 | 6 |
| Dizziness | 76 | 131 | 41 | 41 | 42 | 87 | 34 | 44 |
| Dizziness postural | 1 | 2 | | | | 1 | 1 | 1 |
| Dysaesthesia | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Dysarthria | 2 | 2 | | | | | 2 | 2 |
| Dysgeusia | 4 | 6 | | | 3 | 5 | 1 | 1 |
| Dysstasia | | 1 | | | | 1 | | |
| Epilepsy | 16 | 19 | | | | | 16 | 19 |
| Extrapyramidal disorder | 1 | 1 | | | 1 | 1 | | |
| Facial paralysis | 8 | 10 | | | | | 8 | 10 |
| Facial paresis | 5 | 5 | | | 1 | 1 | 4 | 4 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Generalised tonic-clonic seizure | 2 | 2 |
| Guillain-Barre syndrome | 2 | 2 |
| Headache | 148 | 268 |
| Head discomfort | 1 | 3 |
| Hemiparesis | 5 | 6 |
| Hyperaesthesia | 1 | 2 |
| Hypersomnia | 2 | 4 |
| Hypertonia | 1 | 1 |
| Hypoaesthesia | 10 | 19 |
| Hypokinesia | 1 | 1 |
| Hyporesponsive to stimuli | 1 | 1 |
| Hypotonia | 4 | 6 |
| Idiopathic intracranial hypertension | 1 | 1 |
| Ischaemic cerebral infarction | 1 | 1 |
| Ischaemic stroke | | 1 |
| IVth nerve paresis | 1 | 1 |
| Language disorder | 1 | 2 |
| Loss of consciousness | 8 | 10 |
| Memory impairment | 1 | 1 |
| Migraine | 1 | 2 |
| Monoplegia | 1 | 1 |
| Motor dysfunction | | 1 |
| Movement disorder | 1 | 5 |
| Multiple sclerosis | 1 | 1 |
| Muscle spasticity | 1 | 1 |
| Myoclonus | 2 | 2 |
| Nervous system disorder | 3 | 3 |
| Neuralgia | 3 | 4 |
| Neuralgic amyotrophy | 1 | 2 |
| Nystagmus | 1 | 1 |
| Occipital neuralgia | 1 | 1 |
| Optic neuritis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| 55 | 56 | 129 | 243 | 19 | 25 |
| | | 1 | 2 | | 1 |
| | | | | 5 | 6 |
| | | 1 | 2 | | |
| | | 1 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| 2 | 2 | 9 | 17 | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 3 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 8 | 10 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 3 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 3 | 3 |
| | | 3 | 4 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-----|---------|-----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Orthostatic intolerance | | 1 | | | | | | | 1 |
| Paraesthesia | 26 | 36 | 3 | 3 | 16 | 25 | 10 | 11 | |
| Paresis | 1 | 2 | | | | 1 | 1 | 1 | |
| Poor quality sleep | 2 | 4 | | | 2 | 3 | | | 1 |
| Presyncope | 6 | 7 | | | 4 | 5 | 2 | 2 | |
| Psychomotor hyperactivity | 1 | 1 | | | | | 1 | 1 | |
| Pyramidal tract syndrome | 1 | 1 | | | | | 1 | 1 | |
| Quadriparesis | 1 | 1 | | | | | 1 | 1 | |
| Resting tremor | 1 | 1 | | | | | 1 | 1 | |
| Retrograde amnesia | 1 | 1 | | | | | 1 | 1 | |
| Reversible cerebral vasoconstriction syndrome | 1 | 1 | | | | | 1 | 1 | |
| Seizure | 15 | 20 | | | | | 15 | 20 | |
| Sensory disturbance | 1 | 4 | | | | 3 | 1 | 1 | |
| Sensory loss | | 1 | | | | | | | 1 |
| Somnolence | 8 | 13 | | | 4 | 8 | 4 | 5 | |
| Speech disorder | 1 | 2 | | | 1 | 1 | | | 1 |
| Status epilepticus | 2 | 3 | | | | | 2 | 3 | |
| Stupor | 1 | 1 | | | | | 1 | 1 | |
| Sudden onset of sleep | 1 | 1 | | | | | 1 | 1 | |
| Syncope | 24 | 28 | 1 | 1 | | | 24 | 28 | |
| Taste disorder | | 1 | | | | 1 | | | |
| Tension headache | | 1 | | | | | | | 1 |
| Transient ischaemic attack | 1 | 2 | | | | | 1 | 2 | |
| Tremor | 11 | 18 | | | 4 | 8 | 7 | 10 | |
| Unresponsive to stimuli | 2 | 4 | | | | | 2 | 4 | |
| Vascular dementia | 1 | 1 | | | | | 1 | 1 | |
| Vascular encephalopathy | 1 | 1 | | | | | 1 | 1 | |
| | 494 | 775 | 103 | 104 | 249 | 464 | 245 | 311 | |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortion missed | 1 | 1 | 1 | 1 |
| Abortion spontaneous | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Product issues

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-------------------------------------|--|--|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Product complaint | 1 | 1 | 1 | 1 | | |
| Product leakage | | 1 | | 1 | | |
| Product temperature excursion issue | 25 | 25 | 24 | 24 | 1 | 1 |
| | 26 | 27 | 25 | 26 | 1 | 1 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 3 | 4 | | 1 | 3 | 3 |
| Anxiety | 3 | 4 | 1 | 2 | 2 | 2 |
| Apathy | 2 | 4 | 1 | 1 | 1 | 3 |
| Automatism | 1 | 1 | | | 1 | 1 |
| Communication disorder | 1 | 1 | 1 | 1 | | |
| Confusional state | 7 | 8 | 3 | 4 | 4 | 4 |
| Delirium | 2 | 2 | | | 2 | 2 |
| Depression | 1 | 1 | 1 | 1 | | |
| Disorientation | 4 | 5 | 2 | 3 | 2 | 2 |
| Eating disorder | 1 | 1 | 1 | 1 | | |
| Hallucination, auditory | 1 | 1 | | | 1 | 1 |
| Hallucinations, mixed | 1 | 1 | | | 1 | 1 |
| Initial insomnia | 2 | 2 | 2 | 2 | | |
| Insomnia | 3 | 4 | 3 | 4 | | |
| Mental disorder | 1 | 1 | 1 | 1 | | |
| Middle insomnia | 1 | 2 | 1 | 2 | | |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Personality change | 6 | 7 | 1 | 1 | 5 | 6 |
| Psychological factor affecting medical condition | | 1 | | | | 1 |
| Restlessness | 5 | 7 | 3 | 5 | 2 | 2 |
| Sleep disorder | 5 | 7 | 5 | 7 | | |
| Somatic symptom disorder | 1 | 1 | | | 1 | 1 |
| Stress | | 2 | | 2 | | |
| Tension | 1 | 1 | 1 | 1 | | |
| | 54 | 70 | 28 | 40 | 26 | 30 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 5 | 10 | | | 5 | 10 |
| Bladder discomfort | | 1 | | 1 | | |
| Bladder pain | | 1 | | 1 | | |
| Chronic kidney disease | | 1 | | | | 1 |
| Glomerulonephritis minimal lesion | 1 | 1 | | | 1 | 1 |
| Haematuria | | 1 | | 1 | | |
| Nephrotic syndrome | 1 | 1 | | | 1 | 1 |
| Pollakiuria | | 1 | | 1 | | |
| Proteinuria | 1 | 1 | | | 1 | 1 |
| Renal failure | 5 | 7 | | | 5 | 7 |
| Renal pain | | 1 | | 1 | | |
| | 13 | 26 | | 5 | 13 | 21 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|
| | | | Serious | | Nonserious | |
| | | | I | C | I | C |
| Breast pain | | | 1 | 1 | | |
| Menorrhagia | 1 | 1 | | | 1 | 1 |
| Menstrual disorder | 5 | 5 | | | 5 | 5 |
| Pelvic pain | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 1 | 1 | 7 | 7 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute respiratory distress syndrome | 2 | 2 | | | | | 2 | 2 |
| Acute respiratory failure | 1 | 2 | | | | | 1 | 2 |
| Aspiration | 1 | 1 | | | | | 1 | 1 |
| Asthma | 6 | 8 | | | 3 | 4 | 3 | 4 |
| Bronchial disorder | | 1 | | | | 1 | | |
| Bronchospasm | 1 | 2 | | | | 1 | 1 | 1 |
| Chronic obstructive pulmonary disease | 4 | 4 | | | | | 4 | 4 |
| Cough | 20 | 30 | 1 | 1 | 12 | 21 | 8 | 9 |
| Diaphragmalgia | 1 | 1 | | | 1 | 1 | | |
| Dysphonia | 4 | 6 | | | 4 | 6 | | |
| Dyspnoea | 46 | 67 | 2 | 2 | 16 | 27 | 30 | 40 |
| Dyspnoea at rest | 1 | 1 | | | | | 1 | 1 |
| Dyspnoea exertional | 5 | 6 | | | 2 | 2 | 3 | 4 |
| Epistaxis | 1 | 4 | 1 | 1 | | 3 | 1 | 1 |
| Haemoptysis | | 1 | | | | 1 | | |
| Hyperventilation | 8 | 8 | | | 2 | 2 | 6 | 6 |
| Hypoxia | 1 | 1 | | | 1 | 1 | | |
| Increased upper airway secretion | | 1 | | | | 1 | | |
| Irregular breathing | 1 | 2 | | | | | 1 | 2 |
| Laryngeal oedema | 1 | 3 | | | | | 1 | 3 |
| Laryngospasm | 1 | 1 | | | | | 1 | 1 |
| Lower respiratory tract congestion | 1 | 1 | | | 1 | 1 | | |
| Lung disorder | 1 | 1 | | | 1 | 1 | | |
| Lung infiltration | 1 | 1 | | | | | 1 | 1 |
| Nasal congestion | 1 | 4 | | | 1 | 4 | | |
| Obstructive airways disorder | 1 | 1 | | | | | 1 | 1 |
| Oropharyngeal blistering | 1 | 1 | | | | | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 | | |
| Oropharyngeal pain | 9 | 16 | 1 | 1 | 8 | 15 | 1 | 1 |
| Orthopnoea | | 1 | | | | | | 1 |
| Pharyngeal hypoesthesia | 1 | 2 | | | 1 | 2 | | |
| Pharyngeal inflammation | | 1 | | | | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------|------------------------------------|--------------------------------------|
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal swelling | 5 | 8 |
| Pleurisy | 1 | 1 |
| Pneumonia aspiration | | 3 |
| Pulmonary embolism | 4 | 7 |
| Pulmonary oedema | 2 | 2 |
| Rales | 1 | 1 |
| Respiratory distress | 30 | 39 |
| Respiratory failure | 10 | 12 |
| Respiratory symptom | | 1 |
| Rhinalgia | | 2 |
| Rhinitis allergic | 1 | 1 |
| Rhinorrhoea | 9 | 18 |
| Rhonchi | | 2 |
| Sinus congestion | 2 | 2 |
| Sneezing | 3 | 6 |
| Stridor | 3 | 4 |
| Tachypnoea | 2 | 2 |
| Throat irritation | 4 | 8 |
| Throat tightness | 6 | 10 |
| Wheezing | 4 | 4 |
| | 210 | 316 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| 1 | 1 | 3 | 3 | 2 | 5 |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | | | 4 | 7 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 30 | 39 |
| | | | | 10 | 12 |
| | | | 1 | | |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 9 | 17 | | 1 |
| | | | | | 2 |
| | | 2 | 2 | | |
| | | 3 | 6 | | |
| | | | | 3 | 4 |
| | | 1 | 1 | 1 | 1 |
| 1 | 1 | 4 | 8 | | |
| | | 3 | 4 | 3 | 6 |
| | | 2 | 2 | 2 | 2 |
| 7 | 7 | 82 | 143 | 128 | 173 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acne | | 1 | | | | 1 | | |
| Angioedema | 10 | 12 | | | | | 10 | 12 |
| Blister | | 1 | | | | 1 | | |
| Cold sweat | 5 | 6 | | | 2 | 2 | 3 | 4 |
| Dermatitis allergic | 1 | 4 | | | | 3 | 1 | 1 |
| Dermatitis atopic | 1 | 1 | | | 1 | 1 | | |
| Dry skin | | 1 | | | | 1 | | |
| Eczema | 6 | 7 | | | 6 | 7 | | |
| Erythema | 23 | 34 | 2 | 2 | 17 | 27 | 6 | 7 |
| Erythema multiforme | 1 | 1 | | | | | 1 | 1 |
| Hyperhidrosis | 11 | 19 | 1 | 1 | 9 | 17 | 2 | 2 |
| Hypersensitivity vasculitis | 1 | 1 | | | | | 1 | 1 |
| Livedo reticularis | | 1 | | | | 1 | | |
| Neurodermatitis | 3 | 3 | | | 3 | 3 | | |
| Night sweats | 4 | 4 | | | 4 | 4 | | |
| Pain of skin | 1 | 1 | | | 1 | 1 | | |
| Petechiae | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Photosensitivity reaction | | 1 | | | | 1 | | |
| Pruritus | 19 | 30 | 2 | 2 | 12 | 19 | 7 | 11 |
| Pruritus allergic | 1 | 2 | | | | 1 | 1 | 1 |
| Psoriasis | 1 | 2 | | | | 1 | 1 | 1 |
| Rash | 23 | 41 | 4 | 4 | 8 | 18 | 15 | 23 |
| Rash erythematous | 1 | 1 | | | 1 | 1 | | |
| Rash macular | 2 | 4 | | | 2 | 3 | | 1 |
| Rash maculo-papular | 3 | 4 | | | 3 | 4 | | |
| Rash pruritic | | 3 | | | | 3 | | |
| Rash vesicular | 1 | 1 | | | 1 | 1 | | |
| Rosacea | | 1 | | | | | | 1 |
| Sensitive skin | 1 | 1 | | | 1 | 1 | | |
| Skin burning sensation | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Skin discolouration | 1 | 2 | | | | 1 | 1 | 1 |
| Skin swelling | 1 | 1 | | | 1 | 1 | | |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| | | | Urticaria | 13 | 18 | 1 | 1 | 6 |
| | 139 | 214 | 10 | 10 | 80 | 135 | 59 | 79 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | | | Bedridden | | 1 | |
| Impaired work ability | 1 | 1 | 1 | 1 | | |
| | 1 | 2 | 1 | 1 | | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Aortic aneurysm | 1 | 1 | | | | | 1 | 1 |
| Arterial occlusive disease | 1 | 1 | | | | | 1 | 1 |
| Arteriosclerosis | 1 | 1 | | | | | 1 | 1 |
| Blood pressure fluctuation | | 1 | | | | 1 | | |
| Circulatory collapse | 15 | 19 | 1 | 1 | | | 15 | 19 |
| Cyanosis | 3 | 4 | | | | | 3 | 4 |
| Deep vein thrombosis | 3 | 3 | | | | | 3 | 3 |
| Embolism arterial | 1 | 1 | | | | | 1 | 1 |
| Femoral artery embolism | 1 | 1 | | | | | 1 | 1 |
| Flushing | 14 | 20 | | | 7 | 9 | 7 | 11 |
| Haematoma | 6 | 7 | | | 2 | 3 | 4 | 4 |
| Hot flush | 4 | 5 | | | 4 | 5 | | |
| Hypertension | 21 | 35 | 3 | 3 | 6 | 11 | 15 | 24 |
| Hypertensive crisis | 8 | 8 | | | | | 8 | 8 |
| Hypertensive emergency | 1 | 1 | | | | | 1 | 1 |
| Hypotension | 13 | 21 | | | 1 | 3 | 12 | 18 |
| Infarction | 1 | 1 | | | | | 1 | 1 |
| Microembolism | 1 | 1 | | | | | 1 | 1 |
| Pallor | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Peripheral circulatory failure | 1 | 1 | | | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 | | |
| Peripheral embolism | | 1 | | | | 1 | | |
| Peripheral vascular disorder | 13 | 19 | 1 | 1 | 4 | 6 | 9 | 13 |
| Shock | 2 | 2 | | | | | 2 | 2 |
| Subclavian artery thrombosis | 1 | 1 | | | | | 1 | 1 |
| Thrombosis | 1 | 1 | | | | | 1 | 1 |
| Venous thrombosis limb | 1 | 1 | | | | | 1 | 1 |
| | 118 | 161 | 5 | 5 | 26 | 41 | 92 | 120 |

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Country Where Event Occurred

GIBRALTAR

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Death | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

GREECE

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytosis | | 1 | | | | 1 |
| Lymphadenitis | 11 | 11 | 3 | 3 | 8 | 8 |
| Lymphadenopathy | 13 | 14 | 5 | 6 | 8 | 8 |
| Lymph node pain | 3 | 4 | 2 | 3 | 1 | 1 |
| Lymphopenia | 1 | 1 | 1 | 1 | | |
| | 28 | 31 | 11 | 13 | 17 | 18 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | | 1 | | | | 1 |
| Arrhythmia | 6 | 6 | | | 6 | 6 |
| Atrial fibrillation | | 1 | | | | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | | 3 | | | | 3 |
| Cardiac discomfort | 1 | 1 | | | 1 | 1 |
| Cardiac valve disease | | 1 | | | | 1 |
| Extrasystoles | 2 | 2 | 2 | 2 | | |
| Myocardial infarction | | 1 | | | | 1 |
| Palpitations | 16 | 18 | 11 | 13 | 5 | 5 |
| Tachycardia | 29 | 39 | 14 | 20 | 15 | 19 |
| | 55 | 74 | 27 | 35 | 28 | 39 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | | 1 | | | | 1 |
| Ear pain | 2 | 2 | 2 | 2 | | |
| Hypoacusis | 1 | 1 | | | 1 | 1 |
| Tinnitus | 4 | 6 | 2 | 4 | 2 | 2 |
| Vertigo | 6 | 6 | 5 | 5 | 1 | 1 |
| | 14 | 17 | 9 | 11 | 5 | 6 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blepharospasm | 1 | 1 | 1 | 1 | | |
| Eye irritation | | 1 | | 1 | | |
| Eyelid oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Eyelid ptosis | 1 | 2 | | | 1 | 2 |
| Eyelids pruritus | 1 | 1 | | | 1 | 1 |
| Eye oedema | | 1 | | | | 1 |
| Eye pruritus | 1 | 2 | | 1 | 1 | 1 |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Periorbital oedema | 1 | 2 | 1 | 2 | | |
| Vision blurred | 2 | 2 | 2 | 2 | | |
| | 10 | 15 | 5 | 8 | 5 | 7 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 8 | 9 | 4 | 5 | 4 | 4 |
| Abdominal pain upper | 4 | 5 | 4 | 5 | | |
| Defaecation urgency | | 1 | | | | 1 |
| Diarrhoea | 15 | 18 | 8 | 10 | 7 | 8 |
| Dry mouth | 4 | 6 | 2 | 4 | 2 | 2 |
| Dyspepsia | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphagia | 7 | 11 | 3 | 4 | 4 | 7 |
| Enlarged uvula | 1 | 1 | | | 1 | 1 |
| Eructation | 3 | 3 | 2 | 2 | 1 | 1 |
| Flatulence | 1 | 2 | | | 1 | 2 |
| Gastrointestinal disorder | 7 | 9 | 7 | 9 | | |
| Gastrointestinal hypermotility | | 1 | | | | 1 |
| Hypoaesthesia oral | 15 | 22 | 6 | 10 | 9 | 12 |
| Lip oedema | 4 | 4 | 2 | 2 | 2 | 2 |
| Lip swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Nausea | 23 | 29 | 16 | 20 | 7 | 9 |
| Oral discomfort | | 1 | | 1 | | |
| Pancreatitis | 1 | 1 | | | 1 | 1 |
| Tongue discomfort | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 2 | 2 | | | 2 | 2 |
| Tongue ulceration | | 1 | | 1 | | |
| Vomiting | 9 | 13 | 2 | 6 | 7 | 7 |
| | 110 | 145 | 59 | 82 | 51 | 63 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 16 | 20 | 9 | 13 | 7 | 7 |
| Chest discomfort | 4 | 4 | 2 | 2 | 2 | 2 |
| Chest pain | 7 | 10 | 2 | 3 | 5 | 7 |
| Chills | 48 | 53 | 16 | 20 | 32 | 33 |
| Condition aggravated | 1 | 2 | | | 1 | 2 |
| Death | 2 | 2 | | | 2 | 2 |
| Discomfort | 2 | 3 | 1 | 2 | 1 | 1 |
| Drowning | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 15 | 16 | | | 15 | 16 |
| Drug interaction | | 1 | | | | 1 |
| Face oedema | 2 | 2 | | | 2 | 2 |
| Fatigue | 48 | 58 | 21 | 29 | 27 | 29 |
| Feeling abnormal | 1 | 1 | | | 1 | 1 |
| Feeling cold | 1 | 2 | 1 | 2 | | |
| Feeling hot | 1 | 2 | 1 | 1 | | 1 |
| Gait disturbance | 1 | 3 | | 2 | 1 | 1 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Inflammation | 2 | 2 | | | 2 | 2 |
| Localised oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Local reaction | 1 | 2 | 1 | 2 | | |
| Malaise | 14 | 15 | 6 | 7 | 8 | 8 |
| Mucosal dryness | | 1 | | | | 1 |
| No adverse event | 5 | 7 | 5 | 7 | | |
| Oedema | 4 | 4 | 2 | 2 | 2 | 2 |
| Oedema peripheral | 1 | 1 | 1 | 1 | | |
| Pain | 22 | 23 | 10 | 11 | 12 | 12 |
| Pyrexia | 78 | 90 | 37 | 47 | 41 | 43 |
| Sudden death | 1 | 3 | | | 1 | 3 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Swelling face | 2 | 2 | | | 2 | 2 |
| Therapeutic response unexpected | | 1 | | 1 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site erythema | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site hyperaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 3 | 3 | 3 | 3 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site irritation | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 4 | 5 | 4 | 5 | | |
| Vaccination site pain | 47 | 63 | 37 | 53 | 10 | 10 |
| Vaccination site pruritus | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 2 | 1 | 2 | | |
| | 353 | 424 | 170 | 227 | 183 | 197 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 2 | 3 | 1 | 1 | 1 | 2 |
| Anaphylactic reaction | 7 | 9 | | | 7 | 9 |
| Anaphylactic shock | 2 | 5 | | | 2 | 5 |
| Anaphylactoid reaction | 1 | 2 | | | 1 | 2 |
| Hypersensitivity | 19 | 28 | 7 | 13 | 12 | 15 |
| Reaction to excipient | 1 | 1 | | | 1 | 1 |
| | 32 | 48 | 8 | 14 | 24 | 34 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asymptomatic COVID-19 | 2 | 2 | | | 2 | 2 |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| COVID-19 | 17 | 18 | 2 | 2 | 15 | 16 |
| Gastroenteritis | 1 | 1 | | | 1 | 1 |
| Herpes dermatitis | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Oral herpes | 2 | 3 | 1 | 2 | 1 | 1 |
| Pneumonia | | 1 | | | | 1 |
| Respiratory tract infection | | 1 | | | | 1 |
| Suspected COVID-19 | 1 | 1 | 1 | 1 | | |
| Viral infection | 2 | 2 | 2 | 2 | | |
| | 30 | 34 | 9 | 10 | 21 | 24 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circumstance or information capable of leading to medication error | 2 | 2 | 2 | 2 | | |
| Fall | 1 | 2 | | | 1 | 2 |
| Incomplete course of vaccination | | 1 | | 1 | | |
| Incorrect route of product administration | 3 | 3 | 3 | 3 | | |
| Injury | | 1 | | 1 | | |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Off label use | 3 | 4 | 3 | 4 | | |
| Poor quality product administered | 1 | 4 | 1 | 4 | | |
| Product use issue | 3 | 3 | 3 | 3 | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 15 | 23 | 13 | 20 | 2 | 3 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Antibody test abnormal | 1 | 2 | 1 | 2 | | |
| Aspartate aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Auscultation | | 1 | | 1 | | |
| Blood glucose abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 3 | 5 | | 2 | 3 | 3 |
| Blood pressure diastolic increased | 1 | 2 | 1 | 2 | | |
| Blood pressure increased | 21 | 23 | 14 | 15 | 7 | 8 |
| Blood pressure systolic increased | 2 | 2 | 1 | 1 | 1 | 1 |
| C-reactive protein increased | 2 | 2 | 2 | 2 | | |
| Fibrin D dimer increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Gamma-glutamyltransferase increased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 18 | 18 | 14 | 14 | 4 | 4 |
| Oxygen saturation decreased | 3 | 3 | 1 | 1 | 2 | 2 |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 1 | 1 | 1 | 1 | | |
| | 60 | 67 | 40 | 46 | 20 | 21 |

System Organ Class

| Metabolism and nutrition disorders | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cachexia | 2 | 2 | | | 2 | 2 |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Diabetes mellitus inadequate control | 1 | 1 | | | 1 | 1 |
| Insulin resistance | 1 | 1 | | | 1 | 1 |
| Polydipsia | 1 | 1 | 1 | 1 | | |
| | 7 | 7 | 3 | 3 | 4 | 4 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 43 | 44 | 15 | 16 | 28 | 28 |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Arthritis enteropathic | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 2 | 2 | | |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Joint range of motion decreased | | 1 | | 1 | | |
| Limb discomfort | 1 | 2 | | 1 | 1 | 1 |
| Muscle discomfort | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 3 | 4 | | 1 | 3 | 3 |
| Muscle tightness | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 2 | | 1 | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 | 1 | 1 | | |
| Myalgia | 66 | 69 | 35 | 37 | 31 | 32 |
| Neck pain | 2 | 2 | 2 | 2 | | |
| Pain in extremity | 12 | 18 | 10 | 16 | 2 | 2 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Rheumatoid arthritis | 1 | 2 | | | 1 | 2 |
| Spinal pain | 2 | 2 | | | 2 | 2 |
| Temporomandibular joint syndrome | 1 | 1 | 1 | 1 | | |
| Trismus | 1 | 1 | 1 | 1 | | |
| | 144 | 159 | 72 | 85 | 72 | 74 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Balance disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Burning sensation | 9 | 11 | 7 | 9 | 2 | 2 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Cholinergic syndrome | 3 | 3 | | | 3 | 3 |
| Complex regional pain syndrome | 3 | 3 | 1 | 1 | 2 | 2 |
| Dizziness | 42 | 52 | 27 | 34 | 15 | 18 |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysgeusia | 5 | 10 | 2 | 5 | 3 | 5 |
| Dyskinesia | 3 | 3 | 2 | 2 | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Guillain-Barre syndrome | 2 | 2 | | | 2 | 2 |
| Headache | 63 | 75 | 36 | 47 | 27 | 28 |
| Head discomfort | 2 | 2 | 2 | 2 | | |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hypoaesthesia | 41 | 47 | 27 | 32 | 14 | 15 |
| Lethargy | 3 | 3 | 2 | 2 | 1 | 1 |
| Loss of consciousness | 3 | 4 | | | 3 | 4 |
| Meningism | 1 | 1 | 1 | 1 | | |
| Migraine | 2 | 3 | 1 | 2 | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Polyneuropathy | 1 | 1 | | | 1 | 1 |
| Poor quality sleep | | 1 | | 1 | | |
| Post herpetic neuralgia | 1 | 1 | | | 1 | 1 |
| Presyncope | 7 | 10 | 3 | 4 | 4 | 6 |
| Seizure | | 1 | | | | 1 |
| Somnolence | 12 | 14 | 7 | 9 | 5 | 5 |
| Syncope | 7 | 7 | | | 7 | 7 |
| Taste disorder | 2 | 2 | | | 2 | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 9 | 11 | 6 | 6 | 3 | 5 |
| Trigeminal neuralgia | 1 | 1 | | | 1 | 1 |
| | 235 | 281 | 127 | 160 | 108 | 121 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Liquid product physical issue | 1 | 4 | 1 | 4 |
| | 1 | 4 | 1 | 4 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anxiety | | 1 | | 1 | | |
| Body dysmorphic disorder | 1 | 1 | | | 1 | 1 |
| Confusional state | 5 | 5 | 1 | 1 | 4 | 4 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Dysphoria | | 1 | | | | 1 |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Irritability | 1 | 1 | 1 | 1 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Nervousness | 1 | 1 | | | 1 | 1 |
| Panic reaction | 1 | 1 | | | 1 | 1 |
| Stress | 1 | 1 | 1 | 1 | | |
| Tension | 1 | 1 | 1 | 1 | | |
| | 16 | 18 | 6 | 7 | 10 | 11 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Pollakiuria | 1 | 1 | 1 | 1 | | |
| Polyuria | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 2 | 2 | 1 | 1 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast pain | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory distress syndrome | | 1 | | | | 1 |
| Acute respiratory failure | | 1 | | | | 1 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 8 | 10 | | | 8 | 10 |
| Cough | 16 | 19 | 7 | 7 | 9 | 12 |
| Dry throat | 2 | 4 | | 2 | 2 | 2 |
| Dysphonia | 9 | 12 | 1 | 1 | 8 | 11 |
| Dyspnoea | 19 | 25 | 6 | 8 | 13 | 17 |
| Laryngeal oedema | 3 | 4 | | | 3 | 4 |
| Laryngeal pain | 1 | 1 | | | 1 | 1 |
| Laryngospasm | 4 | 4 | | | 4 | 4 |
| Nasal congestion | | 1 | | 1 | | |
| Nasal pruritus | | 1 | | 1 | | |
| Oropharyngeal discomfort | 2 | 2 | 2 | 2 | | |
| Oropharyngeal pain | 5 | 5 | 2 | 2 | 3 | 3 |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pulmonary thrombosis | 1 | 2 | | | 1 | 2 |
| Rhinitis allergic | | 1 | | 1 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| Tachypnoea | 1 | 2 | 1 | 2 | | |
| Throat irritation | 5 | 8 | 3 | 6 | 2 | 2 |
| Tonsillar hypertrophy | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 1 | 1 | 1 | | |
| | 81 | 109 | 23 | 35 | 58 | 74 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 10 | 12 | | | 10 | 12 |
| Blister | 3 | 4 | 3 | 4 | | |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Erythema | 42 | 44 | 30 | 31 | 12 | 13 |
| Hyperhidrosis | 13 | 16 | 5 | 7 | 8 | 9 |
| Livedo reticularis | 1 | 1 | 1 | 1 | | |
| Mechanical urticaria | 1 | 1 | 1 | 1 | | |
| Pruritus | 41 | 43 | 25 | 26 | 16 | 17 |
| Rash | 40 | 48 | 17 | 23 | 23 | 25 |
| Rash erythematous | 2 | 2 | 2 | 2 | | |
| Rash macular | 1 | 2 | 1 | 2 | | |
| Rash maculo-papular | 3 | 3 | 1 | 1 | 2 | 2 |
| Rash pruritic | 8 | 9 | 4 | 5 | 4 | 4 |
| Skin burning sensation | | 1 | | 1 | | |
| Skin lesion | 1 | 1 | | | 1 | 1 |
| Skin reaction | 1 | 1 | | | 1 | 1 |
| Urticaria | 4 | 4 | 2 | 2 | 2 | 2 |
| | 172 | 193 | 92 | 106 | 80 | 87 |

System Organ Class

Surgical and medical procedures

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Central nervous system stimulation | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure inadequately controlled | | 1 | | 1 | | |
| Capillary disorder | 1 | 1 | 1 | 1 | | |
| Cyanosis | 1 | 2 | 1 | 2 | | |
| Diastolic hypertension | | 1 | | | | 1 |
| Flushing | 16 | 19 | 11 | 12 | 5 | 7 |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hypertension | 18 | 23 | 10 | 14 | 8 | 9 |
| Hypertensive crisis | 6 | 7 | | | 6 | 7 |
| Hypertensive emergency | | 1 | | | | 1 |
| Hypotension | 11 | 12 | 3 | 4 | 8 | 8 |
| Lymphoedema | 1 | 1 | | | 1 | 1 |
| Orthostatic hypotension | 1 | 2 | | 1 | 1 | 1 |
| Pallor | 1 | 1 | 1 | 1 | | |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Shock | 1 | 1 | | | 1 | 1 |
| | 60 | 75 | 28 | 37 | 32 | 38 |

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Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Periorbital oedema | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenia | 1 | 1 | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 |
| Oedema peripheral | 2 | 2 | 2 | 2 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Pain in extremity | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

HUNGARY

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenitis | 2 | 2 | 2 | 2 | | |
| Lymphadenopathy | 16 | 21 | 13 | 17 | 3 | 4 |
| Lymph node pain | 5 | 7 | 4 | 6 | 1 | 1 |
| | 23 | 30 | 19 | 25 | 4 | 5 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Palpitations | 2 | 3 | 1 | 2 | 1 | 1 |
| Pulseless electrical activity | 1 | 1 | | | 1 | 1 |
| Tachycardia | 7 | 7 | 4 | 4 | 3 | 3 |
| | 13 | 14 | 5 | 6 | 8 | 8 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear discomfort | | 1 | | 1 |
| Ear pain | 1 | 2 | 1 | 2 |
| Ear pruritus | 1 | 3 | 1 | 3 |
| Tinnitus | 1 | 2 | 1 | 2 |
| | 3 | 8 | 3 | 8 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eye haemorrhage | 2 | 2 | | | 2 | 2 |
| Eye oedema | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | 1 | 2 | 1 | 2 | | |
| Vision blurred | | 1 | | 1 | | |
| | 4 | 6 | 1 | 3 | 3 | 3 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 2 | 2 | 2 | 2 | | |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 4 | 4 | 4 | 4 | | |
| Dry mouth | | 1 | | | | 1 |
| Dysphagia | 6 | 6 | 2 | 2 | 4 | 4 |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 1 | 3 | 1 | 3 | | |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Nausea | 14 | 20 | 13 | 18 | 1 | 2 |
| Odynophagia | 1 | 1 | 1 | 1 | | |
| Retching | 2 | 2 | 2 | 2 | | |
| Vomiting | 3 | 7 | 3 | 6 | | 1 |
| | 37 | 50 | 31 | 41 | 6 | 9 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 23 | 33 | 20 | 29 | 3 | 4 |
| Axillary pain | | 1 | | 1 | | |
| Chest discomfort | 1 | 2 | 1 | 2 | | |
| Chest pain | 4 | 6 | 4 | 6 | | |
| Chills | 16 | 23 | 16 | 22 | | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Death | 2 | 2 | | | 2 | 2 |
| Drug ineffective | 4 | 7 | | | 4 | 7 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 14 | 19 | 13 | 18 | 1 | 1 |
| Feeling abnormal | 3 | 6 | 3 | 6 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | 1 | 5 | 1 | 4 | | 1 |
| Gait disturbance | | 2 | | 2 | | |
| Illness | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Injection site discomfort | 1 | 1 | 1 | 1 | | |
| Localised oedema | 1 | 1 | 1 | 1 | | |
| Malaise | 12 | 21 | 12 | 19 | | 2 |
| No adverse event | | 1 | | 1 | | |
| Oedema peripheral | | 1 | | | | 1 |
| Pain | 1 | 3 | 1 | 3 | | |
| Peripheral swelling | 2 | 4 | 2 | 4 | | |
| Pyrexia | 32 | 45 | 31 | 42 | 1 | 3 |
| Sensation of foreign body | 2 | 3 | | | 2 | 3 |
| Swelling face | | 2 | | 2 | | |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | |
| Thirst | | 1 | | | | 1 |
| Vaccination site coldness | | 1 | | 1 | | |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site erythema | 3 | 11 | 3 | 11 | | |
| Vaccination site hypoaesthesia | | 1 | | 1 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | | 1 | | 1 | | |
| Vaccination site movement impairment | | 2 | | 2 | | |
| Vaccination site nodule | | 2 | | 2 | | |
| Vaccination site oedema | | 1 | | 1 | | |
| Vaccination site pain | 14 | 25 | 13 | 24 | 1 | 1 |
| Vaccination site pruritus | | 2 | | 2 | | |
| Vaccination site swelling | 4 | 8 | 4 | 8 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| | 147 | 252 | 131 | 223 | 16 | 29 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | | 1 | | | | 1 |
| Anaphylactic reaction | 1 | 2 | | | 1 | 2 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Drug hypersensitivity | 2 | 2 | 2 | 2 | | |
| Hypersensitivity | 4 | 5 | 4 | 5 | | |
| | 8 | 11 | 6 | 7 | 2 | 4 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 6 | 8 | 2 | 2 | 4 | 6 |
| Herpes virus infection | | 1 | | 1 | | |
| Herpes zoster | 4 | 7 | 4 | 7 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Pulpitis dental | 1 | 1 | 1 | 1 | | |
| Sinusitis | 1 | 1 | 1 | 1 | | |
| | 13 | 20 | 8 | 13 | 5 | 7 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cartilage injury | 1 | 1 | | | 1 | 1 |
| Craniofacial fracture | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | 2 | 3 | 2 | 3 | | |
| Fall | 2 | 2 | 1 | 1 | 1 | 1 |
| Incorrect route of product administration | | 1 | | 1 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Muscle strain | 2 | 2 | 2 | 2 | | |
| Off label use | 1 | 3 | 1 | 3 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| | 12 | 16 | 9 | 13 | 3 | 3 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood glucose increased | | 1 | | 1 | | |
| Blood pressure increased | 5 | 8 | 3 | 5 | 2 | 3 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | | 2 | | 2 | | |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 1 | 3 | 1 | 3 | | |
| Oxygen saturation decreased | | 1 | | 1 | | |
| SARS-CoV-2 ant body test positive | 4 | 4 | 4 | 4 | | |
| SARS-CoV-2 test positive | 3 | 4 | 2 | 2 | 1 | 2 |
| | 15 | 25 | 11 | 19 | 4 | 6 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Feeding disorder | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | | 1 | | 1 | | |
| Metabolic acidosis | 1 | 1 | | | 1 | 1 |
| | 4 | 5 | 2 | 3 | 2 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 5 | 7 | 5 | 6 | | 1 |
| Back pain | 1 | 4 | 1 | 4 | | |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Mobility decreased | | 1 | | 1 | | |
| Muscle fatigue | | 1 | | 1 | | |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 2 | 3 | 1 | 2 | 1 | 1 |
| Myalgia | 15 | 23 | 15 | 22 | | 1 |
| Pain in extremity | 14 | 26 | 14 | 26 | | |
| Polyarthritis | 1 | 1 | | | 1 | 1 |
| | 41 | 69 | 39 | 65 | 2 | 4 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Neoplasm progression | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 2 | | 2 | | |
| Anosmia | 2 | 3 | 2 | 3 | | |
| Burning sensation | 3 | 5 | 3 | 5 | | |
| Cervical neuritis | 1 | 1 | 1 | 1 | | |
| Dizziness | 13 | 21 | 10 | 17 | 3 | 4 |
| Dysgeusia | 4 | 5 | 4 | 5 | | |
| Facial paralysis | 3 | 3 | | | 3 | 3 |
| Facial paresis | 2 | 2 | 1 | 1 | 1 | 1 |
| Headache | 24 | 43 | 23 | 39 | 1 | 4 |
| Hyperaesthesia | | 2 | | 2 | | |
| Hypoaesthesia | 3 | 7 | 2 | 6 | 1 | 1 |
| Hypokinesia | 1 | 1 | | | 1 | 1 |
| Lethargy | 2 | 2 | 2 | 2 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Migraine | 2 | 2 | 2 | 2 | | |
| Neuralgia | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 3 | 1 | 2 | | 1 |
| Peripheral nerve paresthesia | 1 | 1 | | | 1 | 1 |
| Poor quality sleep | 1 | 1 | 1 | 1 | | |
| Somnolence | 3 | 5 | 3 | 5 | | |
| Syncope | 2 | 2 | | | 2 | 2 |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 4 | 2 | 3 | | 1 |
| | 74 | 119 | 59 | 98 | 15 | 21 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Anxiety | 1 | 1 | 1 | 1 |
| Confusional state | | 1 | | 1 |
| Depressed mood | 1 | 1 | 1 | 1 |
| Depression | | 1 | | 1 |
| Insomnia | 2 | 2 | 2 | 2 |
| Mood altered | 2 | 2 | 2 | 2 |
| Panic attack | | 1 | | 1 |
| Stress | 1 | 2 | 1 | 2 |
| Tension | 1 | 1 | 1 | 1 |
| | 8 | 12 | 8 | 12 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Micturition urgency | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Nipple pain | 1 | 1 | 1 | 1 |
| Vaginal discharge | | 1 | | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asphyxia | 2 | 2 | | | 2 | 2 |
| Chronic obstructive pulmonary disease | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 6 | 7 | 4 | 4 | 2 | 3 |
| Laryngeal oedema | | 1 | | | | 1 |
| Oropharyngeal pain | 2 | 4 | 2 | 4 | | |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 3 | 3 | 3 | 3 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat irritation | 1 | 2 | 1 | 2 | | |
| | 18 | 23 | 12 | 15 | 6 | 8 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blister | | 1 | | 1 | | |
| Cold sweat | 1 | 2 | 1 | 2 | | |
| Dermatitis allergic | 1 | 1 | 1 | 1 | | |
| Eczema | | 1 | | 1 | | |
| Erythema | 6 | 8 | 6 | 8 | | |
| Hyperhidrosis | 2 | 3 | 2 | 3 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pain of skin | | 1 | | 1 | | |
| Pruritus | 4 | 8 | 3 | 7 | 1 | 1 |
| Rash | 3 | 5 | 2 | 4 | 1 | 1 |
| Rash erythematous | 5 | 5 | 5 | 5 | | |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash maculo-papular | 1 | 2 | 1 | 1 | | 1 |
| Rash pruritic | 3 | 4 | 3 | 4 | | |
| Rash vesicular | | 1 | | 1 | | |
| Sensitive skin | 2 | 2 | 2 | 2 | | |
| Skin burning sensation | 3 | 3 | 2 | 2 | 1 | 1 |
| Skin disorder | 1 | 1 | 1 | 1 | | |
| Skin lesion | | 1 | | 1 | | |
| Urticaria | 2 | 4 | 1 | 3 | 1 | 1 |
| | 36 | 55 | 32 | 50 | 4 | 5 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Flushing | 3 | 3 | 3 | 3 | | |
| Haemorrhage | | 1 | | | | 1 |
| Hyperaemia | 1 | 1 | 1 | 1 | | |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 3 | 1 | 1 | 2 | 2 |
| Lymphoedema | | 1 | | 1 | | |
| Pallor | | 1 | | 1 | | |
| Vasculitis | 1 | 1 | 1 | 1 | | |
| White coat hypertension | 1 | 1 | 1 | 1 | | |
| | 13 | 16 | 7 | 9 | 6 | 7 |

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Country Where Event Occurred

ICELAND

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Bradycardia | | 1 | | | | 1 |
| Cardiac failure | | 2 | | | | 2 |
| Myocardial infarction | | 1 | | | | 1 |
| Tachycardia | 1 | 2 | | 1 | 1 | 1 |
| | 3 | 8 | | 1 | 3 | 7 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear pain | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ocular discomfort | | 1 | | 1 |
| Periorbital swelling | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Anal incontinence | 1 | 1 | 1 | 1 |
| Dry mouth | | 1 | | 1 |
| Gastrointestinal pain | 1 | 1 | 1 | 1 |
| Nausea | 1 | 6 | 1 | 6 |
| Vomiting | | 1 | | 1 |
| | 3 | 10 | 3 | 10 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 3 | 7 | 3 | 7 | | |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 2 | 1 | 2 | | |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 5 | 7 | 5 | 7 | | |
| Death | | 2 | | | | 2 |
| Discomfort | | 1 | | 1 | | |
| Disease progression | | 1 | | | | 1 |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Fatigue | 7 | 14 | 7 | 14 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | | 2 | | 2 | | |
| Malaise | 9 | 16 | 7 | 12 | 2 | 4 |
| Pain | 1 | 2 | 1 | 2 | | |
| Pyrexia | 10 | 25 | 8 | 21 | 2 | 4 |
| Sluggishness | 1 | 1 | 1 | 1 | | |
| Sudden death | | 1 | | | | 1 |
| Swelling | | 1 | | 1 | | |
| Thirst | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 4 | 1 | 4 | | |
| Vaccination site inflammation | 2 | 3 | 2 | 3 | | |
| Vaccination site pain | 8 | 13 | 8 | 13 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 2 | 1 | 2 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| | 56 | 112 | 51 | 99 | 5 | 13 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nasopharyngitis | | 5 | | 5 | | |
| Pneumonia | 2 | 4 | | | 2 | 4 |
| Sepsis | | 1 | | | | 1 |
| | 2 | 10 | | 5 | 2 | 5 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | | 1 | | 1 | | |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 2 | 1 | 2 | | |
| Hepatic enzyme increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| | 7 | 9 | 2 | 4 | 5 | 5 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Fluid overload | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 3 | 4 | 3 | 4 |
| Back pain | | 1 | | 1 |
| Bone pain | | 2 | | 2 |
| Joint stiffness | 1 | 1 | 1 | 1 |
| Joint swelling | 1 | 1 | 1 | 1 |
| Limb discomfort | | 1 | | 1 |
| Muscle twitching | 2 | 2 | 2 | 2 |
| Myalgia | 9 | 12 | 9 | 12 |
| Pain in extremity | 4 | 4 | 4 | 4 |
| | 20 | 28 | 20 | 28 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Dizziness | 4 | 8 | 4 | 8 | | |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Headache | 9 | 22 | 9 | 22 | | |
| Head discomfort | | 1 | | 1 | | |
| Hypoaesthesia | 1 | 5 | 1 | 5 | | |
| Migraine | | 1 | | 1 | | |
| Sensory loss | | 1 | | 1 | | |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | | 1 | | 1 | | |
| | 19 | 44 | 16 | 41 | 3 | 3 |

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System Organ Class

Renal and urinary disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-----------------------|--|--|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urinary incontinence | 1 | 1 | 1 | 1 | | |
| Urine flow decreased | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast inflammation | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 4 | 1 | 3 | | 1 |
| Dry throat | | 1 | | 1 | | |
| Dyspnoea | 1 | 2 | 1 | 2 | | |
| Hypercapnia | 1 | 1 | | | 1 | 1 |
| Hypoxia | 2 | 2 | | | 2 | 2 |
| Lung infiltration | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 3 | 6 | 3 | 6 | | |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pharyngeal swelling | | 1 | | 1 | | |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | 1 | 1 | | |
| Respiration abnormal | | 1 | | | | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | | 2 | | 2 | | |
| | 17 | 29 | 8 | 18 | 9 | 11 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cold sweat | | 1 | | 1 | | |
| Erythema | 2 | 3 | 2 | 3 | | |
| Hyperhidrosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Pruritus | 3 | 4 | 3 | 4 | | |
| Rash | 1 | 1 | 1 | 1 | | |
| Sensitive skin | 2 | 2 | 2 | 2 | | |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| | 11 | 14 | 10 | 13 | 1 | 1 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aortic aneurysm | | 1 | | | | 1 |
| Hot flush | | 1 | | 1 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypoperfusion | 1 | 1 | | | 1 | 1 |
| Pallor | | 1 | | 1 | | |
| Peripheral artery thrombosis | 1 | 1 | | | 1 | 1 |
| | 3 | 6 | 1 | 3 | 2 | 3 |

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Country Where Event Occurred

INDIA

System Organ Class

Product issues

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | |
|-------------|---|
| Nonserious | |
| I | C |
| | 1 |
| | 1 |

Suspected counterfeit product

1

1

1

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

Country Where Event Occurred

IRELAND

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 7 | 8 | | 1 | 7 | 7 |
| Lymph node pain | 4 | 4 | | | 4 | 4 |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| | 12 | 13 | | 1 | 12 | 12 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute cardiac event | 1 | 1 | | | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardiac failure congestive | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Palpitations | 11 | 11 | 1 | 1 | 10 | 10 |
| Supraventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 16 | 16 | | | 16 | 16 |
| | 32 | 32 | 1 | 1 | 31 | 31 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness | | 1 | | | | 1 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Ear pain | 2 | 2 | | | 2 | 2 |
| Tinnitus | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| | 5 | 6 | 1 | 1 | 4 | 5 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blepharospasm | 1 | 1 | | | 1 | 1 |
| Blindness | | 1 | | | | 1 |
| Blindness transient | 1 | 1 | | | 1 | 1 |
| Dry eye | 2 | 2 | | | 2 | 2 |
| Erythema of eyelid | 1 | 1 | | | 1 | 1 |
| Eye discharge | 1 | 1 | | | 1 | 1 |
| Eyelids pruritus | 1 | 1 | | | 1 | 1 |
| Eye movement disorder | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 1 | 1 | | | 1 | 1 |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Lacrimation decreased | 1 | 1 | | | 1 | 1 |
| Periorbital oedema | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 1 | 1 | | | 1 | 1 |
| Swelling of eyelid | 2 | 2 | 1 | 1 | 1 | 1 |
| Vision blurred | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual impairment | | 1 | | | | 1 |
| Vitreous floaters | 2 | 2 | | | 2 | 2 |
| | 20 | 22 | 3 | 3 | 17 | 19 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Abdominal pain upper | 2 | 2 | | | 2 | 2 |
| Cheilitis | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 8 | 8 | 2 | 2 | 6 | 6 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Faeces discoloured | 1 | 1 | | | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Gastric disorder | 1 | 1 | | | 1 | 1 |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haematochezia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 4 | 4 | | | 4 | 4 |
| Lip discolouration | 1 | 1 | | | 1 | 1 |
| Lip swelling | 5 | 5 | | | 5 | 5 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Nausea | 41 | 42 | 7 | 7 | 34 | 35 |
| Pancreatitis relapsing | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 6 | 6 | | | 6 | 6 |
| Retching | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 4 | 4 | | | 4 | 4 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tongue movement disturbance | 1 | 1 | | | 1 | 1 |
| Upper gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vomiting | 16 | 16 | | | 16 | 16 |
| | 105 | 106 | 12 | 12 | 93 | 94 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 27 | 28 | 3 | 4 | 24 | 24 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 8 | 8 | 1 | 1 | 7 | 7 |
| Chest pain | 8 | 8 | | | 8 | 8 |
| Chills | 19 | 19 | 1 | 1 | 18 | 18 |
| Death | 2 | 3 | | | 2 | 3 |
| Discomfort | 5 | 5 | 1 | 1 | 4 | 4 |
| Disease recurrence | 3 | 3 | | | 3 | 3 |
| Drug ineffective | 5 | 5 | | | 5 | 5 |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Fatigue | 41 | 43 | 4 | 6 | 37 | 37 |
| Feeling abnormal | 8 | 8 | 2 | 2 | 6 | 6 |
| Feeling cold | 7 | 7 | 2 | 2 | 5 | 5 |
| Feeling drunk | 2 | 2 | | | 2 | 2 |
| Feeling hot | 12 | 12 | 1 | 1 | 11 | 11 |
| Feeling of body temperature change | 2 | 2 | | | 2 | 2 |
| Gait disturbance | 2 | 2 | | | 2 | 2 |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Inflammation | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 6 | 6 | 2 | 2 | 4 | 4 |
| Injected limb mobility decreased | | 1 | | | | 1 |
| Malaise | 22 | 23 | 3 | 3 | 19 | 20 |
| No adverse event | 1 | 5 | 1 | 5 | | |
| Pain | 19 | 20 | 2 | 2 | 17 | 18 |
| Peripheral swelling | 2 | 2 | | | 2 | 2 |
| Pyrexia | 29 | 31 | 2 | 3 | 27 | 28 |
| Sensation of foreign body | 2 | 2 | | | 2 | 2 |
| Sudden death | 1 | 2 | | | 1 | 2 |
| Swelling | 4 | 4 | | | 4 | 4 |
| Swelling face | 3 | 3 | 1 | 1 | 2 | 2 |
| Tenderness | 1 | 1 | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thirst | 1 | 1 | | | 1 | 1 |
| Vaccination site bruising | 1 | 1 | | | 1 | 1 |
| Vaccination site discolouration | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 2 | | | 2 | 2 |
| Vaccination site irritation | 1 | 1 | | | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 9 | 9 | 2 | 2 | 7 | 7 |
| Vaccination site pruritus | 3 | 3 | | | 3 | 3 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| | 268 | 282 | 29 | 37 | 239 | 245 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Allergy to vaccine | 2 | 2 | 2 | 2 |
| Anaphylactic reaction | 5 | 5 | 5 | 5 |
| Anaphylactic shock | 1 | 1 | 1 | 1 |
| Hypersensitivity | 3 | 3 | 3 | 3 |
| | 11 | 11 | 11 | 11 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 5 | 5 | | | 5 | 5 |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | | | 1 | 1 |
| Herpes zoster reactivation | 1 | 1 | | | 1 | 1 |
| Mastitis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | | | 1 | 1 |
| Sinusitis | 1 | 1 | | | 1 | 1 |
| Suspected COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| | 15 | 15 | 1 | 1 | 14 | 14 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Contusion | 1 | 1 | 1 | 1 | | |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | 2 | 2 | 1 | 1 | 1 | 1 |
| Face injury | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect dose administered | | 5 | | 5 | | |
| Maternal exposure during breast feeding | 1 | 1 | 1 | 1 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Nerve injury | 1 | 1 | | | 1 | 1 |
| Off label use | 3 | 3 | 3 | 3 | | |
| Product preparation issue | 1 | 6 | 1 | 6 | | |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Road traffic accident | 1 | 1 | | | 1 | 1 |
| | 16 | 26 | 12 | 22 | 4 | 4 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 |
| Blood pressure diastolic increased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 3 | 3 | | | 3 | 3 |
| Blood pressure systolic increased | 1 | 1 | 1 | 1 | | |
| Body temperature abnormal | 1 | 1 | | | 1 | 1 |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 2 | 2 | | | 2 | 2 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 2 | 3 | | | 2 | 3 |
| Oxygen saturation decreased | 5 | 5 | | | 5 | 5 |
| Platelet count decreased | 1 | 1 | | | 1 | 1 |
| Pulse abnormal | 1 | 1 | | | 1 | 1 |
| Quality of life decreased | 1 | 1 | | | 1 | 1 |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| | 24 | 25 | 1 | 1 | 23 | 24 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Decreased appetite | 3 | 3 | 3 | 3 |
| Hypoglycaemia | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 19 | 19 | 3 | 3 | 16 | 16 |
| Back pain | 5 | 5 | | | 5 | 5 |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Flank pain | 2 | 2 | | | 2 | 2 |
| Joint stiffness | 2 | 2 | | | 2 | 2 |
| Joint swelling | 1 | 1 | | | 1 | 1 |
| Limb discomfort | 4 | 4 | 1 | 1 | 3 | 3 |
| Mobility decreased | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscle tightness | 1 | 1 | | | 1 | 1 |
| Muscle twitching | 3 | 3 | | | 3 | 3 |
| Muscular weakness | 3 | 3 | | | 3 | 3 |
| Musculoskeletal chest pain | 1 | 1 | | | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 17 | 17 | 2 | 2 | 15 | 15 |
| Myokymia | 1 | 1 | | | 1 | 1 |
| Neck pain | 4 | 4 | | | 4 | 4 |
| Pain in extremity | 18 | 18 | 3 | 3 | 15 | 15 |
| Periarthritis | | 1 | | | | 1 |
| | 88 | 89 | 11 | 11 | 77 | 78 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 4 | 4 | 1 | 1 | 3 | 3 |
| Anosmia | 2 | 2 | 1 | 1 | 1 | 1 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Burning sensation | 6 | 6 | 1 | 1 | 5 | 5 |
| Depressed level of consciousness | | 1 | | | | 1 |
| Disturbance in attention | 3 | 3 | 1 | 1 | 2 | 2 |
| Dizziness | 34 | 35 | 4 | 4 | 30 | 31 |
| Dysarthria | 3 | 3 | | | 3 | 3 |
| Dysgeusia | 2 | 2 | | | 2 | 2 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 9 | 9 | | | 9 | 9 |
| Headache | 57 | 60 | 7 | 9 | 50 | 51 |
| Hyperaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 13 | 13 | 2 | 2 | 11 | 11 |
| Hypotonia | 1 | 1 | | | 1 | 1 |
| IVth nerve paralysis | 1 | 2 | | | 1 | 2 |
| Lethargy | 7 | 7 | 1 | 1 | 6 | 6 |
| Loss of consciousness | 4 | 4 | | | 4 | 4 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Myelitis transverse | 1 | 1 | | | 1 | 1 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 26 | 26 | 3 | 3 | 23 | 23 |
| Poor quality sleep | 1 | 1 | 1 | 1 | | |
| Presyncope | 3 | 3 | 1 | 1 | 2 | 2 |
| Psychomotor hyperactivity | 1 | 1 | | | 1 | 1 |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Somnolence | 3 | 3 | | | 3 | 3 |
| Syncope | 5 | 7 | | | 5 | 7 |
| Tardive dyskinesia | 1 | 1 | | | 1 | 1 |
| Tension headache | 1 | 1 | | | 1 | 1 |
| Tremor | 5 | 5 | 1 | 1 | 4 | 4 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Trigeminal nerve disorder | 1 | 1 | | | 1 | 1 |
| Trigeminal neuralgia | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| | 203 | 211 | 25 | 27 | 178 | 184 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Suspected product quality issue | | 5 | | 5 |
| | | 5 | | 5 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anxiety | 2 | 2 | | | 2 | 2 |
| Confusional state | 4 | 4 | | | 4 | 4 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Emotional distress | 2 | 2 | | | 2 | 2 |
| Insomnia | 8 | 8 | 1 | 1 | 7 | 7 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Panic attack | 2 | 2 | | | 2 | 2 |
| Stress | 1 | 1 | 1 | 1 | | |
| | 22 | 22 | 3 | 3 | 19 | 19 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Menstrual disorder | 1 | 1 | 1 | 1 |
| Metrorrhagia | 1 | 1 | 1 | 1 |
| Vaginal haemorrhage | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma | 2 | 2 | | | 2 | 2 |
| Choking sensation | 1 | 1 | 1 | 1 | | |
| Cough | 6 | 6 | | | 6 | 6 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 15 | 16 | 2 | 2 | 13 | 14 |
| Dyspnoea at rest | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 5 | 5 | 1 | 1 | 4 | 4 |
| Paranasal sinus discomfort | 1 | 1 | | | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 2 | | | 2 | 2 |
| Pharyngeal swelling | 2 | 2 | | | 2 | 2 |
| Rales | 1 | 1 | | | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Throat tightness | 4 | 4 | 1 | 1 | 3 | 3 |
| Wheezing | 5 | 5 | | | 5 | 5 |
| | 50 | 51 | 5 | 5 | 45 | 46 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Cold sweat | 2 | 3 | | | 2 | 3 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Erythema | 5 | 5 | 2 | 2 | 3 | 3 |
| Hyperhidrosis | 13 | 13 | 1 | 1 | 12 | 12 |
| Night sweats | 2 | 2 | 1 | 1 | 1 | 1 |
| Pruritus | 13 | 13 | 2 | 2 | 11 | 11 |
| Rash | 11 | 11 | 2 | 2 | 9 | 9 |
| Rash erythematous | 6 | 6 | 1 | 1 | 5 | 5 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Skin tightness | 1 | 1 | | | 1 | 1 |
| Urticaria | 10 | 10 | 1 | 1 | 9 | 9 |
| Urticarial vasculitis | 1 | 1 | | | 1 | 1 |
| Urticaria papular | 1 | 1 | 1 | 1 | | |
| | 70 | 71 | 12 | 12 | 58 | 59 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Impaired driving ability | 2 | 2 | 2 | 2 |
| Impaired work ability | 5 | 5 | 5 | 5 |
| Loss of personal independence in daily activities | 2 | 2 | 2 | 2 |
| | 9 | 9 | 9 | 9 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cyanosis | | 1 | | 1 | | |
| Flushing | 5 | 5 | | | 5 | 5 |
| Hypertension | 11 | 11 | | | 11 | 11 |
| Hypotension | 4 | 4 | | | 4 | 4 |
| Pallor | 4 | 4 | 1 | 1 | 3 | 3 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| | 25 | 26 | 1 | 2 | 24 | 24 |

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Country Where Event Occurred

ISRAEL

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autoimmune haemolytic anaemia | 1 | 1 | | | 1 | 1 |
| Haemolytic anaemia | | 1 | | | | 1 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 2 | | | 1 | 2 |
| Lymphadenopathy | 2 | 7 | 2 | 7 | | |
| Lymphocytosis | | 1 | | 1 | | |
| Lymphopenia | | 1 | | | | 1 |
| | 5 | 14 | 2 | 8 | 3 | 6 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | | 1 | | | | 1 |
| Angina pectoris | 2 | 3 | | | 2 | 3 |
| Arrhythmia | 2 | 4 | | | 2 | 4 |
| Atrial fibrillation | 2 | 4 | | | 2 | 4 |
| Cardiac arrest | 1 | 7 | | | 1 | 7 |
| Cardiac disorder | | 2 | | | | 2 |
| Cardiac failure | 1 | 2 | | | 1 | 2 |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | | 2 | | | | 2 |
| Myocarditis | 3 | 3 | | | 3 | 3 |
| Palpitations | 1 | 9 | 1 | 9 | | |
| Pericarditis | 2 | 4 | | | 2 | 4 |
| Sinus tachycardia | | 1 | | 1 | | |
| Tachycardia | 2 | 6 | 2 | 5 | | 1 |
| | 17 | 49 | 3 | 15 | 14 | 34 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear discomfort | 1 | 3 | 1 | 3 | | |
| Ear pain | 2 | 5 | 2 | 5 | | |
| Tinnitus | | 1 | | 1 | | |
| Vertigo | | 1 | | | | 1 |
| | 3 | 10 | 3 | 9 | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenopia | 1 | 1 | 1 | 1 | | |
| Dyschromatopsia | 1 | 1 | 1 | 1 | | |
| Eye haemorrhage | | 1 | | | | 1 |
| Eye irritation | | 2 | | 1 | | 1 |
| Eye pain | 3 | 5 | 2 | 2 | 1 | 3 |
| Eye swelling | 1 | 2 | | 1 | 1 | 1 |
| Lacrimation increased | | 2 | | 1 | | 1 |
| Photopsia | | 1 | | 1 | | |
| Uveitis | 1 | 1 | | | 1 | 1 |
| Vision blurred | 2 | 5 | 2 | 5 | | |
| | 9 | 21 | 6 | 13 | 3 | 8 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 4 | 1 | 4 | | |
| Abdominal pain upper | 1 | 2 | 1 | 2 | | |
| Anaesthesia oral | | 1 | | 1 | | |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 3 | 10 | 3 | 9 | | 1 |
| Dry mouth | | 1 | | 1 | | |
| Dyspepsia | 1 | 6 | 1 | 6 | | |
| Dysphagia | | 5 | | 4 | | 1 |
| Eosinophilic oesophagitis | | 1 | | 1 | | |
| Gastric haemorrhage | 1 | 1 | | | 1 | 1 |
| Gastrointestinal necrosis | 1 | 1 | | | 1 | 1 |
| Gingival pain | | 1 | | 1 | | |
| Hypoaesthesia oral | | 8 | | 7 | | 1 |
| Hypoaesthesia teeth | | 1 | | 1 | | |
| Lip disorder | | 1 | | 1 | | |
| Lip pruritus | | 2 | | 2 | | |
| Lip swelling | | 2 | | 1 | | 1 |
| Nausea | 11 | 35 | 10 | 31 | 1 | 4 |
| Odynophagia | | 2 | | 2 | | |
| Oral discomfort | 1 | 1 | 1 | 1 | | |
| Oral pain | 1 | 1 | 1 | 1 | | |
| Pancreatitis | | 1 | | | | 1 |
| Paraesthesia oral | 2 | 13 | 1 | 11 | 1 | 2 |
| Swollen tongue | | 4 | | | | 4 |
| Tongue discomfort | | 1 | | 1 | | |
| Toothache | | 2 | | 2 | | |
| Vomiting | 2 | 12 | 2 | 10 | | 2 |
| | 26 | 120 | 22 | 101 | 4 | 19 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Adverse event | | 1 |
| Application site hypersensitivity | | 1 |
| Asthenia | 26 | 86 |
| Chest discomfort | | 1 |
| Chest pain | 4 | 7 |
| Chills | 21 | 46 |
| Condition aggravated | 2 | 3 |
| Crying | | 1 |
| Death | 1 | 6 |
| Disease recurrence | 2 | 4 |
| Drug ineffective | 15 | 30 |
| Facial pain | 1 | 1 |
| Fatigue | 21 | 53 |
| Feeling abnormal | 3 | 13 |
| Feeling cold | 5 | 12 |
| Feeling hot | | 5 |
| Feeling of body temperature change | | 1 |
| Gait disturbance | 1 | 3 |
| General physical health deterioration | 1 | 1 |
| Hangover | | 1 |
| Illness | 1 | 2 |
| Inflammation | 1 | 1 |
| Influenza like illness | 3 | 11 |
| Injection site erythema | | 1 |
| Injection site inflammation | | 1 |
| Injection site pain | 1 | 4 |
| Malaise | 5 | 24 |
| No adverse event | 2 | 2 |
| Oedema | 1 | 1 |
| Pain | 8 | 20 |
| Peripheral swelling | | 2 |
| Pyrexia | 27 | 65 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 1 | | |
| | | 23 | 81 | 3 | 5 |
| | | | 1 | | |
| | | 4 | 6 | | 1 |
| | | 21 | 45 | | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 6 |
| | | 2 | 3 | | 1 |
| | 1 | 1 | 1 | 14 | 29 |
| | | 1 | 1 | | |
| | | 20 | 51 | 1 | 2 |
| | | 3 | 10 | | 3 |
| | | 5 | 12 | | |
| | | | 5 | | |
| | | | 1 | | |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 3 | 11 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | 5 | 20 | | 4 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 6 | 18 | 2 | 2 |
| | | | 1 | | 1 |
| | | 23 | 58 | 4 | 7 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Sudden cardiac death | | 1 | | | | | | 1 |
| Sudden death | 1 | 1 | | | | | 1 | 1 |
| Swelling | 2 | 2 | | | 2 | 2 | | |
| Swelling face | | 2 | | | | 2 | | |
| Systemic inflammatory response syndrome | | 1 | | | | | | 1 |
| Tenderness | | 1 | | | | 1 | | |
| Therapeutic response unexpected | | 2 | | | | 2 | | |
| Vaccination site bruising | | 1 | | | | 1 | | |
| Vaccination site erythema | 3 | 8 | | | 3 | 8 | | |
| Vaccination site hypersensitivity | | 1 | | | | 1 | | |
| Vaccination site joint movement impairment | | 1 | | | | 1 | | |
| Vaccination site lymphadenopathy | 2 | 2 | | | 2 | 2 | | |
| Vaccination site movement impairment | | 2 | | | | 2 | | |
| Vaccination site pain | 12 | 71 | | | 12 | 71 | | |
| Vaccination site pruritus | | 1 | | | | 1 | | |
| Vaccination site reaction | | 1 | | | | 1 | | |
| Vaccination site swelling | 1 | 9 | | | 1 | 9 | | |
| | 173 | 517 | | 1 | 142 | 445 | 31 | 72 |

System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hepatitis | | 1 | | | | 1 |
| Hepatitis acute | 1 | 1 | | | 1 | 1 |
| Jaundice | | 1 | | 1 | | |
| | 1 | 3 | | 1 | 1 | 2 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | | 3 | | 1 | | 2 |
| Anaphylactic reaction | 2 | 5 | | | 2 | 5 |
| Anaphylactic shock | | 1 | | | | 1 |
| Drug hypersensitivity | 1 | 2 | 1 | 1 | | 1 |
| Hypersensitivity | 2 | 6 | | 1 | 2 | 5 |
| | 5 | 17 | 1 | 3 | 4 | 14 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Coronavirus infection | 1 | 2 | | | 1 | 1 | | 1 |
| COVID-19 | 16 | 22 | | 1 | 1 | 1 | 15 | 21 |
| Endocarditis | 1 | 1 | | | | | 1 | 1 |
| Eye infection | 1 | 2 | | | | 1 | 1 | 1 |
| Gastroenteritis viral | | 1 | | | | 1 | | |
| Herpes zoster | 9 | 10 | | | 9 | 10 | | |
| Infection | | 1 | | | | 1 | | |
| Influenza | 1 | 3 | | | 1 | 3 | | |
| Nasopharyngitis | 3 | 5 | | | 3 | 5 | | |
| Oral herpes | 2 | 5 | | | 1 | 3 | 1 | 2 |
| Otitis media | | 1 | | | | 1 | | |
| Pneumonia | 3 | 3 | | | | | 3 | 3 |
| Pulpitis dental | | 1 | | | | 1 | | |
| Sepsis | | 1 | | | | | | 1 |
| Suspected COVID-19 | | 1 | | | | | | 1 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 | | |
| Vaccination site cellulitis | 1 | 2 | | | | 1 | 1 | 1 |
| | 39 | 62 | | 1 | 17 | 30 | 22 | 32 |

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* AE=Adverse Event

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Cartilage injury | 1 | 1 | | | | | 1 | 1 |
| Contusion | | 1 | | | | | | 1 |
| Exposure during pregnancy | | 1 | | | | 1 | | |
| Exposure to SARS-CoV-2 | | | | 1 | | | | |
| Exposure via breast milk | 1 | 5 | | | 1 | 5 | | |
| Fall | 1 | 4 | | | | 1 | 1 | 3 |
| Head injury | | 1 | | | | | | 1 |
| Hip fracture | | 1 | | | | | | 1 |
| Inappropriate schedule of product administration | 1 | 6 | | | 1 | 6 | | |
| Incomplete course of vaccination | | 1 | | | | 1 | | |
| Intentional dose omission | | 1 | | | | 1 | | |
| Maternal exposure during pregnancy | 4 | 4 | | | 4 | 4 | | |
| Off label use | 4 | 6 | | | 4 | 6 | | |
| Overdose | | 4 | | | | 4 | | |
| Pelvic fracture | | 1 | | | | | | 1 |
| Poor quality product administered | 1 | 30 | | | 1 | 30 | | |
| Product administered to patient of inappropriate age | 1 | 1 | | | 1 | 1 | | |
| Product preparation error | | 4 | | | | 4 | | |
| Product preparation issue | | 1 | | | | 1 | | |
| Product use issue | 2 | 4 | | | 2 | 4 | | |
| Rib fracture | | 1 | | | | | | 1 |
| Tooth injury | | 1 | | | | 1 | | |
| Underdose | | 3 | | | | 3 | | |
| Vaccination failure | 1 | 1 | | | | | 1 | 1 |
| Wrong technique in product usage process | | 2 | | | | 2 | | |
| | 17 | 85 | | 1 | 14 | 75 | 3 | 10 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Antibody test abnormal | | 1 | | 1 | | |
| Blood chloride increased | | 2 | | 1 | | 1 |
| Blood glucose increased | | 3 | | 1 | | 2 |
| Blood pressure decreased | | 1 | | 1 | | |
| Blood pressure increased | 2 | 11 | 2 | 6 | | 5 |
| Blood pressure systolic increased | | 1 | | 1 | | |
| Body temperature decreased | 2 | 3 | 2 | 3 | | |
| Coronavirus test positive | | 1 | | | | 1 |
| C-reactive protein increased | | 1 | | 1 | | |
| Glomerular filtration rate decreased | | 1 | | | | 1 |
| Heart rate increased | 2 | 10 | 1 | 9 | 1 | 1 |
| Inflammatory marker increased | | 1 | | | | 1 |
| International normalised ratio increased | | 1 | | | | 1 |
| Lymphocyte count increased | | 1 | | 1 | | |
| Mean cell haemoglobin concentration decreased | | 1 | | 1 | | |
| Mean cell haemoglobin decreased | | 3 | | 2 | | 1 |
| Mean cell volume decreased | | 1 | | 1 | | |
| Mean platelet volume increased | | 1 | | 1 | | |
| Neutrophil count increased | | 1 | | | | 1 |
| Oxygen saturation decreased | | 2 | | 1 | | 1 |
| Pulse abnormal | | 1 | | | | 1 |
| Red blood cell count increased | | 1 | | 1 | | |
| Respiratory rate increased | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 3 | 3 | 3 | 3 | | |
| SARS-CoV-2 test positive | 1 | 7 | 1 | 1 | | 6 |
| Weight decreased | | 2 | | 1 | | 1 |
| | 10 | 62 | 9 | 37 | 1 | 25 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alcohol intolerance | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 1 | 5 | 1 | 4 | | 1 |
| Food craving | | 1 | | 1 | | |
| Food refusal | 1 | 1 | | | 1 | 1 |
| | 3 | 8 | 2 | 6 | 1 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 15 | 26 | 12 | 21 | 3 | 5 |
| Arthritis reactive | 1 | 1 | | | 1 | 1 |
| Arthropathy | | 1 | | 1 | | |
| Back pain | 5 | 12 | 4 | 11 | 1 | 1 |
| Bone pain | 2 | 3 | 2 | 3 | | |
| Facial asymmetry | | 1 | | 1 | | |
| Joint noise | 1 | 1 | 1 | 1 | | |
| Joint swelling | 1 | 2 | | 1 | 1 | 1 |
| Limb discomfort | | 2 | | 2 | | |
| Mobility decreased | 2 | 3 | 1 | 1 | 1 | 2 |
| Muscle rigidity | 1 | 1 | 1 | 1 | | |
| Muscle twitching | | 1 | | 1 | | |
| Muscular weakness | 3 | 4 | 2 | 3 | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 16 | 48 | 15 | 45 | 1 | 3 |
| Neck pain | 3 | 6 | 3 | 6 | | |
| Pain in extremity | 14 | 44 | 14 | 44 | | |
| Pain in jaw | | 3 | | 3 | | |
| Torticollis | | 1 | | | | 1 |
| | 65 | 161 | 56 | 146 | 9 | 15 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 2 | 1 | 2 | | |
| Anosmia | 1 | 3 | 1 | 3 | | |
| Balance disorder | | 1 | | 1 | | |
| Brain injury | 1 | 1 | | | 1 | 1 |
| Cerebellar haemorrhage | | 1 | | | | 1 |
| Cerebral ischaemia | | 1 | | | | 1 |
| Cerebrovascular accident | | 3 | | | | 3 |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | | 1 | | | | 1 |
| Dizziness | 8 | 36 | 6 | 29 | 2 | 7 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 9 | 1 | 9 | | |
| Dyskinesia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dysstasia | 1 | 2 | 1 | 1 | | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 8 | 20 | | | 8 | 20 |
| Formication | 1 | 3 | 1 | 3 | | |
| Headache | 32 | 79 | 30 | 73 | 2 | 6 |
| Head discomfort | 1 | 4 | 1 | 3 | | 1 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 2 | 27 | 1 | 24 | 1 | 3 |
| Ischaemic stroke | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 3 | 6 | | | 3 | 6 |
| Migraine | 1 | 2 | 1 | 2 | | |
| Motor dysfunction | | 1 | | | | 1 |
| Movement disorder | | 2 | | 1 | | 1 |
| Multiple sclerosis | | 1 | | | | 1 |
| Multiple sclerosis relapse | | 3 | | | | 3 |
| Muscle contractions involuntary | 2 | 4 | 2 | 4 | | |
| Myasthenia gravis | 1 | 1 | | | 1 | 1 |
| Neuralgia | | 1 | | 1 | | |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neuralgic amyotrophy | | 2 | | 2 | | |
| Neuritis | | 1 | | 1 | | |
| Paraesthesia | 5 | 26 | 3 | 23 | 2 | 3 |
| Paralysis | 2 | 3 | | | 2 | 3 |
| Paraplegia | | 1 | | | | 1 |
| Parosmia | 1 | 3 | 1 | 3 | | |
| Poor quality sleep | | 1 | | 1 | | |
| Presyncope | 1 | 2 | 1 | 2 | | |
| Psychomotor hyperactivity | 1 | 1 | 1 | 1 | | |
| Reduced facial expression | | 1 | | 1 | | |
| Seizure | 9 | 9 | | | 9 | 9 |
| Sensory disturbance | 1 | 3 | | 2 | 1 | 1 |
| Sensory loss | | 1 | | 1 | | |
| Somnolence | 1 | 2 | 1 | 2 | | |
| Speech disorder | 2 | 4 | 1 | 3 | 1 | 1 |
| Syncope | | 7 | | | | 7 |
| Taste disorder | | 2 | | 2 | | |
| Tremor | 1 | 5 | 1 | 5 | | |
| | 96 | 296 | 57 | 207 | 39 | 89 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortion spontaneous | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Liquid product physical issue | 1 | 15 | 1 | 15 |
| Product complaint | | 1 | | 1 |
| Product deposit | | 1 | | 1 |
| Product packaging quantity issue | | 12 | | 12 |
| | 1 | 29 | 1 | 29 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 1 | 1 | 1 | 1 | | |
| Anger | | 1 | | 1 | | |
| Anxiety | 1 | 2 | 1 | 2 | | |
| Confusional state | 1 | 2 | | 1 | 1 | 1 |
| Depressed mood | 2 | 3 | 1 | 2 | 1 | 1 |
| Depression | 1 | 2 | | 1 | 1 | 1 |
| Hallucination | 1 | 1 | | | 1 | 1 |
| Initial insomnia | | 1 | | 1 | | |
| Insomnia | 3 | 5 | 3 | 5 | | |
| Loss of libido | 1 | 1 | 1 | 1 | | |
| Mental disorder | 1 | 1 | 1 | 1 | | |
| Mood altered | 1 | 1 | 1 | 1 | | |
| Personality change | | 1 | | 1 | | |
| Restlessness | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Sleep disorder due to general medical condition, insomnia type | | 1 | | 1 | | |
| Stress | | 1 | | 1 | | |
| Suicidal ideation | 1 | 1 | | | 1 | 1 |
| Thinking abnormal | 1 | 1 | 1 | 1 | | |
| Tic | | 1 | | 1 | | |
| | 17 | 29 | 11 | 23 | 6 | 6 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast inflammation | 1 | 1 | 1 | 1 |
| Dysmenorrhoea | 1 | 1 | 1 | 1 |
| Menorrhagia | 1 | 1 | 1 | 1 |
| Menstrual disorder | 1 | 1 | 1 | 1 |
| Pelvic pain | | 1 | | 1 |
| Vaginal haemorrhage | 2 | 2 | 2 | 2 |
| | 6 | 7 | 6 | 7 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphonia | | 1 | | | | 1 |
| Aspiration | 1 | 1 | | | 1 | 1 |
| Asthma | 1 | 2 | | 1 | 1 | 1 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Choking | | 2 | | | | 2 |
| Cough | 2 | 8 | 2 | 8 | | |
| Dyspnoea | 9 | 24 | 4 | 11 | 5 | 13 |
| Dyspnoea exertional | 2 | 3 | 2 | 3 | | |
| Hypoventilation | | 1 | | | | 1 |
| Lung disorder | | 1 | | 1 | | |
| Oropharyngeal discomfort | | 1 | | 1 | | |
| Oropharyngeal pain | 1 | 9 | 1 | 9 | | |
| Pharyngeal paraesthesia | | 1 | | 1 | | |
| Pharyngeal swelling | 1 | 3 | | 2 | 1 | 1 |
| Pleural effusion | | 1 | | | | 1 |
| Pleuritic pain | | 1 | | | | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | 1 | 2 | | | 1 | 2 |
| Respiratory distress | | 1 | | | | 1 |
| Rhinalgia | | 1 | | 1 | | |
| Rhinorrhoea | | 3 | | 3 | | |
| Sneezing | | 2 | | 2 | | |
| Suffocation feeling | | 1 | | 1 | | |
| Throat tightness | | 1 | | | | 1 |
| Tracheal oedema | 1 | 1 | | | 1 | 1 |
| Wheezing | | 1 | | | | 1 |
| Yawning | | 1 | | 1 | | |
| | 21 | 75 | 9 | 45 | 12 | 30 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alopecia | | 1 | | 1 | | |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Cold sweat | | 1 | | 1 | | |
| Erythema | 2 | 8 | 1 | 7 | 1 | 1 |
| Hyperhidrosis | 2 | 5 | 2 | 5 | | |
| Mechanical urticaria | 1 | 1 | 1 | 1 | | |
| Miliaria | | 1 | | 1 | | |
| Palmar erythema | | 1 | | 1 | | |
| Pruritus | | 3 | | 2 | | 1 |
| Rash | 1 | 11 | 1 | 8 | | 3 |
| Rash macular | | 1 | | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| Skin burning sensation | | 2 | | 2 | | |
| Skin disorder | | 1 | | 1 | | |
| Urticaria | 1 | 7 | 1 | 4 | | 3 |
| | 8 | 45 | 6 | 36 | 2 | 9 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Impaired quality of life | | 1 | | 1 |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circulatory collapse | | 1 | | | | 1 |
| Hypertension | 1 | 6 | 1 | 2 | | 4 |
| Hypotension | | 2 | | 1 | | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Thrombosis | | 3 | | | | 3 |
| | 2 | 13 | 2 | 4 | | 9 |

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Country Where Event Occurred

ITALY

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemia | 2 | 2 | 2 | 2 | | |
| Coagulopathy | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 11 | 13 | 3 | 5 | 8 | 8 |
| Lymphadenopathy | 137 | 172 | 43 | 75 | 94 | 97 |
| Lymph node pain | 15 | 20 | 6 | 11 | 9 | 9 |
| Lymphocytosis | 1 | 1 | 1 | 1 | | |
| Lymphopenia | 1 | 1 | | | 1 | 1 |
| Thrombocytopenia | 2 | 2 | | | 2 | 2 |
| | 170 | 212 | 55 | 94 | 115 | 118 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|-----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Acute coronary syndrome | | 3 | | | | | | | 3 |
| Acute myocardial infarction | | 2 | | | | | | | 2 |
| Angina pectoris | 3 | 3 | | | | | 3 | | 3 |
| Arrhythmia | 8 | 8 | | | | | 8 | | 8 |
| Atrial fibrillation | 4 | 4 | | | | | 4 | | 4 |
| Atrial tachycardia | 1 | 1 | | | 1 | 1 | | | |
| Atrioventricular block complete | | 1 | | | | | | | 1 |
| Bradycardia | 8 | 10 | 1 | 1 | | | 8 | | 10 |
| Cardiac arrest | 3 | 3 | | | | | 3 | | 3 |
| Cardiac failure | 1 | 2 | | | | | 1 | | 2 |
| Coronary artery disease | 1 | 1 | | | | | 1 | | 1 |
| Extrasystoles | 6 | 6 | | | 5 | 5 | 1 | | 1 |
| Myocardial infarction | | 1 | | | | | | | 1 |
| Myocardial ischaemia | | 1 | | | | | | | 1 |
| Myocarditis | 2 | 2 | | | | | 2 | | 2 |
| Palpitations | 11 | 14 | | | 5 | 8 | 6 | | 6 |
| Pericardial effusion | 1 | 1 | | | | | 1 | | 1 |
| Pericarditis | 4 | 4 | | | | | 4 | | 4 |
| Sinus bradycardia | 1 | 1 | | | 1 | 1 | | | |
| Sinus tachycardia | 4 | 7 | | | | 2 | 4 | | 5 |
| Supraventricular tachycardia | 1 | 1 | | | 1 | 1 | | | |
| Tachyarrhythmia | 1 | 1 | | | 1 | 1 | | | |
| Tachycardia | 98 | 126 | 3 | 3 | 19 | 41 | 79 | | 85 |
| Tachycardia paroxysmal | 1 | 3 | | | | 1 | 1 | | 2 |
| Ventricular extrasystoles | 3 | 3 | | | 1 | 1 | 2 | | 2 |
| Ventricular tachycardia | 1 | 1 | | | | | 1 | | 1 |
| Wandering pacemaker | 1 | 1 | | | | | 1 | | 1 |
| | 164 | 211 | 4 | 4 | 34 | 62 | 130 | | 149 |

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System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Macroglossia | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Deafness | 2 | 2 | | | | | 2 | 2 |
| Deafness bilateral | | 1 | | | | | | 1 |
| Deafness neurosensory | 2 | 2 | | | | | 2 | 2 |
| Ear discomfort | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Ear pain | 12 | 13 | | | 5 | 6 | 7 | 7 |
| Ear pruritus | 3 | 4 | | | 3 | 4 | | |
| Ear swelling | 1 | 1 | | | 1 | 1 | | |
| Hypoacusis | 2 | 2 | | | | | 2 | 2 |
| Tinnitus | 9 | 9 | | | 3 | 3 | 6 | 6 |
| Vertigo | 66 | 90 | 1 | 1 | 25 | 47 | 41 | 43 |
| Vertigo positional | 1 | 1 | | | | | 1 | 1 |
| | 101 | 128 | 1 | 1 | 39 | 63 | 62 | 65 |

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System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autoimmune thyroiditis | 1 | 1 | | | 1 | 1 |
| Basedow's disease | 1 | 1 | | | 1 | 1 |
| Goitre | 1 | 1 | | | 1 | 1 |
| Thyroid disorder | 1 | 1 | 1 | 1 | | |
| Thyroid pain | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 1 | 1 | 4 | 4 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Accommodation disorder | 1 | 1 | | | | | 1 | 1 |
| Asthenopia | 3 | 4 | | | 3 | 4 | | |
| Blepharospasm | 1 | 1 | | | | | 1 | 1 |
| Blindness | 3 | 3 | | | | | 3 | 3 |
| Conjunctival haemorrhage | 3 | 3 | | | | | 3 | 3 |
| Conjunctival hyperaemia | 2 | 2 | | | | | 2 | 2 |
| Conjunctival irritation | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Corneal bleeding | | 1 | | | | | | 1 |
| Diplopia | 7 | 7 | | | 2 | 2 | 5 | 5 |
| Dry eye | 1 | 1 | | | 1 | 1 | | |
| Episcleritis | 1 | 1 | | | | | 1 | 1 |
| Erythema of eyelid | 1 | 1 | | | | | 1 | 1 |
| Eye colour change | 1 | 1 | | | | | 1 | 1 |
| Eye disorder | 1 | 1 | | | 1 | 1 | | |
| Eye haematoma | 1 | 1 | | | | | 1 | 1 |
| Eye irritation | 9 | 11 | 1 | 1 | 4 | 6 | 5 | 5 |
| Eyelid myoclonus | 1 | 1 | | | | | 1 | 1 |
| Eyelid oedema | 6 | 7 | 1 | 1 | | | 6 | 7 |
| Eyelid ptosis | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Eyelid retraction | 1 | 1 | | | | | 1 | 1 |
| Eye oedema | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Eye pain | 10 | 12 | | | 5 | 7 | 5 | 5 |
| Eye pruritus | 2 | 5 | | | | 2 | 2 | 3 |
| Eye swelling | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Lacrimation increased | 2 | 4 | | | 1 | 3 | 1 | 1 |
| Macular rupture | 1 | 1 | | | | | 1 | 1 |
| Metamorphopsia | 1 | 1 | | | | | 1 | 1 |
| Miosis | 1 | 1 | | | 1 | 1 | | |
| Ocular discomfort | 1 | 1 | | | 1 | 1 | | |
| Ocular hyperaemia | 4 | 6 | | | 3 | 4 | 1 | 2 |
| Oculogyric crisis | 1 | 1 | | | | | 1 | 1 |
| Optic neuropathy | 1 | 1 | | | | | 1 | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Orbital oedema | 1 | 1 | | | | | 1 | 1 |
| Papilloedema | 1 | 1 | | | | | 1 | 1 |
| Periorbital discomfort | 1 | 1 | | | | | 1 | 1 |
| Periorbital oedema | 1 | 2 | | | | | 1 | 2 |
| Periorbital swelling | 1 | 3 | | | | 2 | 1 | 1 |
| Photophobia | 5 | 6 | | | 3 | 4 | 2 | 2 |
| Photopsia | 3 | 3 | | | | | 3 | 3 |
| Retinal degeneration | 1 | 1 | | | | | 1 | 1 |
| Retinal detachment | 2 | 2 | | | | | 2 | 2 |
| Retinal disorder | 1 | 1 | | | | | 1 | 1 |
| Retinal vascular thrombosis | 1 | 1 | | | | | 1 | 1 |
| Scleral discolouration | 1 | 1 | | | | | 1 | 1 |
| Swelling of eyelid | 2 | 3 | | | 2 | 3 | | |
| Uveitis | 2 | 2 | | | | | 2 | 2 |
| Vision blurred | 11 | 16 | | | 3 | 8 | 8 | 8 |
| Visual acuity reduced | 1 | 1 | | | | | 1 | 1 |
| Visual impairment | 6 | 7 | | | 2 | 3 | 4 | 4 |
| Vitreous detachment | 1 | 1 | | | | | 1 | 1 |
| Vitreous disorder | 1 | 1 | | | | | 1 | 1 |
| Vitreous floaters | 2 | 2 | | | | | 2 | 2 |
| Xanthopsia | 1 | 1 | | | | | 1 | 1 |
| | 122 | 147 | 2 | 2 | 36 | 56 | 86 | 91 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 1 | 2 | | | | 1 | 1 | 1 |
| Abdominal distension | 5 | 5 | | | 1 | 1 | 4 | 4 |
| Abdominal pain | 50 | 64 | | | 25 | 38 | 25 | 26 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 | | |
| Abdominal pain upper | 26 | 34 | | | 9 | 17 | 17 | 17 |
| Acquired macroglossia | 1 | 1 | | | | | 1 | 1 |
| Anaesthesia oral | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Anal incontinence | | 1 | | | | 1 | | |
| Anal sphincter atony | 1 | 1 | | | | | 1 | 1 |
| Aphthous ulcer | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Constipation | | 1 | | | | 1 | | |
| Diarrhoea | 88 | 116 | | | 33 | 61 | 55 | 55 |
| Diarrhoea haemorrhagic | 1 | 1 | | | | | 1 | 1 |
| Dry mouth | 16 | 29 | 1 | 1 | 4 | 15 | 12 | 14 |
| Dyspepsia | 7 | 8 | | | 5 | 6 | 2 | 2 |
| Dysphagia | 30 | 40 | 2 | 2 | 10 | 16 | 20 | 24 |
| Enterocolitis | 1 | 1 | | | | | 1 | 1 |
| Faeces soft | 1 | 1 | | | | | 1 | 1 |
| Flatulence | | 2 | | | | 2 | | |
| Gastritis | | 1 | | | | 1 | | |
| Gastrointestinal disorder | 4 | 6 | | | 3 | 5 | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal pain | 1 | 1 | | | 1 | 1 | | |
| Gastrointestinal sounds abnormal | | 1 | | | | 1 | | |
| Gingival swelling | 1 | 2 | | | | 1 | 1 | 1 |
| Glossodynia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Haematochezia | 2 | 2 | | | | | 2 | 2 |
| Hypertrophy of tongue papillae | 1 | 1 | | | | | 1 | 1 |
| Hypoesthesia oral | 7 | 15 | | | 4 | 12 | 3 | 3 |
| Intestinal pseudo-obstruction | 1 | 1 | | | | | 1 | 1 |
| Lip oedema | 18 | 27 | | | 2 | 9 | 16 | 18 |
| Lip pain | 2 | 2 | | | 2 | 2 | | |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Lip pruritus | 6 | 8 |
| Lip swelling | 7 | 9 |
| Mouth swelling | 1 | 1 |
| Mouth ulceration | 2 | 2 |
| Mucous stools | 1 | 1 |
| Nausea | 225 | 277 |
| Odynophagia | 2 | 2 |
| Oedema mouth | 2 | 5 |
| Oesophageal pain | 1 | 1 |
| Oesophageal spasm | 1 | 1 |
| Oral discomfort | 5 | 6 |
| Oral dysaesthesia | | 1 |
| Oral mucosal erythema | 1 | 1 |
| Oral pain | 2 | 2 |
| Oral pruritus | 4 | 4 |
| Palatal oedema | 5 | 7 |
| Palatal swelling | 1 | 2 |
| Paraesthesia oral | 58 | 80 |
| Parotid gland enlargement | | 1 |
| Plicated tongue | 1 | 1 |
| Regurgitation | 1 | 1 |
| Retching | 5 | 7 |
| Salivary hypersecretion | 2 | 2 |
| Stomatitis | 1 | 1 |
| Swollen tongue | 7 | 10 |
| Tongue discolouration | 1 | 1 |
| Tongue discomfort | 1 | 2 |
| Tongue disorder | 1 | 2 |
| Tongue dry | | 3 |
| Tongue erythema | 1 | 1 |
| Tongue oedema | 12 | 16 |
| Tongue pruritus | 3 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 4 | 4 | 4 |
| | | 1 | 2 | 6 | 7 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| 2 | 2 | 84 | 133 | 141 | 144 |
| | | | | 2 | 2 |
| | | 1 | 3 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | 2 | 3 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 4 | 4 |
| | | 1 | 2 | 4 | 5 |
| | | 1 | 2 | | |
| 2 | 2 | 14 | 31 | 44 | 49 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 5 | 5 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | 2 | 7 | 8 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | | 2 |
| | | | | 1 | 1 |
| | | 3 | 5 | 9 | 11 |
| | | | 1 | 3 | 3 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Toothache | 1 | 1 | | | 1 | 1 | | |
| Volvulus | 1 | 1 | | | | | 1 | 1 |
| Vomiting | 86 | 101 | | | 21 | 34 | 65 | 67 |
| Vomiting projectile | 2 | 2 | | | | | 2 | 2 |
| | 726 | 944 | 7 | 7 | 241 | 431 | 485 | 513 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Administration site movement impairment | 1 | 1 | | | | | 1 | 1 |
| Administration site reaction | | 1 | | | | | | 1 |
| Application site coldness | 1 | 1 | | | 1 | 1 | | |
| Asthenia | 242 | 288 | 3 | 3 | 104 | 147 | 138 | 141 |
| Axillary pain | 17 | 23 | | | 8 | 13 | 9 | 10 |
| Chest discomfort | 23 | 28 | 1 | 1 | 8 | 12 | 15 | 16 |
| Chest pain | 25 | 29 | 1 | 1 | 2 | 6 | 23 | 23 |
| Chills | 241 | 286 | 2 | 3 | 114 | 157 | 127 | 129 |
| Condition aggravated | 2 | 3 | | | | | 2 | 3 |
| Crying | | 1 | | | | 1 | | |
| Death | 1 | 3 | | | | | 1 | 3 |
| Discomfort | 3 | 4 | | | 3 | 4 | | |
| Disease recurrence | 4 | 5 | | | | 1 | 4 | 4 |
| Drug ineffective | 55 | 64 | | | 2 | 2 | 53 | 62 |
| Enanthema | 1 | 1 | | | | | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | | | | | 1 | 1 |
| Face oedema | 9 | 11 | | | 1 | 2 | 8 | 9 |
| Facial pain | 4 | 5 | | | | 1 | 4 | 4 |
| Fatigue | 151 | 178 | | 1 | 59 | 85 | 92 | 93 |
| Feeling abnormal | 5 | 7 | | | 2 | 3 | 3 | 4 |
| Feeling cold | 21 | 26 | | 1 | 6 | 10 | 15 | 16 |
| Feeling drunk | 1 | 1 | | | 1 | 1 | | |
| Feeling hot | 37 | 54 | 1 | 1 | 11 | 25 | 26 | 29 |
| Feeling of body temperature change | 4 | 5 | | | 1 | 2 | 3 | 3 |
| Gait disturbance | 8 | 8 | | | 2 | 2 | 6 | 6 |
| Gait inability | 3 | 3 | | | 2 | 2 | 1 | 1 |
| General physical health deterioration | | 1 | | | | | | 1 |
| Hyperpyrexia | 146 | 148 | | | | | 146 | 148 |
| Hyperthermia | 10 | 12 | | | 4 | 5 | 6 | 7 |
| Hypothermia | 10 | 10 | | | | | 10 | 10 |
| Idiosyncratic drug reaction | 1 | 1 | | | | | 1 | 1 |
| Illness | 2 | 3 | | | 1 | 2 | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Inflammation | 2 | 3 |
| Inflammatory pain | 1 | 1 |
| Influenza like illness | 13 | 20 |
| Injection site hypersensitivity | 1 | 1 |
| Injection site pain | 6 | 9 |
| Injection site pruritus | 1 | 1 |
| Injection site rash | 1 | 1 |
| Injection site urticaria | 2 | 2 |
| Localised oedema | 4 | 6 |
| Malaise | 78 | 101 |
| Mucosal dryness | | 1 |
| Mucosal hyperaemia | 1 | 1 |
| Multiple organ dysfunction syndrome | 2 | 2 |
| No adverse event | 1 | 1 |
| Oedema | 3 | 3 |
| Oedema mucosal | 2 | 2 |
| Oedema peripheral | 5 | 6 |
| Pain | 71 | 85 |
| Peripheral swelling | 12 | 14 |
| Pyrexia | 566 | 685 |
| Sensation of foreign body | 7 | 9 |
| Sense of oppression | 2 | 2 |
| Sudden death | 4 | 5 |
| Swelling | 10 | 14 |
| Swelling face | 11 | 14 |
| Tenderness | 1 | 2 |
| Vaccination site bruising | 2 | 2 |
| Vaccination site discolouration | | 1 |
| Vaccination site discomfort | | 3 |
| Vaccination site erythema | 31 | 45 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site hypersensitivity | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 6 | 13 | 7 | 7 |
| | | 1 | 1 | | |
| | | 2 | 5 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 3 | 5 | 1 | 1 |
| | | 30 | 50 | 48 | 51 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | 2 | 3 | 3 | 3 |
| | | 35 | 47 | 36 | 38 |
| | | 4 | 6 | 8 | 8 |
| 5 | 6 | 215 | 328 | 351 | 357 |
| | | 1 | 3 | 6 | 6 |
| | | | | 2 | 2 |
| | | | | 4 | 5 |
| | | 5 | 8 | 5 | 6 |
| 1 | 1 | 2 | 4 | 9 | 10 |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | 3 | | |
| | | 13 | 26 | 18 | 19 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Vaccination site hypoaesthesia | 3 | 3 |
| Vaccination site induration | 4 | 5 |
| Vaccination site inflammation | 2 | 3 |
| Vaccination site ischaemia | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 |
| Vaccination site joint swelling | | 1 |
| Vaccination site joint warmth | | 1 |
| Vaccination site lymphadenopathy | 3 | 5 |
| Vaccination site mass | 1 | 1 |
| Vaccination site movement impairment | 3 | 6 |
| Vaccination site oedema | 16 | 23 |
| Vaccination site pain | 229 | 404 |
| Vaccination site paraesthesia | 8 | 14 |
| Vaccination site pruritus | 8 | 12 |
| Vaccination site rash | 1 | 2 |
| Vaccination site reaction | 7 | 7 |
| Vaccination site swelling | 36 | 50 |
| Vaccination site urticaria | 3 | 9 |
| Vaccination site vesicles | 2 | 2 |
| Vaccination site warmth | 11 | 17 |
| | 2,210 | 2,823 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|-----|---------|------|------|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | 2 | 2 | 1 | 1 | | |
| | | 1 | 2 | 3 | 3 | | |
| | | 1 | 2 | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | 1 | 1 | | | | |
| | | | 1 | | | | |
| | | | 1 | | | | |
| | | 2 | 3 | 1 | 2 | | |
| | | 1 | 1 | | | | |
| | | 3 | 6 | | | | |
| | | 4 | 11 | 12 | 12 | | |
| 3 | 3 | 128 | 300 | 101 | 104 | | |
| | | 3 | 9 | 5 | 5 | | |
| | | 4 | 7 | 4 | 5 | | |
| | | 1 | 2 | | | | |
| | | 3 | 3 | 4 | 4 | | |
| | | 17 | 30 | 19 | 20 | | |
| | | 1 | 6 | 2 | 3 | | |
| | | 1 | 1 | 1 | 1 | | |
| | | 4 | 9 | 7 | 8 | | |
| | | 17 | 21 | 835 | 1393 | 1375 | 1430 |

System Organ Class

Hepatobiliary disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------|--|--|
| Hepatitis acute | 1 | 1 |
| Hypertransaminaemia | 2 | 2 |
| | 3 | 3 |

| Spontaneous | |
|-------------|---|
| Serious | |
| I | C |
| 1 | 1 |
| 2 | 2 |
| 3 | 3 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Allergy to vaccine | 5 | 6 | | | | | 5 | 6 |
| Anaphylactic reaction | 13 | 28 | | | | | 13 | 28 |
| Anaphylactic shock | 6 | 13 | | | | | 6 | 13 |
| Anaphylactoid reaction | 2 | 2 | | | | | 2 | 2 |
| Drug hypersensitivity | 4 | 4 | | | | | 4 | 4 |
| Hypersensitivity | 23 | 26 | 1 | 1 | 3 | 4 | 20 | 22 |
| Reaction to excipient | 1 | 1 | | | | | 1 | 1 |
| Seasonal allergy | 1 | 1 | | | | | 1 | 1 |
| Type I hypersensitivity | 4 | 4 | | | | | 4 | 4 |
| | 59 | 85 | 1 | 1 | 3 | 4 | 56 | 81 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # | Cumulative Total # |
|--------------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Asymptomatic COVID-19 | 1 | 1 |
| Breast abscess | 1 | 1 |
| Conjunctivitis | 6 | 6 |
| COVID-19 | 60 | 71 |
| Cystitis | 1 | 1 |
| Dysentery | 98 | 98 |
| Ear infection | 2 | 2 |
| Encephalitis | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| Herpes ophthalmic | 1 | 1 |
| Herpes simplex | 1 | 1 |
| Herpes virus infection | 2 | 2 |
| Herpes zoster | 5 | 7 |
| Herpes zoster infection neurological | 1 | 1 |
| Herpes zoster oticus | 1 | 1 |
| Influenza | 6 | 6 |
| Intervertebral discitis | 1 | 1 |
| Labyrinthitis | 2 | 2 |
| Listeriosis | 1 | 1 |
| Lymphangitis | 3 | 4 |
| Mastitis | 2 | 3 |
| Nasopharyngitis | 3 | 5 |
| Ophthalmic herpes simplex | 1 | 1 |
| Oral candidiasis | 1 | 1 |
| Oral herpes | 6 | 8 |
| Pharyngitis | 3 | 6 |
| Pneumonia | 2 | 2 |
| Pneumonia bacterial | 1 | 1 |
| Q fever | 6 | 6 |
| Respiratory tract infection | 1 | 1 |
| Rhinitis | 3 | 3 |
| Root canal infection | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 4 | 4 |
| | | 5 | 8 | 55 | 63 |
| | | 1 | 1 | | |
| 1 | 1 | | | 98 | 98 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 3 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 5 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | | | 2 | 3 |
| | | 2 | 3 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 3 | 5 | 5 |
| | | 1 | 4 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 6 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | | |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Sepsis | 2 | 2 | | | | | 2 | 2 |
| Septic shock | 1 | 1 | | | | | 1 | 1 |
| Severe acute respiratory syndrome | 1 | 1 | | | | | 1 | 1 |
| Soft tissue infection | 1 | 1 | | | | | 1 | 1 |
| Tonsillitis | 1 | 1 | | | 1 | 1 | | |
| Tooth infection | 1 | 1 | | | 1 | 1 | | |
| Tracheitis | 1 | 1 | | | | | 1 | 1 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 | | |
| Vaccination site cellulitis | 1 | 1 | | | | | 1 | 1 |
| | 235 | 257 | 1 | 1 | 27 | 37 | 208 | 220 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Arthropod sting | 1 | 1 | | | | | 1 | 1 |
| Barotrauma | 1 | 1 | | | 1 | 1 | | |
| Central cord syndrome | 1 | 1 | | | | | 1 | 1 |
| Circumstance or information capable of leading to medication error | | 1 | | | | 1 | | |
| Cold burn | 1 | 1 | | | 1 | 1 | | |
| Contusion | 1 | 1 | | | 1 | 1 | | |
| Exposure during pregnancy | | 1 | | | | 1 | | |
| Exposure to SARS-CoV-2 | 1 | 1 | | | 1 | 1 | | |
| Exposure via breast milk | | 1 | | | | 1 | | |
| Facial bones fracture | 1 | 1 | | | | | 1 | 1 |
| Fall | 2 | 3 | | | | | 2 | 3 |
| Foreign body in throat | 1 | 1 | | | | | 1 | 1 |
| Head injury | 1 | 1 | | | | | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 2 | | | 2 | 2 | | |
| Incorrect dose administered | | 3 | | | | 3 | | |
| Incorrect route of product administration | 7 | 10 | | | 7 | 10 | | |
| Lack of vaccination site rotation | | | 1 | 1 | | | | |
| Maternal exposure during pregnancy | 6 | 6 | | | 5 | 5 | 1 | 1 |
| Off label use | 16 | 19 | | | 15 | 18 | 1 | 1 |
| Overdose | 29 | 32 | | | 29 | 32 | | |
| Poor quality product administered | | 1 | | | | 1 | | |
| Product administered at inappropriate site | 6 | 7 | | | 6 | 7 | | |
| Product administered to patient of inappropriate age | | 1 | | | | 1 | | |
| Product administration error | | 1 | | | | 1 | | |
| Product label confusion | | 1 | | | | 1 | | |
| Product preparation issue | 6 | 7 | | | 6 | 7 | | |
| Product use issue | 12 | 14 | | | 10 | 12 | 2 | 2 |
| Stoma site pain | 1 | 1 | | | | | 1 | 1 |
| Thermal burns of eye | 1 | 1 | | | | | 1 | 1 |
| Underdose | 5 | 10 | | | 5 | 10 | | |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vaccination complication | 15 | 17 | 1 | 1 | 4 | 6 | 11 | 11 |
| Vaccination failure | 2 | 2 | | | | | 2 | 2 |
| Wound | 1 | 1 | | | | | 1 | 1 |
| Wrong technique in product usage process | | 2 | | | | 2 | | |
| | 120 | 153 | 2 | 2 | 93 | 125 | 27 | 28 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Alanine aminotransferase increased | 2 | 2 | | | 2 | 2 | | |
| Amylase increased | 1 | 1 | | | | | 1 | 1 |
| Blood alkaline phosphatase increased | 1 | 1 | | | | | 1 | 1 |
| Blood glucose increased | 1 | 2 | | | | 1 | 1 | 1 |
| Blood potassium decreased | 1 | 1 | | | 1 | 1 | | |
| Blood pressure decreased | 9 | 10 | 1 | 1 | 5 | 5 | 4 | 5 |
| Blood pressure diastolic increased | | 1 | | | | 1 | | |
| Blood pressure increased | 25 | 32 | | | 4 | 9 | 21 | 23 |
| Blood pressure systolic increased | 2 | 2 | | | 2 | 2 | | |
| Body temperature decreased | | 2 | | | | 2 | | |
| Body temperature increased | 4 | 9 | | | 2 | 6 | 2 | 3 |
| Breath sounds | 1 | 1 | | | | | 1 | 1 |
| Breath sounds abnormal | 1 | 1 | | | | | 1 | 1 |
| Chest expansion decreased | 1 | 1 | | | 1 | 1 | | |
| Coma scale abnormal | | 1 | | | | | | 1 |
| C-reactive protein increased | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 | | | | | 1 | 1 |
| Eosinophil count decreased | 1 | 1 | | | | | 1 | 1 |
| Eosinophil count increased | 1 | 1 | | | | | 1 | 1 |
| Fibrin D dimer increased | 1 | 1 | | | 1 | 1 | | |
| Gamma-glutamyltransferase increased | 1 | 1 | | | | | 1 | 1 |
| Haptoglobin increased | 1 | 1 | | | | | 1 | 1 |
| Heart rate abnormal | 1 | 1 | | | | | 1 | 1 |
| Heart rate decreased | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Heart rate increased | 9 | 9 | | | 1 | 1 | 8 | 8 |
| Inspiratory capacity abnormal | | 1 | | | | 1 | | |
| International normalised ratio increased | 1 | 1 | | | 1 | 1 | | |
| Lymphocyte count decreased | 1 | 1 | | | 1 | 1 | | |
| Lymphocyte count increased | 1 | 1 | | | | | 1 | 1 |
| Mean cell volume increased | 1 | 1 | | | 1 | 1 | | |
| Monocyte count decreased | 1 | 1 | | | | | 1 | 1 |
| Monocyte count increased | 1 | 1 | | | 1 | 1 | | |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Myocardial necrosis marker increased | 1 | 1 |
| Neutrophil count increased | 1 | 1 |
| Oxygen saturation decreased | 26 | 28 |
| Pulse abnormal | 1 | 1 |
| Quality of life decreased | 2 | 2 |
| Red blood cell count decreased | 1 | 1 |
| Red cell distribution width increased | 1 | 1 |
| Respiratory rate increased | 1 | 1 |
| SARS-CoV-2 ant body test negative | | 1 |
| SARS-CoV-2 ant body test positive | 3 | 5 |
| SARS-CoV-2 test positive | 4 | 7 |
| Sinus rhythm | 1 | 1 |
| Thyroid hormones increased | 1 | 1 |
| Transaminases increased | 2 | 2 |
| Troponin T increased | 1 | 1 |
| Urine output decreased | 1 | 1 |
| Weight decreased | | 1 |
| White blood cell count decreased | 1 | 1 |
| White blood cell count increased | 2 | 2 |
| | 125 | 154 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 4 | 23 | 24 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 3 | 2 | 2 |
| | | 2 | 4 | 2 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 1 | 1 | 34 | 55 | 91 | 99 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 13 | 15 | 6 | 8 | 7 | 7 |
| Dehydration | 2 | 3 | | | 2 | 3 |
| Feeding disorder | 1 | 1 | | | 1 | 1 |
| Fluid retention | 1 | 1 | 1 | 1 | | |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | | 1 | | 1 | | |
| | 18 | 22 | 7 | 10 | 11 | 12 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Arthralgia | 238 | 282 |
| Back pain | 27 | 33 |
| Bone pain | 38 | 43 |
| Extremity contracture | | 1 |
| Joint lock | 1 | 1 |
| Joint range of motion decreased | 4 | 5 |
| Joint stiffness | 1 | 1 |
| Joint swelling | 1 | 1 |
| Joint warmth | 1 | 1 |
| Limb discomfort | 7 | 13 |
| Mobility decreased | 3 | 3 |
| Muscle contracture | 4 | 4 |
| Muscle oedema | 1 | 1 |
| Muscle rigidity | 3 | 4 |
| Muscle spasms | 11 | 13 |
| Muscle swelling | 1 | 1 |
| Muscle tightness | 2 | 2 |
| Muscular weakness | 16 | 19 |
| Musculoskeletal chest pain | 3 | 3 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal disorder | 2 | 2 |
| Musculoskeletal pain | 53 | 62 |
| Musculoskeletal stiffness | 10 | 12 |
| Myalgia | 274 | 325 |
| Myalgia intercostal | 1 | 1 |
| Myositis | | |
| Neck pain | 18 | 22 |
| Nuchal rigidity | 5 | 7 |
| Pain in extremity | 104 | 141 |
| Pain in jaw | 4 | 4 |
| Rheumatic disorder | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 2 | 2 | 105 | 147 | 133 | 135 |
| 3 | 3 | 9 | 13 | 18 | 20 |
| | | 22 | 27 | 16 | 16 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | 4 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 10 | 3 | 3 |
| | | | | 3 | 3 |
| | | 2 | 2 | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 3 |
| | | 4 | 6 | 7 | 7 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 6 | 9 | 10 | 10 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 21 | 30 | 32 | 32 |
| 1 | 1 | 3 | 5 | 7 | 7 |
| 3 | 3 | 124 | 173 | 150 | 152 |
| | | 1 | 1 | | |
| 1 | 1 | | | | |
| | | 6 | 10 | 12 | 12 |
| | | 2 | 3 | 3 | 4 |
| | | 46 | 81 | 58 | 60 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Sjogren's syndrome | 1 | 1 | | | | | 1 | 1 |
| Spinal pain | 4 | 8 | | | 3 | 7 | 1 | 1 |
| Temporomandibular joint syndrome | 1 | 1 | | | | | 1 | 1 |
| Torticollis | 1 | 2 | | | 1 | 2 | | |
| | 843 | 1,022 | 10 | 10 | 365 | 534 | 478 | 488 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Angiomyolipoma | 1 | 1 | 1 | 1 |
| Brain neoplasm | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ageusia | 9 | 10 | | | 5 | 6 | 4 | 4 |
| Allodynia | | 1 | | | | 1 | | |
| Altered state of consciousness | 1 | 1 | | | | | 1 | 1 |
| Amnesia | 1 | 1 | | | 1 | 1 | | |
| Anaesthesia | 5 | 7 | | | 2 | 4 | 3 | 3 |
| Anosmia | 5 | 6 | | | 2 | 3 | 3 | 3 |
| Anterograde amnesia | 2 | 2 | | | | | 2 | 2 |
| Aphasia | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Aura | | 1 | | | | 1 | | |
| Balance disorder | 5 | 7 | | | | 2 | 5 | 5 |
| Band sensation | 2 | 3 | | | | 1 | 2 | 2 |
| Burning sensation | 7 | 8 | | | 2 | 3 | 5 | 5 |
| Carotid artery dissection | 1 | 1 | | | | | 1 | 1 |
| Cerebellar haemorrhage | | 1 | | | | | | 1 |
| Cerebral disorder | 1 | 1 | | | | | 1 | 1 |
| Cerebral venous sinus thrombosis | 1 | 1 | | | | | 1 | 1 |
| Cerebrovascular accident | | 1 | | | | | | 1 |
| Cervical radiculopathy | 1 | 1 | | | | | 1 | 1 |
| Cervicobrachial syndrome | 1 | 1 | | | 1 | 1 | | |
| Clonus | 5 | 5 | | | 1 | 1 | 4 | 4 |
| Coma | 2 | 2 | | | | | 2 | 2 |
| Coordination abnormal | 1 | 1 | | | | | 1 | 1 |
| Cranial nerve disorder | 1 | 2 | | | 1 | 1 | | 1 |
| Cranial nerve paralysis | 1 | 1 | | | | | 1 | 1 |
| Demyelinating polyneuropathy | 1 | 1 | | | | | 1 | 1 |
| Depressed level of consciousness | 29 | 32 | | | 1 | 1 | 28 | 31 |
| Diplegia | 1 | 1 | | | | | 1 | 1 |
| Disturbance in attention | 5 | 5 | | | 1 | 1 | 4 | 4 |
| Dizziness | 101 | 123 | | | 45 | 66 | 56 | 57 |
| Dysaesthesia | 3 | 7 | | | 2 | 6 | 1 | 1 |
| Dysgeusia | 15 | 30 | | | 6 | 19 | 9 | 11 |
| Dysgraphia | 1 | 1 | | | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Dyskinesia | 1 | 1 |
| Dysmetria | 1 | 1 |
| Dysstasia | 1 | 1 |
| Encephalopathy | 1 | 1 |
| Epilepsy | 6 | 6 |
| Facial nerve disorder | 3 | 3 |
| Facial neuralgia | 1 | 1 |
| Facial paralysis | 30 | 33 |
| Facial paresis | 9 | 9 |
| Facial spasm | | 1 |
| Febrile convulsion | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Headache | 452 | 586 |
| Head discomfort | 4 | 5 |
| Hemianaesthesia | 5 | 5 |
| Hemianopia heteronymous | 1 | 1 |
| Hemidysaesthesia | 3 | 3 |
| Hemihyperaesthesia | 1 | 1 |
| Hemiparaesthesia | 22 | 22 |
| Hemiparesis | 7 | 8 |
| Hemiplegia | 4 | 4 |
| Hyperaesthesia | 1 | 2 |
| Hyperkinesia | 1 | 1 |
| Hyperreflexia | 1 | 1 |
| Hypersomnia | 1 | 1 |
| Hypoaesthesia | 28 | 40 |
| Hypoglossal nerve disorder | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hyporeflexia | 1 | 1 |
| Hyposmia | 1 | 1 |
| Hypotonia | 4 | 4 |
| Ischaemic stroke | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 6 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 30 | 33 |
| | | 2 | 2 | 7 | 7 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 5 | 6 | 201 | 332 | 251 | 254 |
| | | 3 | 4 | 1 | 1 |
| | | | | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 22 | 22 |
| | | | | 7 | 8 |
| | | | | 4 | 4 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | 10 | 21 | 18 | 19 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | 2 | 2 |
| | | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Loss of consciousness | 42 | 43 |
| Memory impairment | 1 | 1 |
| Meningeal disorder | 1 | 1 |
| Mental impairment | 2 | 2 |
| Migraine | 27 | 37 |
| Monoparesis | | 1 |
| Monoplegia | 4 | 4 |
| Movement disorder | 7 | 7 |
| Muscle contractions involuntary | 2 | 3 |
| Myasthenia gravis crisis | 1 | 1 |
| Myoclonus | 1 | 1 |
| Narcolepsy | 1 | 1 |
| Neuralgia | 9 | 11 |
| Neuralgic amyotrophy | | |
| Neuritis | 1 | 2 |
| Neurological symptom | 1 | 1 |
| Neuropathy peripheral | 6 | 6 |
| Neurotoxicity | 1 | 1 |
| Nystagmus | 1 | 1 |
| Optic neuritis | 4 | 4 |
| Paraesthesia | 131 | 164 |
| Paralysis | 3 | 3 |
| Paraparesis | 1 | 1 |
| Paresis | 2 | 2 |
| Paresis cranial nerve | | 1 |
| Parosmia | 2 | 3 |
| Partial seizures | 1 | 1 |
| Peripheral sensorimotor neuropathy | 1 | 1 |
| Peripheral sensory neuropathy | 1 | 1 |
| Presyncope | 43 | 53 |
| Quadriparesis | 1 | 1 |
| Radiculopathy | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 42 | 43 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 10 | 20 | 17 | 17 |
| | | | 1 | | |
| | | | | 4 | 4 |
| | | | | 7 | 7 |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 7 | 7 |
| 1 | 1 | | | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| 1 | 1 | 36 | 66 | 95 | 98 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 8 | 17 | 35 | 36 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|---|-----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Reduced facial expression | | 1 | | | | | | | 1 |
| Restless legs syndrome | 1 | 1 | | | | | 1 | | 1 |
| Retrograde amnesia | 2 | 2 | | | 1 | 1 | 1 | | 1 |
| Sciatica | 1 | 2 | | | | 1 | 1 | | 1 |
| Sedation | 2 | 2 | | | 2 | 2 | | | |
| Seizure | 6 | 6 | | | | | 6 | | 6 |
| Seizure like phenomena | 1 | 1 | | | | | 1 | | 1 |
| Sensory disturbance | 2 | 2 | | | | | 2 | | 2 |
| Sensory loss | 4 | 4 | | | 1 | 1 | 3 | | 3 |
| Sinus headache | 1 | 1 | | | 1 | 1 | | | |
| Somnolence | 35 | 52 | | | 16 | 33 | 19 | | 19 |
| Speech disorder | 2 | 3 | | | 1 | 2 | 1 | | 1 |
| Stupor | 4 | 6 | | | | 1 | 4 | | 5 |
| Syncope | 74 | 76 | 1 | 1 | | | 74 | | 76 |
| Taste disorder | 5 | 5 | | | | | 5 | | 5 |
| Tension headache | 1 | 1 | | | | | 1 | | 1 |
| Tonic clonic movements | 1 | 2 | | | | | 1 | | 2 |
| Tonic convulsion | 1 | 1 | | | | | 1 | | 1 |
| Tremor | 42 | 54 | 1 | 1 | 9 | 20 | 33 | | 34 |
| Trigeminal nerve disorder | 4 | 4 | | | 1 | 1 | 3 | | 3 |
| Trigeminal neuralgia | 1 | 1 | | | | | 1 | | 1 |
| VIth nerve paralysis | 1 | 1 | | | | | 1 | | 1 |
| VIth nerve paresis | 1 | 1 | | | | | 1 | | 1 |
| | 1,298 | 1,606 | 10 | 11 | 387 | 664 | 911 | | 942 |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortion | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 9 | 12 | 4 | 7 | 5 | 5 |
| Anxiety | 5 | 8 | 1 | 4 | 4 | 4 |
| Apathy | 1 | 1 | | | 1 | 1 |
| Confusional state | 24 | 31 | 9 | 15 | 15 | 16 |
| Delirium | 1 | 1 | | | 1 | 1 |
| Disorientation | 6 | 7 | | 1 | 6 | 6 |
| Euphoric mood | 1 | 1 | 1 | 1 | | |
| Hallucination | 2 | 2 | | | 2 | 2 |
| Hallucination, auditory | 1 | 1 | | | 1 | 1 |
| Hallucination, olfactory | 1 | 1 | | | 1 | 1 |
| Hallucinations, mixed | 1 | 1 | | | 1 | 1 |
| Hallucination, visual | 1 | 1 | | | 1 | 1 |
| Immunisation anxiety related reaction | 1 | 1 | 1 | 1 | | |
| Initial insomnia | 2 | 2 | 1 | 1 | 1 | 1 |
| Insomnia | 17 | 21 | 7 | 11 | 10 | 10 |
| Irritability | 1 | 2 | | 1 | 1 | 1 |
| Mental disorder | 1 | 1 | | | 1 | 1 |
| Middle insomnia | 3 | 3 | 3 | 3 | | |
| Mood altered | 2 | 2 | 1 | 1 | 1 | 1 |
| Nightmare | 1 | 1 | 1 | 1 | | |
| Panic attack | 2 | 2 | 1 | 1 | 1 | 1 |
| Panic reaction | 1 | 1 | 1 | 1 | | |
| Restlessness | 3 | 4 | | | 3 | 4 |
| Sopor | 2 | 2 | 1 | 1 | 1 | 1 |
| Tension | 1 | 1 | | | 1 | 1 |
| Terminal insomnia | 2 | 2 | 2 | 2 | | |
| | 92 | 112 | 34 | 52 | 58 | 60 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anuria | 2 | 2 | | | 2 | 2 |
| Azotaemia | 1 | 1 | | | 1 | 1 |
| Chromaturia | 1 | 1 | 1 | 1 | | |
| Cystitis haemorrhagic | 4 | 4 | | | 4 | 4 |
| Dysuria | 2 | 3 | 1 | 1 | 1 | 2 |
| Haematuria | 3 | 3 | 1 | 1 | 2 | 2 |
| Neurogenic bladder | 1 | 1 | | | 1 | 1 |
| Polyuria | 1 | 2 | | 1 | 1 | 1 |
| Renal failure | 1 | 3 | | | 1 | 3 |
| Renal pain | 1 | 2 | 1 | 2 | | |
| Urinary incontinence | 1 | 1 | | | 1 | 1 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| | 19 | 24 | 4 | 6 | 15 | 18 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast discomfort | | 1 | | | | 1 |
| Breast pain | 2 | 3 | 1 | 1 | 1 | 2 |
| Breast swelling | | 1 | | | | 1 |
| Menstrual disorder | 1 | 1 | 1 | 1 | | |
| Metrorrhagia | 2 | 2 | | | 2 | 2 |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vulvovaginal burning sensation | 1 | 1 | 1 | 1 | | |
| | 7 | 10 | 3 | 3 | 4 | 7 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute respiratory failure | 3 | 4 | | | | | 3 | 4 |
| Allergic cough | 1 | 1 | | | | | 1 | 1 |
| Allergic respiratory symptom | | 1 | | | | | | 1 |
| Aphonia | 4 | 4 | | | 3 | 3 | 1 | 1 |
| Apnoea | 1 | 1 | | | | | 1 | 1 |
| Asphyxia | | 1 | | | | | | 1 |
| Asthma | 5 | 5 | | | | | 5 | 5 |
| Asthmatic crisis | 6 | 6 | | | | | 6 | 6 |
| Bronchospasm | 13 | 14 | 1 | 1 | | | 13 | 14 |
| Bronchostenosis | 1 | 1 | | | | | 1 | 1 |
| Catarrh | 2 | 2 | | | | | 2 | 2 |
| Choking | 1 | 1 | | | | | 1 | 1 |
| Chronic respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Cough | 56 | 65 | 1 | 1 | 11 | 19 | 45 | 46 |
| Diaphragmatic spasm | 1 | 1 | | | | | 1 | 1 |
| Dry throat | 1 | 2 | | | 1 | 2 | | |
| Dysaesthesia pharynx | 1 | 1 | | | 1 | 1 | | |
| Dysphonia | 16 | 18 | | | 5 | 7 | 11 | 11 |
| Dyspnoea | 114 | 131 | 2 | 3 | 12 | 20 | 102 | 111 |
| Dyspnoea at rest | 1 | 1 | | | | | 1 | 1 |
| Dyspnoea exertional | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Epiglottic oedema | 1 | 1 | | | | | 1 | 1 |
| Epistaxis | 7 | 7 | | | 4 | 4 | 3 | 3 |
| Hyperventilation | 6 | 7 | 1 | 1 | 1 | 2 | 5 | 5 |
| Hypoxia | 3 | 3 | | | | | 3 | 3 |
| Interstitial lung disease | 2 | 2 | | | | | 2 | 2 |
| Intranasal hypoaesthesia | | 1 | | | | 1 | | |
| Intranasal paraesthesia | | 1 | | | | 1 | | |
| Laryngeal dyspnoea | 2 | 2 | | | | | 2 | 2 |
| Laryngeal obstruction | 3 | 3 | | | | | 3 | 3 |
| Laryngeal oedema | 33 | 42 | | | | | 33 | 42 |
| Laryngeal pain | | 1 | | | | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Laryngeal stenosis | 2 | 2 |
| Laryngospasm | 5 | 6 |
| Nasal congestion | 3 | 5 |
| Nasal obstruction | 1 | 1 |
| Nasal oedema | 1 | 1 |
| Obstructive airways disorder | 3 | 4 |
| Oropharyngeal discomfort | 6 | 6 |
| Oropharyngeal oedema | 2 | 2 |
| Oropharyngeal pain | 23 | 27 |
| Orthopnoea | 1 | 1 |
| Pharyngeal erythema | 3 | 4 |
| Pharyngeal hypoaesthesia | 1 | 1 |
| Pharyngeal oedema | 4 | 4 |
| Pharyngeal paraesthesia | 6 | 9 |
| Pharyngeal swelling | 7 | 8 |
| Pleurisy | 1 | 1 |
| Pneumonitis | 2 | 2 |
| Productive cough | 2 | 2 |
| Pulmonary embolism | 1 | 2 |
| Pulmonary pain | 1 | 1 |
| Rales | 1 | 1 |
| Respiratory arrest | 1 | 2 |
| Respiratory depression | 1 | 1 |
| Respiratory disorder | 2 | 3 |
| Respiratory distress | 4 | 5 |
| Respiratory failure | 1 | 1 |
| Respiratory fatigue | 6 | 6 |
| Respiratory tract oedema | 1 | 1 |
| Rhinalgia | 1 | 1 |
| Rhinitis allergic | 1 | 1 |
| Rhinorrhoea | 4 | 8 |
| Rhonchi | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 1 | 4 | 5 |
| | | 2 | 4 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 3 |
| | | 2 | 2 | 4 | 4 |
| | | | | 2 | 2 |
| | | 7 | 11 | 16 | 16 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | 2 | 6 | 7 |
| | | 3 | 3 | 4 | 5 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 4 | 8 | | |
| | | 1 | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Sneezing | | 1 |
| Stertor | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Tachypnoea | 5 | 6 |
| Throat irritation | 20 | 24 |
| Throat tightness | 27 | 41 |
| Tonsillar erythema | | 1 |
| Tonsillar hypertrophy | | 1 |
| Tracheal pain | 1 | 1 |
| Upper airway obstruction | 1 | 1 |
| Upper respiratory tract inflammation | 1 | 1 |
| Use of accessory respiratory muscles | 1 | 1 |
| Vasomotor rhinitis | | 1 |
| Vocal cord dysfunction | 1 | 1 |
| Wheezing | 5 | 5 |
| | 451 | 541 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|----|---------|-----|-----|-----|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | | 1 | | | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | 2 | 3 | 3 | 3 | | |
| | | 3 | 6 | 17 | 18 | | |
| 2 | 2 | 2 | 11 | 25 | 30 | | |
| | | | 1 | | | | |
| | | | 1 | | | | |
| | | 1 | 1 | | | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | | 1 | | | | |
| | | | | 1 | 1 | | |
| | | 2 | 2 | 3 | 3 | | |
| | | 7 | 8 | 72 | 126 | 379 | 415 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Angioedema | 29 | 31 | | | | | 29 | 31 |
| Blister | 2 | 2 | | | 2 | 2 | | |
| Butterfly rash | 1 | 1 | | | | | 1 | 1 |
| Circumoral swelling | 1 | 1 | | | | | 1 | 1 |
| Cold sweat | 8 | 8 | | | 1 | 1 | 7 | 7 |
| Dermatitis | | 1 | | | | | | 1 |
| Dermatitis allergic | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Dermatitis atopic | 1 | 1 | | | 1 | 1 | | |
| Dermatitis bullous | 6 | 6 | | | | | 6 | 6 |
| Dermatitis exfoliative | 1 | 1 | | | | | 1 | 1 |
| Dermatitis exfoliative generalised | 1 | 2 | | | | | 1 | 2 |
| Dry skin | 4 | 4 | | | | | 4 | 4 |
| Erythema | 73 | 105 | | | 14 | 40 | 59 | 65 |
| Erythema multiforme | 1 | 1 | | | | | 1 | 1 |
| Haemorrhage subcutaneous | 1 | 1 | | | | | 1 | 1 |
| Hyperhidrosis | 40 | 55 | | | 12 | 25 | 28 | 30 |
| Lipodystrophy acquired | 1 | 1 | | | | | 1 | 1 |
| Mechanical urticaria | 4 | 5 | 2 | 2 | 1 | 2 | 3 | 3 |
| Night sweats | 3 | 4 | | | 2 | 3 | 1 | 1 |
| Panniculitis | 1 | 1 | | | | | 1 | 1 |
| Papule | 1 | 1 | | | | | 1 | 1 |
| Pemphigoid | 1 | 1 | | | | | 1 | 1 |
| Petechiae | 3 | 3 | | | 3 | 3 | | |
| Photosensitivity reaction | 1 | 1 | | | | | 1 | 1 |
| Pityriasis | 1 | 1 | | | 1 | 1 | | |
| Pityriasis rosea | | 1 | | | | 1 | | |
| Pruritus | 69 | 97 | 1 | 1 | 15 | 39 | 54 | 58 |
| Psoriasis | 1 | 1 | | | | | 1 | 1 |
| Purpura | 1 | 1 | | | | | 1 | 1 |
| Rash | 72 | 98 | 2 | 2 | 15 | 38 | 57 | 60 |
| Rash erythematous | 6 | 9 | | | 1 | 4 | 5 | 5 |
| Rash macular | 2 | 2 | | | 1 | 1 | 1 | 1 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Rash morbilliform | 1 | 1 | | | 1 | 1 | | |
| Rash pruritic | 11 | 12 | | | 2 | 3 | 9 | 9 |
| Rash vesicular | 2 | 2 | | | 2 | 2 | | |
| Rosacea | 1 | 1 | | | 1 | 1 | | |
| Scab | 1 | 1 | | | | | 1 | 1 |
| Skin burning sensation | 1 | 1 | | | | | 1 | 1 |
| Skin discolouration | 1 | 1 | | | | | 1 | 1 |
| Skin lesion | 1 | 1 | | | | | 1 | 1 |
| Skin reaction | 5 | 7 | | | 1 | 3 | 4 | 4 |
| Skin swelling | 1 | 1 | | | | | 1 | 1 |
| Skin tightness | 1 | 1 | | | | | 1 | 1 |
| Skin warm | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Toxic skin eruption | 1 | 1 | | | | | 1 | 1 |
| Urticaria | 71 | 106 | | | 12 | 43 | 59 | 63 |
| | 441 | 591 | 5 | 5 | 90 | 216 | 351 | 375 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Immobile | 1 | 1 | | | 1 | 1 |
| Loss of personal independence in daily activities | 3 | 3 | 2 | 2 | 1 | 1 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Arteriosclerosis | | 1 | | | | | | | 1 |
| Blood pressure fluctuation | 2 | 2 | | | 1 | 1 | 1 | 1 | 1 |
| Circulatory collapse | 1 | 2 | | | | | 1 | 2 | 2 |
| Cyanosis | 4 | 4 | | | 1 | 1 | 3 | 3 | 3 |
| Deep vein thrombosis | 2 | 3 | | | | | 2 | 3 | 3 |
| Diastolic hypotension | 1 | 1 | | | | | 1 | 1 | 1 |
| Flushing | 20 | 30 | | | 5 | 15 | 15 | 15 | 15 |
| Haematoma | | 1 | | | | 1 | | | |
| Hot flush | 14 | 22 | | | 2 | 10 | 12 | 12 | 12 |
| Hyperaemia | 2 | 2 | | | | | 2 | 2 | 2 |
| Hypertension | 40 | 46 | | | 5 | 7 | 35 | 39 | 39 |
| Hypertensive crisis | 45 | 52 | | | | | 45 | 52 | 52 |
| Hypotension | 42 | 53 | 1 | 1 | 9 | 17 | 33 | 36 | 36 |
| Hypotensive crisis | 3 | 3 | | | | | 3 | 3 | 3 |
| Lymphoedema | 4 | 5 | | | 2 | 3 | 2 | 2 | 2 |
| Orthostatic hypotension | 1 | 1 | | | 1 | 1 | | | |
| Pallor | 7 | 10 | | | 1 | 4 | 6 | 6 | 6 |
| Peripheral coldness | 4 | 9 | 1 | 1 | 2 | 7 | 2 | 2 | 2 |
| Peripheral venous disease | 1 | 1 | | | 1 | 1 | | | |
| Systolic hypertension | | 1 | | | | | | | 1 |
| Thrombophlebitis superficial | 1 | 1 | | | | | 1 | 1 | 1 |
| Vascular rupture | 1 | 1 | | | | | 1 | 1 | 1 |
| Vasculitis | 1 | 1 | | | | | 1 | 1 | 1 |
| Vasoconstriction | 3 | 4 | | | | 1 | 3 | 3 | 3 |
| Vasodilatation | 1 | 1 | | | | | 1 | 1 | 1 |
| Venous thrombosis limb | 1 | 1 | | | | | 1 | 1 | 1 |
| | 201 | 258 | 2 | 2 | 30 | 69 | 171 | 189 | |

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Country Where Event Occurred
JAPAN

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Mouth haemorrhage | 1 | 1 | 1 | 1 | | |
| Oral discomfort | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chills | 1 | 1 | 1 | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Swelling | 1 | 1 | 1 | 1 | | |
| | 9 | 9 | 8 | 8 | 1 | 1 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 2 | 2 | 1 | 1 | 1 | 1 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Brain oedema | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 1 | 1 | 4 | 4 |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortion | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Affect lability | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Respiratory distress | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dermatitis allergic | 1 | 1 | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 |
| Urticaria | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

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System Organ Class

Surgical and medical procedures

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hospitalisation | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Haemorrhage | 1 | 1 | 1 | 1 |
| Pallor | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

JORDAN

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 2 | 2 | 2 | 2 |
| Vaccination site pain | 2 | 2 | 2 | 2 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle spasms | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Headache | 1 | 1 | 1 | 1 |
| Taste disorder | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

KUWAIT

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Fatigue | | 1 | | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Swelling | | 1 | | 1 | | |
| Tenderness | 1 | 2 | 1 | 2 | | |
| Vaccination site pain | | 1 | | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| | 3 | 9 | 2 | 8 | 1 | 1 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| COVID-19 | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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* AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Myalgia | | 1 | | 1 |
| Neck pain | | 1 | | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| | 1 | 3 | 1 | 3 |

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Country Where Event Occurred

LATVIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenitis | 1 | 2 | | 1 | 1 | 1 |
| Lymphadenopathy | 7 | 7 | 6 | 6 | 1 | 1 |
| Lymph node pain | 5 | 6 | 3 | 3 | 2 | 3 |
| | 13 | 15 | 9 | 10 | 4 | 5 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Atrial fibrillation | 1 | 1 | 1 | 1 |
| Bradycardia | 1 | 1 | 1 | 1 |
| Extrasystoles | 1 | 1 | 1 | 1 |
| Palpitations | 3 | 3 | 3 | 3 |
| Tachycardia | 4 | 4 | 4 | 4 |
| | 10 | 10 | 10 | 10 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Hypoacusis | 1 | 1 | 1 | 1 | | |
| Vertigo | 3 | 3 | 3 | 3 | | |
| | 6 | 6 | 4 | 4 | 2 | 2 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal sensation in eye | 1 | 1 | 1 | 1 | | |
| Blepharitis | 1 | 1 | 1 | 1 | | |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Eye pain | 8 | 9 | 8 | 9 | | |
| Photophobia | 2 | 2 | 1 | 1 | 1 | 1 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| | 14 | 15 | 11 | 12 | 3 | 3 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 4 | 4 | 4 | 4 | | |
| Abdominal pain upper | 2 | 2 | | | 2 | 2 |
| Diarrhoea | 4 | 5 | 4 | 5 | | |
| Dry mouth | 1 | 2 | 1 | 1 | | 1 |
| Nausea | 14 | 15 | 13 | 14 | 1 | 1 |
| Palatal swelling | | 1 | | 1 | | |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Vomiting | 5 | 6 | 4 | 5 | 1 | 1 |
| | 31 | 36 | 26 | 30 | 5 | 6 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 12 | 16 | 9 | 12 | 3 | 4 |
| Chest pain | 1 | 2 | 1 | 2 | | |
| Chills | 30 | 31 | 30 | 31 | | |
| Condition aggravated | | 1 | | 1 | | |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 3 | | | 1 | 3 |
| Fatigue | 36 | 39 | 29 | 32 | 7 | 7 |
| Feeling hot | | 1 | | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Illness | | 2 | | 2 | | |
| Malaise | 2 | 3 | 2 | 3 | | |
| Pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Pyrexia | 45 | 49 | 40 | 43 | 5 | 6 |
| Thirst | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site discolouration | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 6 | 7 | 4 | 5 | 2 | 2 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 2 | 2 | | | 2 | 2 |
| Vaccination site oedema | 5 | 6 | 4 | 4 | 1 | 2 |
| Vaccination site pain | 44 | 50 | 40 | 46 | 4 | 4 |
| Vaccination site pruritus | 2 | 4 | 1 | 3 | 1 | 1 |
| Vaccination site rash | 2 | 2 | | | 2 | 2 |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vaccination site warmth | 2 | 2 | 1 | 1 | 1 | 1 |
| | 201 | 232 | 167 | 193 | 34 | 39 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Bacille Calmette-Guerin scar reactivation | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | | 4 | | 2 | | 2 |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| | 1 | 5 | 1 | 3 | | 2 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Exposure during pregnancy | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure decreased | | 1 | | 1 | | |
| Blood pressure increased | 1 | 3 | | 1 | 1 | 2 |
| Body temperature increased | 33 | 39 | 33 | 38 | | 1 |
| C-reactive protein increased | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 1 | 2 | | | 1 | 2 |
| | 36 | 46 | 34 | 41 | 2 | 5 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Decreased appetite | 4 | 4 | 4 | 4 |
| Increased appetite | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 28 | 33 | 25 | 29 | 3 | 4 |
| Back pain | 2 | 2 | 2 | 2 | | |
| Bone pain | 2 | 2 | 2 | 2 | | |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 4 | 4 | 2 | 2 | 2 | 2 |
| Musculoskeletal discomfort | 1 | 2 | 1 | 2 | | |
| Musculoskeletal stiffness | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 32 | 36 | 28 | 32 | 4 | 4 |
| Neck pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain in extremity | 3 | 6 | 3 | 5 | | 1 |
| | 78 | 91 | 66 | 77 | 12 | 14 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Burning sensation | 2 | 3 | | | 2 | 3 |
| Coordination abnormal | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 6 | 6 | 3 | 3 | 3 | 3 |
| Dizziness | 13 | 14 | 10 | 11 | 3 | 3 |
| Dysgeusia | 2 | 3 | 1 | 1 | 1 | 2 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Headache | 41 | 46 | 36 | 39 | 5 | 7 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Hyperaesthesia | 3 | 3 | 2 | 2 | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Mental impairment | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Neuralgia | | 1 | | | | 1 |
| Paraesthesia | 3 | 4 | 1 | 1 | 2 | 3 |
| Peripheral sensory neuropathy | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Somnolence | 8 | 8 | 6 | 6 | 2 | 2 |
| Syncope | 1 | 2 | | | 1 | 2 |
| Tunnel vision | 1 | 1 | | | 1 | 1 |
| | 89 | 100 | 61 | 65 | 28 | 35 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | | 1 | | | | 1 |
| Bradyphrenia | 1 | 1 | 1 | 1 | | |
| Depressed mood | 1 | 1 | 1 | 1 | | |
| Depression | 1 | 1 | 1 | 1 | | |
| Insomnia | 2 | 2 | 1 | 1 | 1 | 1 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Sleep disorder due to general medical condition, insomnia type | 1 | 1 | 1 | 1 | | |
| | 7 | 8 | 6 | 6 | 1 | 2 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma | | 1 | | 1 | | |
| Cough | 4 | 5 | 4 | 5 | | |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 2 | 3 | | 1 | 2 | 2 |
| Epistaxis | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nasal oedema | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 6 | 6 | 5 | 5 | 1 | 1 |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Throat irritation | 3 | 4 | 3 | 4 | | |
| Upper respiratory tract congestion | 1 | 1 | 1 | 1 | | |
| | 21 | 25 | 17 | 21 | 4 | 4 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cold sweat | | 1 | | | | 1 |
| Erythema | 1 | 2 | 1 | 1 | | 1 |
| Hyperhidrosis | 6 | 6 | 5 | 5 | 1 | 1 |
| Night sweats | | 1 | | 1 | | |
| Pruritus | 1 | 2 | | | 1 | 2 |
| Rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 2 | 2 | 2 | 2 | | |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Skin tightness | 1 | 1 | | | 1 | 1 |
| | 15 | 19 | 10 | 11 | 5 | 8 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hot flush | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypertensive crisis | 2 | 2 | | | 2 | 2 |
| Peripheral coldness | | 2 | | 1 | | 1 |
| | 5 | 7 | 2 | 3 | 3 | 4 |

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Country Where Event Occurred

LEBANON

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Angioedema | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

LITHUANIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 3 | 3 | 2 | 2 | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Tachycardia | | 1 | | 1 | | |
| | 1 | 2 | | 1 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 3 | | 2 | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | 1 | 1 | | |
| Nausea | 2 | 3 | | 1 | 2 | 2 |
| Vomiting | 3 | 3 | 1 | 1 | 2 | 2 |
| | 10 | 13 | 4 | 7 | 6 | 6 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 2 | 3 | | 1 | 2 | 2 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 3 | 1 | 3 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Feeling drunk | | 1 | | 1 | | |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Local reaction | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 2 | | 1 | 1 | 1 |
| Pyrexia | 2 | 8 | 2 | 8 | | |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 2 | 3 | 1 | 2 | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 4 | 7 | 3 | 6 | 1 | 1 |
| Vaccination site swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site warmth | 2 | 2 | 1 | 1 | 1 | 1 |
| | 26 | 41 | 13 | 28 | 13 | 13 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactic reaction | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accidental overdose | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Overdose | | 1 | | 1 | | |
| Product preparation issue | 1 | 1 | | | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Underdose | | 1 | | 1 | | |
| Vaccination complication | | 1 | | 1 | | |
| | 5 | 8 | 3 | 6 | 2 | 2 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 5 | | 1 | 4 | 4 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| | 9 | 10 | 2 | 3 | 7 | 7 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 4 | 2 | 4 | | |
| Back pain | | 1 | | 1 | | |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 6 | 1 | 6 | | |
| Myositis | 1 | 1 | 1 | 1 | | |
| Neck pain | | 1 | | 1 | | |
| Pain in extremity | 2 | 4 | 2 | 4 | | |
| Polymyositis | 1 | 1 | | | 1 | 1 |
| Tendon pain | 1 | 1 | 1 | 1 | | |
| | 10 | 21 | 9 | 20 | 1 | 1 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 3 | | 2 | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Headache | 5 | 9 | 2 | 6 | 3 | 3 |
| Hypoaesthesia | 5 | 6 | 4 | 5 | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Taste disorder | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 4 | 1 | 2 | 2 | 2 |
| | 22 | 30 | 8 | 16 | 14 | 14 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Stress | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dyspnoea | 3 | 3 | 1 | 1 | 2 | 2 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | | 1 | | 1 | | |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Sensitive skin | | 1 | | 1 | | |
| Skin mass | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | 1 | 3 | 2 | 2 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

LUXEMBOURG

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 |
| Diarrhoea | 2 | 2 | 2 | 2 |
| Dry mouth | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Tongue ulceration | 1 | 1 | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 |
| | 7 | 7 | 7 | 7 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chills | 3 | 3 | | | 3 | 3 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 6 | 6 | | | 6 | 6 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | | | 1 | 1 |
| Pyrexia | 3 | 3 | | | 3 | 3 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 2 | | | 2 | 2 |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| | 22 | 22 | 1 | 1 | 21 | 21 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Herpes zoster | | 1 | | 1 | | |
| Influenza | 1 | 1 | 1 | 1 | | |
| Oral herpes | | 1 | | 1 | | |
| Sepsis | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | 1 | 3 | 2 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chillblains | 1 | 1 | 1 | 1 | | |
| Vaccination complication | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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 * AE=Adverse Event
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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Heart rate increased | 1 | 1 | 1 | 1 |
| Pulse abnormal | 1 | 1 | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Decreased appetite | 1 | 1 | 1 | 1 |
| Feeding disorder | 1 | 1 | 1 | 1 |
| Hypernatraemia | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 4 | 4 | | | 4 | 4 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 2 | | | 2 | 2 |
| | 9 | 9 | 1 | 1 | 8 | 8 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Altered state of consciousness | 1 | 1 | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 |
| Epilepsy | 1 | 1 | 1 | 1 |
| Headache | 5 | 5 | 5 | 5 |
| Loss of consciousness | 1 | 1 | 1 | 1 |
| Migraine | 1 | 1 | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 |
| Presyncope | 1 | 1 | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 |
| | 15 | 15 | 15 | 15 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Insomnia | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Acute kidney injury | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dyspnoea | 1 | 1 | 1 | 1 |
| Dyspnoea exertional | 1 | 1 | 1 | 1 |
| Lung disorder | 1 | 1 | 1 | 1 |
| Pulmonary pain | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dry skin | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 |
| Rash | 1 | 1 | 1 | 1 |
| Skin haemorrhage | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hypotension | 1 | 1 | 1 | 1 |
| Pallor | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

MALTA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Palpitations | 1 | 2 | | 1 | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 2 | | | 1 | 2 |
| | 3 | 5 | | 1 | 3 | 4 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | 2 | 2 | | |
| Defaecation urgency | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 3 | 1 | 2 | 1 | 1 |
| Nausea | 2 | 4 | 1 | 3 | 1 | 1 |
| Vomiting | 2 | 3 | 1 | 2 | 1 | 1 |
| | 9 | 13 | 6 | 10 | 3 | 3 |

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* AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Administration site movement impairment | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Chills | 2 | 3 | 2 | 3 | | |
| Drug ineffective | | 1 | | | | 1 |
| Fatigue | 7 | 9 | 5 | 7 | 2 | 2 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Injection site pain | | 1 | | 1 | | |
| Malaise | 3 | 4 | 3 | 4 | | |
| Pain | 4 | 5 | 4 | 5 | | |
| Pyrexia | 7 | 8 | 5 | 6 | 2 | 2 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 6 | 7 | 6 | 7 | | |
| Vaccination site urticaria | 1 | 2 | | 1 | 1 | 1 |
| | 36 | 46 | 30 | 39 | 6 | 7 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactic reaction | 3 | 4 | 3 | 4 |
| Hypersensitivity | | 1 | | 1 |
| | 3 | 5 | 3 | 5 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| COVID-19 | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Off label use | | 1 | | 1 |
| Overdose | 1 | 1 | 1 | 1 |
| Product administered at inappropriate site | | 1 | | 1 |
| Product use issue | | 1 | | 1 |
| | 1 | 4 | 1 | 4 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Decreased appetite | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Limb discomfort | 3 | 3 | 2 | 2 | 1 | 1 |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 3 | 5 | 2 | 4 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 6 | 6 | 4 | 4 | 2 | 2 |
| | 17 | 19 | 13 | 15 | 4 | 4 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Facial paralysis | 2 | 3 | | | 2 | 3 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Hypoesthesia | 2 | 3 | 1 | 2 | 1 | 1 |
| Lethargy | 2 | 5 | 2 | 5 | | |
| Paraesthesia | 3 | 5 | 3 | 5 | | |
| Somnolence | 1 | 2 | 1 | 2 | | |
| Syncope | 2 | 2 | | | 2 | 2 |
| | 16 | 25 | 9 | 17 | 7 | 8 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fear of injection | 1 | 1 | 1 | 1 |
| Insomnia | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma | 1 | 2 | | | 1 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 2 | | | 1 | 2 |
| | 12 | 15 | 2 | 2 | 10 | 13 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | 1 | 2 | | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash erythematous | 2 | 3 | | 1 | 2 | 2 |
| Rash pruritic | | 1 | | | | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| | 8 | 11 | 2 | 4 | 6 | 7 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Hot flush | 1 | 2 | 1 | 2 | | |
| Hypertension | 1 | 2 | | | 1 | 2 |
| | 3 | 5 | 1 | 2 | 2 | 3 |

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Country Where Event Occurred

MEXICO

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 31 | 34 | 27 | 30 | 4 | 4 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Lymphopenia | | 1 | | | | 1 |
| Thrombocytopenic purpura | 1 | 1 | 1 | 1 | | |
| | 33 | 37 | 29 | 32 | 4 | 5 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | | 1 | | | | 1 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Bradycardia | 3 | 3 | | | 3 | 3 |
| Palpitations | 4 | 5 | 4 | 5 | | |
| Sinus tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Tachyarrhythmia | 1 | 1 | 1 | 1 | | |
| Tachycardia | 185 | 196 | 151 | 161 | 34 | 35 |
| | 198 | 211 | 157 | 168 | 41 | 43 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Auricular swelling | 1 | 1 | 1 | 1 | | |
| Deafness | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 3 | 3 | 3 | 3 | | |
| Ear disorder | 1 | 1 | 1 | 1 | | |
| Ear pain | 3 | 4 | 3 | 4 | | |
| External ear inflammation | 1 | 1 | 1 | 1 | | |
| Tinnitus | 4 | 4 | 4 | 4 | | |
| Tympanic membrane disorder | 1 | 1 | 1 | 1 | | |
| Vertigo | 9 | 10 | 6 | 7 | 3 | 3 |
| | 25 | 27 | 20 | 22 | 5 | 5 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blindness | 1 | 1 | | | 1 | 1 |
| Conjunctival hyperaemia | 1 | 1 | 1 | 1 | | |
| Eye disorder | 1 | 1 | 1 | 1 | | |
| Eye inflammation | | 1 | | 1 | | |
| Eye irritation | 4 | 4 | 4 | 4 | | |
| Eyelid oedema | 3 | 3 | 3 | 3 | | |
| Eyelid rash | 1 | 1 | 1 | 1 | | |
| Eye movement disorder | 1 | 1 | | | 1 | 1 |
| Eye pain | 8 | 9 | 8 | 9 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Eye swelling | | 2 | | 1 | | 1 |
| Foreign body sensation in eyes | 1 | 1 | 1 | 1 | | |
| Lacrimation increased | 3 | 3 | 3 | 3 | | |
| Metamorphopsia | 1 | 1 | 1 | 1 | | |
| Ocular discomfort | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Photopsia | 1 | 1 | 1 | 1 | | |
| Vision blurred | 12 | 12 | 10 | 10 | 2 | 2 |
| | 42 | 46 | 38 | 41 | 4 | 5 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 59 | 63 | 53 | 57 | 6 | 6 |
| Abdominal pain upper | 1 | 3 | | 2 | 1 | 1 |
| Abnormal faeces | 1 | 1 | | | 1 | 1 |
| Bowel movement irregularity | 1 | 1 | 1 | 1 | | |
| Colitis | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 66 | 72 | 56 | 61 | 10 | 11 |
| Dry mouth | 7 | 7 | 4 | 4 | 3 | 3 |
| Dysphagia | 6 | 6 | 5 | 5 | 1 | 1 |
| Epigastric discomfort | | 1 | | 1 | | |
| Gastrointestinal disorder | | 1 | | | | 1 |
| Gastrointestinal motility disorder | | 1 | | 1 | | |
| Haematochezia | 3 | 3 | | | 3 | 3 |
| Hypoaesthesia oral | 6 | 6 | 5 | 5 | 1 | 1 |
| Intussusception | 2 | 2 | | | 2 | 2 |
| Lip oedema | 2 | 3 | 2 | 3 | | |
| Mouth haemorrhage | 1 | 1 | | | 1 | 1 |
| Nausea | 177 | 194 | 154 | 168 | 23 | 26 |
| Odynophagia | 24 | 24 | 19 | 19 | 5 | 5 |
| Oral dysaesthesia | 1 | 1 | 1 | 1 | | |
| Paraesthesia oral | 6 | 8 | 5 | 6 | 1 | 2 |
| Parotid gland enlargement | | 1 | | 1 | | |
| Salivary hypersecretion | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 3 | 3 | 2 | 2 | 1 | 1 |
| Toothache | 1 | 1 | 1 | 1 | | |
| Vomiting | 64 | 68 | 54 | 57 | 10 | 11 |
| | 433 | 473 | 363 | 396 | 70 | 77 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Asthenia | 257 | 280 | 228 | 249 | 29 | 31 |
| Axillary pain | 2 | 2 | 2 | 2 | | |
| Chest discomfort | 7 | 8 | 6 | 7 | 1 | 1 |
| Chest pain | 37 | 38 | 32 | 33 | 5 | 5 |
| Chills | 201 | 216 | 174 | 189 | 27 | 27 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Crying | 10 | 10 | 9 | 9 | 1 | 1 |
| Decreased activity | 1 | 1 | 1 | 1 | | |
| Discharge | 1 | 1 | 1 | 1 | | |
| Discomfort | 13 | 20 | 11 | 18 | 2 | 2 |
| Disease recurrence | 2 | 2 | 2 | 2 | | |
| Drug ineffective | 10 | 20 | | | 10 | 20 |
| Face oedema | 2 | 3 | 2 | 3 | | |
| Fatigue | 210 | 216 | 186 | 192 | 24 | 24 |
| Feeling abnormal | 2 | 2 | | | 2 | 2 |
| Feeling cold | 2 | 3 | 2 | 3 | | |
| Feeling hot | 5 | 7 | 2 | 4 | 3 | 3 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| General physical health deterioration | 6 | 6 | 6 | 6 | | |
| Hunger | 1 | 1 | 1 | 1 | | |
| Hyperpyrexia | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 3 | 3 | 3 | 3 | | |
| Hypothermia | 3 | 3 | | | 3 | 3 |
| Induration | 42 | 42 | 38 | 38 | 4 | 4 |
| Inflammation | 45 | 47 | 38 | 39 | 7 | 8 |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Irritability postvaccinal | 2 | 2 | 2 | 2 | | |
| Localised oedema | 1 | 1 | 1 | 1 | | |
| Local reaction | 27 | 29 | 24 | 26 | 3 | 3 |
| Malaise | 28 | 28 | 23 | 23 | 5 | 5 |
| Mass | 1 | 1 | 1 | 1 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nodule | 50 | 51 | 44 | 45 | 6 | 6 |
| Oedema | 78 | 85 | 62 | 69 | 16 | 16 |
| Oedema peripheral | 3 | 3 | 3 | 3 | | |
| Pain | 246 | 260 | 219 | 232 | 27 | 28 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pyrexia | 162 | 193 | 143 | 173 | 19 | 20 |
| Secretion discharge | 1 | 1 | 1 | 1 | | |
| Sensation of foreign body | 3 | 3 | 2 | 2 | 1 | 1 |
| Swelling | 3 | 4 | 2 | 3 | 1 | 1 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Tenderness | 4 | 4 | 4 | 4 | | |
| Thirst | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site discomfort | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 5 | 7 | 4 | 6 | 1 | 1 |
| Vaccination site hyperaesthesia | 1 | 2 | 1 | 2 | | |
| Vaccination site hypersensitivity | 18 | 19 | 18 | 19 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 14 | 16 | 11 | 13 | 3 | 3 |
| Vaccination site inflammation | 6 | 7 | 6 | 7 | | |
| Vaccination site joint pain | | 1 | | 1 | | |
| Vaccination site movement impairment | 2 | 2 | 2 | 2 | | |
| Vaccination site nodule | 8 | 11 | 7 | 10 | 1 | 1 |
| Vaccination site oedema | 7 | 8 | 6 | 7 | 1 | 1 |
| Vaccination site pain | 92 | 133 | 87 | 127 | 5 | 6 |
| Vaccination site paraesthesia | 3 | 3 | 3 | 3 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site rash | | 1 | | 1 | | |
| Vaccination site reaction | 10 | 11 | 9 | 10 | 1 | 1 |
| Vaccination site warmth | 7 | 8 | 7 | 8 | | |
| | 1,657 | 1,838 | 1445 | 1610 | 212 | 228 |

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System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deficiency of bile secretion | 1 | 1 | | | 1 | 1 |
| Hepatic pain | 1 | 1 | 1 | 1 | | |
| Hyperbilirubinaemia | 1 | 1 | | | 1 | 1 |
| Jaundice | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 4 | 7 | 3 | 6 | 1 | 1 |
| Anaphylactic reaction | 7 | 8 | | | 7 | 8 |
| Anaphylactic shock | 19 | 20 | | | 19 | 20 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Decreased immune responsiveness | 1 | 1 | 1 | 1 | | |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 22 | 25 | 16 | 19 | 6 | 6 |
| Sensitisation | 2 | 2 | 2 | 2 | | |
| | 57 | 65 | 22 | 28 | 35 | 37 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Atypical pneumonia | 1 | 1 | | | 1 | 1 |
| Cellulitis | 10 | 10 | | | 10 | 10 |
| Conjunctivitis | 3 | 3 | 3 | 3 | | |
| COVID-19 | 14 | 20 | 3 | 4 | 11 | 16 |
| COVID-19 pneumonia | 1 | 4 | | | 1 | 4 |
| Disseminated Bacillus Calmette-Guerin infection | 1 | 1 | | | 1 | 1 |
| Ear infection | 2 | 2 | 2 | 2 | | |
| Influenza | 2 | 2 | 2 | 2 | | |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 3 | 3 | 2 | 2 | 1 | 1 |
| Otitis externa | 1 | 1 | 1 | 1 | | |
| Otitis media acute | 1 | 1 | 1 | 1 | | |
| Parotitis | | 1 | | 1 | | |
| Pharyngitis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 8 | 11 | | | 8 | 11 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Suspected COVID-19 | 3 | 4 | 3 | 3 | | 1 |
| Sweating fever | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 1 | 1 | 1 | | |
| Vaccination site cellulitis | 1 | 1 | 1 | 1 | | |
| | 58 | 72 | 20 | 22 | 38 | 50 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Expired product administered | 1 | 1 | 1 | 1 | | |
| Eye injury | 10 | 10 | 7 | 7 | 3 | 3 |
| Inappropriate schedule of product administration | 2 | 3 | 2 | 3 | | |
| Incomplete course of vaccination | 1 | 1 | 1 | 1 | | |
| Maternal exposure during pregnancy | 5 | 6 | 5 | 6 | | |
| Occupational exposure to SARS-CoV-2 | 1 | 1 | 1 | 1 | | |
| Off label use | 4 | 6 | 4 | 6 | | |
| Peroneal nerve injury | | 1 | | | | 1 |
| Product use issue | 4 | 6 | 4 | 6 | | |
| Traumatic lung injury | 2 | 2 | 2 | 2 | | |
| | 30 | 37 | 27 | 33 | 3 | 4 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood glucose decreased | | 1 | | | | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure diastolic increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 15 | 16 | 9 | 9 | 6 | 7 |
| Body temperature decreased | 1 | 1 | 1 | 1 | | |
| Body temperature fluctuation | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 42 | 46 | 36 | 40 | 6 | 6 |
| Coagulation time prolonged | | 1 | | | | 1 |
| General physical condition abnormal | 1 | 1 | | | 1 | 1 |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 5 | 5 | 4 | 4 | 1 | 1 |
| Oxygen saturation abnormal | 4 | 4 | 2 | 2 | 2 | 2 |
| Oxygen saturation decreased | 21 | 22 | 12 | 12 | 9 | 10 |
| SARS-CoV-2 ant body test negative | 3 | 3 | 3 | 3 | | |
| SARS-CoV-2 test positive | 2 | 3 | 1 | 1 | 1 | 2 |
| Transaminases increased | 2 | 2 | | | 2 | 2 |
| White blood cell count increased | | 1 | | | | 1 |
| | 101 | 111 | 71 | 75 | 30 | 36 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 32 | 34 | 26 | 28 | 6 | 6 |
| Dehydration | 1 | 2 | | | 1 | 2 |
| Electrolyte imbalance | 1 | 1 | | | 1 | 1 |
| Hypernatraemia | | 1 | | | | 1 |
| | 34 | 38 | 26 | 28 | 8 | 10 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 201 | 236 | 180 | 214 | 21 | 22 |
| Axillary mass | 1 | 1 | 1 | 1 | | |
| Back pain | 10 | 11 | 10 | 11 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | | | 1 | 1 |
| Masticatory pain | | 1 | | 1 | | |
| Mobility decreased | 3 | 6 | 3 | 6 | | |
| Muscle contracture | | 1 | | 1 | | |
| Muscle rigidity | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 1 | 4 | 1 | 3 | | 1 |
| Muscular weakness | 9 | 10 | 5 | 6 | 4 | 4 |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 233 | 266 | 208 | 240 | 25 | 26 |
| Neck pain | 2 | 3 | 2 | 3 | | |
| Pain in extremity | 17 | 20 | 15 | 18 | 2 | 2 |
| Pain in jaw | 2 | 2 | 1 | 1 | 1 | 1 |
| Sacroiliitis | | 1 | | | | 1 |
| Systemic lupus erythematosus | 1 | 1 | | | 1 | 1 |
| | 484 | 567 | 429 | 508 | 55 | 59 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 3 | 4 | 2 | 3 | 1 | 1 |
| Akathisia | | 1 | | 1 | | |
| Allodynia | 2 | 2 | 2 | 2 | | |
| Anosmia | 9 | 10 | 7 | 8 | 2 | 2 |
| Aura | 1 | 1 | | | 1 | 1 |
| Axonal neuropathy | | 1 | | | | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Brain oedema | 1 | 1 | | | 1 | 1 |
| Burning sensation | | 2 | | | | 2 |
| Demyelination | 1 | 3 | | | 1 | 3 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Diplegia | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 239 | 257 | 201 | 218 | 38 | 39 |
| Dysarthria | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 9 | 11 | 6 | 8 | 3 | 3 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Encephalitis post immunisation | | 1 | | | | 1 |
| Epilepsy | | 1 | | | | 1 |
| Facial paralysis | 4 | 4 | | | 4 | 4 |
| Febrile convulsion | 5 | 5 | 3 | 3 | 2 | 2 |
| Generalised tonic-clonic seizure | 3 | 3 | | | 3 | 3 |
| Guillain-Barre syndrome | 2 | 2 | | | 2 | 2 |
| Headache | 365 | 420 | 319 | 371 | 46 | 49 |
| Head discomfort | 2 | 2 | 2 | 2 | | |
| Hemiparaesthesia | 1 | 1 | | | 1 | 1 |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hemiplegia | 2 | 2 | | | 2 | 2 |
| Hyperaesthesia | 2 | 2 | 2 | 2 | | |
| Hypersomnia | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 16 | 19 | 9 | 11 | 7 | 8 |
| Hypokinesia | 1 | 1 | 1 | 1 | | |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hyposmia | 1 | 1 | 1 | 1 | | |
| Lateropulsion | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 5 | 6 | | | 5 | 6 |
| Mononeuropathy | 1 | 2 | | | 1 | 2 |
| Muscle contractions involuntary | 2 | 3 | 1 | 2 | 1 | 1 |
| Muscle spasticity | | 1 | | | | 1 |
| Myelitis transverse | | 1 | | | | 1 |
| Nerve degeneration | | 1 | | | | 1 |
| Neuritis | | 2 | | | | 2 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 41 | 50 | 31 | 37 | 10 | 13 |
| Paralysis | 8 | 9 | | | 8 | 9 |
| Peripheral motor neuropathy | | 1 | | | | 1 |
| Presyncope | 1 | 1 | 1 | 1 | | |
| Radiculopathy | | 2 | | | | 2 |
| Sciatica | | 1 | | | | 1 |
| Sciatic nerve neuropathy | | 1 | | | | 1 |
| Seizure | 16 | 22 | | | 16 | 22 |
| Sensory disturbance | 1 | 1 | 1 | 1 | | |
| Sensory loss | | 2 | | 1 | | 1 |
| Slow response to stimuli | | 1 | | 1 | | |
| Somnolence | 7 | 8 | 7 | 8 | | |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Syncope | 27 | 29 | | | 27 | 29 |
| Tension headache | 1 | 1 | 1 | 1 | | |
| Tremor | 7 | 7 | 7 | 7 | | |
| | 799 | 922 | 608 | 694 | 191 | 228 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Affect lability | 1 | 1 | 1 | 1 | | |
| Anxiety | 15 | 15 | 10 | 10 | 5 | 5 |
| Disorientation | 4 | 4 | 3 | 3 | 1 | 1 |
| Feeling of despair | 1 | 1 | 1 | 1 | | |
| Irritability | 20 | 20 | 17 | 17 | 3 | 3 |
| Nervousness | 3 | 3 | 3 | 3 | | |
| Sleep inertia | 1 | 1 | | | 1 | 1 |
| | 45 | 45 | 35 | 35 | 10 | 10 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Choluria | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast pain | 1 | 1 | 1 | 1 |
| Metrorrhagia | 1 | 1 | 1 | 1 |
| Pelvic pain | | 1 | | 1 |
| | 2 | 3 | 2 | 3 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma | | 1 | | 1 | | |
| Bronchial disorder | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 27 | 27 | 12 | 12 | 15 | 15 |
| Cough | 122 | 131 | 104 | 113 | 18 | 18 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dysphonia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 297 | 305 | 211 | 216 | 86 | 89 |
| Dyspnoea exertional | 4 | 4 | 4 | 4 | | |
| Epistaxis | 2 | 2 | 2 | 2 | | |
| Haemoptysis | 1 | 1 | 1 | 1 | | |
| Hypoventilation | 1 | 1 | | | 1 | 1 |
| Laryngeal oedema | 3 | 3 | | | 3 | 3 |
| Laryngospasm | 2 | 3 | | 1 | 2 | 2 |
| Nasal congestion | 6 | 7 | 6 | 7 | | |
| Obstructive airways disorder | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 6 | 6 | 3 | 3 | 3 | 3 |
| Oropharyngeal pain | 131 | 134 | 119 | 122 | 12 | 12 |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pharyngeal disorder | 1 | 1 | 1 | 1 | | |
| Pharyngeal hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Pharyngeal inflammation | 2 | 2 | | | 2 | 2 |
| Pharyngeal oedema | 2 | 2 | | | 2 | 2 |
| Pharyngeal paraesthesia | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Rales | 1 | 1 | 1 | 1 | | |
| Respiratory disorder | 1 | 1 | 1 | 1 | | |
| Respiratory distress | 291 | 293 | | | 291 | 293 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 100 | 106 | 88 | 94 | 12 | 12 |
| Sneezing | | 1 | | 1 | | |
| Suffocation feeling | 2 | 2 | 1 | 1 | 1 | 1 |
| Tachypnoea | 5 | 5 | 2 | 2 | 3 | 3 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Throat irritation | 6 | 8 | 4 | 6 | 2 | 2 |
| Throat tightness | 1 | 1 | 1 | 1 | | |
| Upper airway obstruction | 1 | 1 | | | 1 | 1 |
| Wheezing | 2 | 2 | 1 | 1 | 1 | 1 |
| | 1,027 | 1,061 | 567 | 596 | 460 | 465 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | | 2 | | | | 2 |
| Dermatosis | 1 | 1 | 1 | 1 | | |
| Erythema | 54 | 56 | 48 | 50 | 6 | 6 |
| Hyperhidrosis | 13 | 14 | 10 | 11 | 3 | 3 |
| Mechanical urticaria | | 1 | | 1 | | |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Papule | 1 | 1 | 1 | 1 | | |
| Petechiae | 2 | 2 | | | 2 | 2 |
| Prurigo | 1 | 1 | 1 | 1 | | |
| Pruritus | 59 | 64 | 49 | 53 | 10 | 11 |
| Purpura | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash | 59 | 73 | 42 | 53 | 17 | 20 |
| Rash erythematous | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash maculo-papular | 2 | 3 | 2 | 3 | | |
| Sensitive skin | 139 | 139 | 123 | 123 | 16 | 16 |
| Skin disorder | 1 | 1 | 1 | 1 | | |
| Skin haemorrhage | 1 | 1 | 1 | 1 | | |
| Skin lesion | 1 | 1 | 1 | 1 | | |
| Skin swelling | 1 | 1 | 1 | 1 | | |
| Stevens-Johnson syndrome | 2 | 2 | | | 2 | 2 |
| Urticaria | 3 | 3 | 3 | 3 | | |
| | 345 | 371 | 287 | 307 | 58 | 64 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Loss of personal independence in daily activities | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cyanosis | 2 | 3 | 2 | 3 | | |
| Flushing | 2 | 2 | 2 | 2 | | |
| Haemorrhage | 3 | 3 | | | 3 | 3 |
| Hot flush | 2 | 3 | 2 | 3 | | |
| Hypertension | 35 | 37 | 20 | 21 | 15 | 16 |
| Hypertensive crisis | 17 | 19 | | | 17 | 19 |
| Hypotension | 5 | 5 | 2 | 2 | 3 | 3 |
| Hypovolaemic shock | 2 | 2 | | | 2 | 2 |
| Pallor | 2 | 2 | 2 | 2 | | |
| Peripheral coldness | 2 | 2 | 2 | 2 | | |
| Raynaud's phenomenon | 1 | 1 | 1 | 1 | | |
| Shock | 2 | 2 | | | 2 | 2 |
| | 75 | 81 | 33 | 36 | 42 | 45 |

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Country Where Event Occurred

NETHERLANDS

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | 7 | 7 | 7 | 7 |
| Lymph node pain | 1 | 1 | 1 | 1 |
| | 8 | 8 | 8 | 8 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 3 | 3 | | | 3 | 3 |
| Bundle branch block right | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac disorder | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 5 | 5 | | | 5 | 5 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 2 | 2 | | | 2 | 2 |
| Palpitations | 2 | 3 | 1 | 1 | 1 | 2 |
| Sinus tachycardia | 1 | 1 | 1 | 1 | | |
| Supraventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 3 | 3 | 1 | 1 | 2 | 2 |
| | 25 | 26 | 4 | 4 | 21 | 22 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness neurosensory | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Hyperacusis | 1 | 1 | 1 | 1 | | |
| Sudden hearing loss | 4 | 4 | | | 4 | 4 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Vertigo | 2 | 2 | 1 | 1 | 1 | 1 |
| | 10 | 10 | 4 | 4 | 6 | 6 |

System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Pituitary apoplexy | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accommodation disorder | 1 | 1 | 1 | 1 | | |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Conjunctival oedema | 1 | 1 | | | 1 | 1 |
| Diplopia | 1 | 1 | 1 | 1 | | |
| Gaze palsy | 1 | 1 | | | 1 | 1 |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Pupillary disorder | 1 | 1 | 1 | 1 | | |
| Swelling of eyelid | 1 | 1 | | | 1 | 1 |
| Vision blurred | 3 | 3 | 3 | 3 | | |
| | 11 | 11 | 6 | 6 | 5 | 5 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 2 | 1 | 2 | | |
| Diarrhoea | 1 | 2 | 1 | 2 | | |
| Dysphagia | 4 | 5 | 1 | 1 | 3 | 4 |
| Faeces discoloured | 1 | 1 | 1 | 1 | | |
| Gastrointestinal haemorrhage | 2 | 2 | | | 2 | 2 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Nausea | 39 | 41 | 30 | 32 | 9 | 9 |
| Oral pruritus | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 2 | 3 | 1 | 2 | 1 | 1 |
| Retching | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 4 | 4 | | | 4 | 4 |
| Tongue disorder | 2 | 2 | | | 2 | 2 |
| Tongue oedema | | 1 | | | | 1 |
| Vomiting | 4 | 5 | 3 | 4 | 1 | 1 |
| | 65 | 73 | 38 | 44 | 27 | 29 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|----|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Axillary pain | | 1 | | 1 | | | |
| Chest discomfort | 1 | 2 | 1 | 1 | | | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | | |
| Chills | 31 | 33 | 26 | 27 | 5 | | 6 |
| Condition aggravated | 2 | 2 | | | 2 | | 2 |
| Death | 8 | 8 | | | 8 | | 8 |
| Drug ineffective | 1 | 1 | | | 1 | | 1 |
| Extensive swelling of vaccinated limb | 3 | 3 | 3 | 3 | | | |
| Fatigue | 33 | 34 | 23 | 24 | 10 | | 10 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | | |
| Feeling cold | 1 | 1 | 1 | 1 | | | |
| Feeling drunk | 1 | 1 | 1 | 1 | | | |
| Feeling hot | 1 | 1 | 1 | 1 | | | |
| Hyperpyrexia | 12 | 12 | | | 12 | | 12 |
| Influenza like illness | | 1 | | 1 | | | |
| Injection site erythema | 2 | 2 | 2 | 2 | | | |
| Injection site inflammation | 1 | 1 | 1 | 1 | | | |
| Injection site pain | 2 | 2 | 2 | 2 | | | |
| Injection site pruritus | 1 | 1 | 1 | 1 | | | |
| Injection site swelling | 2 | 2 | 2 | 2 | | | |
| Injection site warmth | 2 | 2 | 2 | 2 | | | |
| Malaise | 59 | 61 | 38 | 39 | 21 | | 22 |
| Pain | 1 | 1 | 1 | 1 | | | |
| Peripheral swelling | 1 | 1 | | | 1 | | 1 |
| Pyrexia | 21 | 21 | 7 | 7 | 14 | | 14 |
| Sudden cardiac death | 1 | 1 | | | 1 | | 1 |
| Sudden death | 4 | 4 | | | 4 | | 4 |
| Swelling face | 4 | 5 | 1 | 2 | 3 | | 3 |
| Vaccination site bruising | 2 | 2 | 2 | 2 | | | |
| Vaccination site erythema | 6 | 7 | 6 | 7 | | | |
| Vaccination site haematoma | 3 | 3 | 3 | 3 | | | |
| Vaccination site inflammation | 11 | 12 | 11 | 12 | | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 25 | 27 | 23 | 25 | 2 | 2 |
| Vaccination site pruritus | 1 | 2 | 1 | 2 | | |
| Vaccination site swelling | 9 | 10 | 9 | 10 | | |
| Vaccination site warmth | 10 | 11 | 10 | 11 | | |
| | 264 | 280 | 180 | 193 | 84 | 87 |

System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hepatic failure | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Allergy to vaccine | | 1 | | 1 |
| Anaphylactic reaction | 8 | 10 | 8 | 10 |
| Anaphylactic shock | 2 | 2 | 2 | 2 |
| Hypersensitivity | 5 | 5 | 5 | 5 |
| | 15 | 18 | 15 | 18 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| COVID-19 | 3 | 3 | 3 | 3 |
| Cystitis | 1 | 1 | 1 | 1 |
| Herpes ophthalmic | 1 | 1 | 1 | 1 |
| Lymphangitis | 1 | 1 | 1 | 1 |
| Nasopharyngitis | 1 | 1 | 1 | 1 |
| Pneumonia | 2 | 2 | 2 | 2 |
| Rhinitis | 1 | 1 | 1 | 1 |
| Sialoadenitis | 2 | 2 | 2 | 2 |
| Urinary tract infection | 1 | 1 | 1 | 1 |
| Vestibular neuronitis | 1 | 1 | 1 | 1 |
| | 14 | 14 | 14 | 14 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Exposure to SARS-CoV-2 | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | | 1 | | 1 | | |
| Fall | 2 | 2 | | | 2 | 2 |
| Incorrect route of product administration | | 1 | | 1 | | |
| Occupational exposure to product | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Product label confusion | | 1 | | 1 | | |
| Product preparation error | | 1 | | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| | 6 | 11 | 4 | 9 | 2 | 2 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Preferred Term | | | | | | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 | |
| Blood pressure increased | 2 | 2 | 2 | 2 | | | |
| Body temperature increased | 7 | 7 | 5 | 5 | 2 | 2 | |
| Electrocardiogram ST segment abnormal | 1 | 1 | | | 1 | 1 | |
| Heart rate decreased | 1 | 1 | 1 | 1 | | | |
| Heart rate increased | 1 | 1 | | | 1 | 1 | |
| Oxygen saturation decreased | 7 | 7 | | | 7 | 7 | |
| Weight decreased | 1 | 1 | | | 1 | 1 | |
| | 21 | 21 | 8 | 8 | 13 | 13 | |

System Organ Class

| Metabolism and nutrition disorders | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Preferred Term | | | | | | | |
| Decreased appetite | 2 | 2 | 2 | 2 | | | |
| Dehydration | 1 | 1 | | | 1 | 1 | |
| Feeding disorder | 1 | 1 | 1 | 1 | | | |
| Fluid retention | 1 | 1 | 1 | 1 | | | |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 | |
| Hyponatraemia | 1 | 1 | 1 | 1 | | | |
| | 7 | 7 | 5 | 5 | 2 | 2 | |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 14 | 14 | 14 | 14 | | |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle twitching | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 2 | 2 | 2 | 2 | | |
| Musculoskeletal disorder | 1 | 1 | 1 | 1 | | |
| Myalgia | 33 | 36 | 30 | 33 | 3 | 3 |
| Pain in extremity | 4 | 4 | 4 | 4 | | |
| Torticollis | 1 | 1 | 1 | 1 | | |
| | 57 | 60 | 52 | 55 | 5 | 5 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apallic syndrome | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Basilar artery thrombosis | 1 | 1 | | | 1 | 1 |
| Cerebral haemorrhage | 2 | 2 | | | 2 | 2 |
| Cerebral infarction | 2 | 2 | | | 2 | 2 |
| Cerebral ischaemia | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 4 | 4 | | | 4 | 4 |
| Depressed level of consciousness | 3 | 3 | | | 3 | 3 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 11 | 13 | 8 | 9 | 3 | 4 |
| Dysarthria | 1 | 1 | 1 | 1 | | |
| Epilepsy | 10 | 10 | | | 10 | 10 |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Generalised tonic-clonic seizure | 2 | 2 | | | 2 | 2 |
| Headache | 41 | 45 | 37 | 41 | 4 | 4 |
| Head discomfort | | 1 | | | | 1 |
| Hemianaesthesia | 1 | 1 | 1 | 1 | | |
| Hemiparesis | 3 | 3 | | | 3 | 3 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Ischaemic cerebral infarction | 2 | 2 | | | 2 | 2 |
| Loss of consciousness | 3 | 3 | | | 3 | 3 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Nystagmus | 1 | 1 | 1 | 1 | | |
| Paraesthesia | | 1 | | | | 1 |
| Postictal state | 1 | 1 | 1 | 1 | | |
| Presyncope | 2 | 2 | 2 | 2 | | |
| Seizure | 2 | 2 | | | 2 | 2 |
| Somnolence | 2 | 2 | 1 | 1 | 1 | 1 |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Status epilepticus | 2 | 2 | | | 2 | 2 |
| Syncope | 14 | 14 | 1 | 1 | 13 | 13 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | 4 | 4 | 4 | 4 | | |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| | 128 | 136 | 60 | 65 | 68 | 71 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | | 1 | | | | 1 |
| Confusional state | 3 | 3 | 1 | 1 | 2 | 2 |
| Derealisation | 1 | 1 | 1 | 1 | | |
| Disorganised speech | 1 | 1 | 1 | 1 | | |
| Hallucination | 1 | 1 | 1 | 1 | | |
| Mood altered | 1 | 1 | 1 | 1 | | |
| Psychotic symptom | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| | 9 | 10 | 6 | 6 | 3 | 4 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Polyuria | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Postmenopausal haemorrhage | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Choking | 1 | 1 | | | 1 | 1 |
| Choking sensation | 1 | 2 | | | 1 | 2 |
| Cough | 4 | 5 | 1 | 2 | 3 | 3 |
| Dyspnoea | 18 | 18 | 5 | 5 | 13 | 13 |
| Dyspnoea exertional | 1 | 1 | 1 | 1 | | |
| Hyperventilation | 2 | 3 | 1 | 1 | 1 | 2 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 2 | 1 | 2 | | |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pharyngeal oedema | | 1 | | | | 1 |
| Pharyngeal paraesthesia | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 5 | 6 | 1 | 1 | 4 | 5 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 1 | 1 | | | 1 | 1 |
| Sneezing | | 1 | | 1 | | |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Throat tightness | 2 | 2 | | | 2 | 2 |
| | 45 | 52 | 12 | 15 | 33 | 37 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 6 | 7 | | | 6 | 7 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| Erythema | 1 | 3 | | 1 | 1 | 2 |
| Hyperhidrosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pruritus | 2 | 3 | 1 | 1 | 1 | 2 |
| Rash | 3 | 4 | 2 | 2 | 1 | 2 |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Rash maculo-papular | | 1 | | 1 | | |
| Urticaria | 7 | 9 | 4 | 5 | 3 | 4 |
| | 25 | 33 | 11 | 14 | 14 | 19 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Bedridden | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Flushing | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hypertension | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypovolaemic shock | 1 | 1 | | | 1 | 1 |
| Pallor | 3 | 3 | | | 3 | 3 |
| Peripheral coldness | 2 | 3 | 1 | 2 | 1 | 1 |
| Thrombosis | 2 | 2 | | | 2 | 2 |
| | 18 | 19 | 5 | 6 | 13 | 13 |

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Country Where Event Occurred
NORTHERN MARIANA ISLANDS

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Chest discomfort | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Fatigue | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | | 1 | | 1 |
| Pain in extremity | | 1 | | 1 |
| | | 2 | | 2 |

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Dizziness | | 1 | | 1 |
| Headache | | 1 | | 1 |
| Poor quality sleep | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Psychiatric disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disorientation | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

NORWAY

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Leukocytosis | 1 | 1 | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute coronary syndrome | | 1 | | | | 1 |
| Acute myocardial infarction | 2 | 3 | | | 2 | 3 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 | | | 1 | 1 |
| Bradycardia | 3 | 3 | | | 3 | 3 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 2 | 3 | | | 2 | 3 |
| Cardiovascular disorder | | 1 | | | | 1 |
| Coronary artery occlusion | 1 | 1 | | | 1 | 1 |
| Intracardiac thrombus | | 1 | | | | 1 |
| Tachycardia | 4 | 4 | 2 | 2 | 2 | 2 |
| | 17 | 22 | 2 | 2 | 15 | 20 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear discomfort | 2 | 2 | 2 | 2 |
| Ear pain | 1 | 1 | 1 | 1 |
| Ear swelling | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blepharospasm | | 1 | | 1 | | |
| Eye haemorrhage | 2 | 2 | | | 2 | 2 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 2 | 2 | 1 | 1 | 1 | 1 |
| Photophobia | 2 | 2 | 2 | 2 | | |
| Pupil fixed | | 2 | | | | 2 |
| | 7 | 10 | 4 | 5 | 3 | 5 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 5 | 5 | 4 | 4 | 1 | 1 |
| Abdominal pain upper | 4 | 4 | 2 | 2 | 2 | 2 |
| Abdominal wall haemorrhage | 1 | 1 | | | 1 | 1 |
| Anal incontinence | 1 | 1 | | | 1 | 1 |
| Constipation | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 16 | 18 | 13 | 13 | 3 | 5 |
| Dry mouth | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphagia | 5 | 6 | | | 5 | 6 |
| Faeces discoloured | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastritis | 1 | 1 | 1 | 1 | | |
| Gastrointestinal haemorrhage | | 1 | | | | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 | | |
| Melaena | 1 | 1 | | | 1 | 1 |
| Nausea | 29 | 32 | 23 | 24 | 6 | 8 |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Retching | | 1 | | 1 | | |
| Vomiting | 17 | 22 | 7 | 8 | 10 | 14 |
| | 89 | 102 | 56 | 59 | 33 | 43 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Adverse reaction | 1 | 1 | 1 | 1 | | |
| Asthenia | 3 | 3 | 2 | 2 | 1 | 1 |
| Chest discomfort | | 1 | | | | 1 |
| Chest pain | 4 | 4 | 1 | 1 | 3 | 3 |
| Chills | 13 | 14 | 10 | 11 | 3 | 3 |
| Concomitant disease aggravated | | 1 | | | | 1 |
| Condition aggravated | 2 | 3 | 1 | 1 | 1 | 2 |
| Death | 17 | 25 | | | 17 | 25 |
| Decreased activity | 1 | 1 | 1 | 1 | | |
| Discomfort | 2 | 2 | 2 | 2 | | |
| Disease recurrence | 1 | 2 | | | 1 | 2 |
| Fatigue | 44 | 50 | 36 | 39 | 8 | 11 |
| Feeling abnormal | 4 | 4 | 3 | 3 | 1 | 1 |
| Feeling cold | 2 | 2 | 2 | 2 | | |
| Feeling drunk | 1 | 1 | 1 | 1 | | |
| Feeling hot | 3 | 5 | 3 | 4 | | 1 |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| General physical health deterioration | 28 | 36 | 3 | 3 | 25 | 33 |
| General symptom | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 4 | 5 | 3 | 3 | 1 | 2 |
| Injection site muscle weakness | | 1 | | 1 | | |
| Local reaction | | 1 | | | | 1 |
| Malaise | 12 | 15 | 11 | 12 | 1 | 3 |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 3 | 3 | 2 | 2 | 1 | 1 |
| Pain | 7 | 7 | 5 | 5 | 2 | 2 |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pyrexia | 43 | 49 | 22 | 24 | 21 | 25 |
| Secretion discharge | 1 | 1 | | | 1 | 1 |
| Sudden death | 3 | 5 | | | 3 | 5 |
| Swelling face | 1 | 1 | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Terminal state | 2 | 2 | | | 2 | 2 |
| Thirst | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 5 | 6 | 5 | 5 | | 1 |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 16 | 19 | 15 | 17 | 1 | 2 |
| Vaccination site paraesthesia | 2 | 2 | 2 | 2 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 3 | 1 | 2 | | 1 |
| Vaccination site warmth | 2 | 2 | 2 | 2 | | |
| | 238 | 287 | 142 | 154 | 96 | 133 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 5 | 5 | | | 5 | 5 |
| Hypersensitivity | 3 | 4 | 2 | 2 | 1 | 2 |
| | 8 | 9 | 2 | 2 | 6 | 7 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacterial sepsis | 1 | 1 | | | 1 | 1 |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Diverticulitis | 1 | 1 | | | 1 | 1 |
| Gastroenteritis | 1 | 1 | | | 1 | 1 |
| Infection | 6 | 7 | 1 | 1 | 5 | 6 |
| Infective exacerbation of chronic obstructive airways disease | 1 | 1 | | | 1 | 1 |
| Influenza | 2 | 2 | 2 | 2 | | |
| Lower respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Pneumonia | 10 | 13 | | | 10 | 13 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 2 | 3 | 2 | 3 | | |
| | 31 | 36 | 7 | 8 | 24 | 28 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Concussion | 1 | 1 | | | 1 | 1 |
| Fall | 7 | 7 | 2 | 2 | 5 | 5 |
| Femoral neck fracture | 1 | 1 | | | 1 | 1 |
| Fracture | 1 | 1 | | | 1 | 1 |
| Frostbite | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect dose administered | | 1 | | 1 | | |
| Incorrect route of product administration | 2 | 2 | 2 | 2 | | |
| Intercepted product preparation error | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | | 6 | | 6 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product preparation error | | 2 | | 2 | | |
| Skin laceration | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 16 | 27 | 6 | 17 | 10 | 10 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacterial test positive | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 3 | 5 | 1 | 1 | 2 | 4 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature decreased | | 1 | | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| C-reactive protein increased | 15 | 15 | 4 | 4 | 11 | 11 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 6 | 8 | 2 | 2 | 4 | 6 |
| Heart rate irregular | 1 | 2 | | 1 | 1 | 1 |
| International normalised ratio increased | 1 | 1 | | | 1 | 1 |
| Nitrite urine present | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 7 | 10 | 1 | 1 | 6 | 9 |
| Respiratory rate decreased | 1 | 1 | 1 | 1 | | |
| Respiratory rate increased | 2 | 5 | 2 | 2 | | 3 |
| White blood cell count increased | 1 | 1 | | | 1 | 1 |
| | 42 | 56 | 14 | 18 | 28 | 38 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 9 | 11 | 4 | 4 | 5 | 7 |
| Dehydration | 1 | 1 | | | 1 | 1 |
| Food refusal | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hyperkalaemia | 1 | 1 | | | 1 | 1 |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypophagia | 1 | 2 | | | 1 | 2 |
| Malnutrition | 1 | 1 | | | 1 | 1 |
| | 16 | 19 | 4 | 4 | 12 | 15 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 5 | 6 | 5 | 6 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Back pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 3 | 3 | 1 | 1 | 2 | 2 |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal stiffness | 4 | 4 | 4 | 4 | | |
| Myalgia | 13 | 13 | 11 | 11 | 2 | 2 |
| Neck pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Pain in extremity | 5 | 6 | 4 | 5 | 1 | 1 |
| Tendon pain | 1 | 1 | 1 | 1 | | |
| | 44 | 46 | 36 | 38 | 8 | 8 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Metastases to peritoneum | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Altered state of consciousness | 6 | 6 | | | 6 | 6 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Burning sensation | | 1 | | | | 1 |
| Cerebral haemorrhage | 2 | 3 | | | 2 | 3 |
| Cerebral infarction | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 7 | 9 | | | 7 | 9 |
| Cerebrovascular disorder | 1 | 1 | | | 1 | 1 |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Coordination abnormal | | 1 | | | | 1 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 3 | 5 | | | 3 | 5 |
| Dizziness | 11 | 13 | 8 | 9 | 3 | 4 |
| Drooling | 1 | 1 | 1 | 1 | | |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysgeusia | 2 | 2 | 2 | 2 | | |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Facial paresis | 2 | 2 | | | 2 | 2 |
| Headache | 33 | 35 | 29 | 31 | 4 | 4 |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 2 | 2 | 2 | 2 | | |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Ischaemic stroke | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | 3 | 4 | | | 3 | 4 |
| Motor dysfunction | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Presyncope | 4 | 4 | | | 4 | 4 |
| Psychomotor hyperactivity | 1 | 1 | 1 | 1 | | |
| Somnolence | 7 | 9 | 5 | 5 | 2 | 4 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Speech disorder | 3 | 3 | 2 | 2 | 1 | 1 |
| Syncope | 9 | 11 | | | 9 | 11 |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | 1 | 2 | | | 1 | 2 |
| Unresponsive to stimuli | 3 | 3 | | | 3 | 3 |
| | 123 | 140 | 54 | 57 | 69 | 83 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product temperature excursion issue | | 6 | | 6 |
| | | 6 | | 6 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | 1 | 2 | | 1 | 1 | 1 |
| Apathy | | 1 | | | | 1 |
| Communication disorder | 1 | 1 | 1 | 1 | | |
| Confusional state | 11 | 14 | 5 | 5 | 6 | 9 |
| Delirium | 1 | 2 | | | 1 | 2 |
| Hallucination | 2 | 3 | | | 2 | 3 |
| Listless | 1 | 1 | 1 | 1 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Restlessness | 5 | 6 | 1 | 2 | 4 | 4 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| | 24 | 32 | 10 | 12 | 14 | 20 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Acute kidney injury | | 1 | | 1 |
| Chronic kidney disease | 1 | 1 | 1 | 1 |
| Urinary incontinence | 1 | 1 | 1 | 1 |
| Urinary retention | 1 | 1 | 1 | 1 |
| | 3 | 4 | 3 | 4 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast enlargement | 1 | 1 | 1 | 1 |
| Breast pain | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apnoea | 2 | 2 | | | 2 | 2 |
| Aspiration | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Cough | 9 | 10 | 6 | 6 | 3 | 4 |
| Dysphonia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 26 | 30 | 8 | 8 | 18 | 22 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Hyperventilation | 2 | 4 | 2 | 3 | | 1 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Increased bronchial secretion | 2 | 2 | 1 | 1 | 1 | 1 |
| Intranasal hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Intranasal paraesthesia | 1 | 1 | 1 | 1 | | |
| Nasal congestion | 4 | 4 | 4 | 4 | | |
| Obstructive airways disorder | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 7 | 7 | 5 | 5 | 2 | 2 |
| Paranasal sinus discomfort | 1 | 1 | 1 | 1 | | |
| Pharyngeal swelling | 1 | 1 | 1 | 1 | | |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Productive cough | 4 | 4 | | | 4 | 4 |
| Rales | 2 | 3 | 2 | 2 | | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory alkalosis | | 1 | | | | 1 |
| Respiratory arrest | 2 | 3 | | | 2 | 3 |
| Respiratory failure | 4 | 4 | | | 4 | 4 |
| Rhinorrhoea | 5 | 5 | 5 | 5 | | |
| Sputum increased | 1 | 1 | 1 | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Throat clearing | 1 | 1 | 1 | 1 | | |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 90 | 100 | 43 | 44 | 47 | 56 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cold sweat | 4 | 7 | 2 | 2 | 2 | 5 |
| Dry skin | 1 | 1 | 1 | 1 | | |
| Erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Livedo reticularis | 1 | 1 | 1 | 1 | | |
| Pruritus | 4 | 4 | 2 | 2 | 2 | 2 |
| Rash | 5 | 5 | 3 | 3 | 2 | 2 |
| Rash pruritic | 2 | 2 | 1 | 1 | 1 | 1 |
| Urticaria | 2 | 2 | | | 2 | 2 |
| | 22 | 25 | 12 | 12 | 10 | 13 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Bedridden | 4 | 4 | 4 | 4 |
| | 4 | 4 | 4 | 4 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Flushing | 1 | 2 | 1 | 2 | | |
| Hypertension | 2 | 2 | 2 | 2 | | |
| Hypotension | 6 | 8 | | | 6 | 8 |
| Malignant hypertension | 1 | 2 | | | 1 | 2 |
| Pallor | 3 | 5 | | | 3 | 5 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| | 15 | 21 | 4 | 5 | 11 | 16 |

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Country Where Event Occurred

OMAN

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea | | 1 | | 1 |
| Gastritis | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | | 1 | | 1 |
| Pain | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Headache | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product supply issue | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

PANAMA

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Flatulence | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

POLAND

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coagulopathy | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 23 | 29 | 10 | 16 | 13 | 13 |
| Lymph node pain | 15 | 16 | 6 | 7 | 9 | 9 |
| | 39 | 46 | 17 | 24 | 22 | 22 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arrhythmia | 3 | 4 | | | 3 | 4 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 2 | 2 | | | 2 | 2 |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Myocardial hypoxia | 1 | 1 | | | 1 | 1 |
| Palpitations | 2 | 2 | 2 | 2 | | |
| Tachycardia | 10 | 12 | 2 | 2 | 8 | 10 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| | 21 | 24 | 4 | 4 | 17 | 20 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness | 2 | 2 | | | 2 | 2 |
| Ear pain | | 1 | | 1 | | |
| Ear swelling | 1 | 1 | | | 1 | 1 |
| Hyperacusis | 1 | 1 | 1 | 1 | | |
| Tinnitus | 4 | 4 | 4 | 4 | | |
| Vertigo | 5 | 5 | 1 | 1 | 4 | 4 |
| | 13 | 14 | 6 | 7 | 7 | 7 |

System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Goitre | 1 | 1 | 1 | 1 |
| Thyroiditis | 1 | 1 | 1 | 1 |
| Thyroid pain | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival hyperaemia | | 1 | | 1 | | |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |
| Eye pain | 4 | 5 | | 1 | 4 | 4 |
| Hypoaesthesia eye | 1 | 1 | | | 1 | 1 |
| Iritis | | 1 | | 1 | | |
| Lacrimation increased | 1 | 1 | | | 1 | 1 |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Vision blurred | | 1 | | 1 | | |
| Visual impairment | 1 | 1 | 1 | 1 | | |
| | 9 | 13 | 2 | 6 | 7 | 7 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 4 | 7 | 2 | 5 | 2 | 2 |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 1 | 2 | 1 | 1 | | 1 |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 7 | 13 | 3 | 9 | 4 | 4 |
| Dry mouth | | 1 | | 1 | | |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Gastrointestinal disorder | 1 | 1 | | | 1 | 1 |
| Gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Hyperaesthesia teeth | | 1 | | 1 | | |
| Hypoaesthesia oral | 4 | 6 | 1 | 2 | 3 | 4 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Nausea | 21 | 31 | 14 | 24 | 7 | 7 |
| Pancreatitis acute | | 1 | | | | 1 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Retching | | 1 | | 1 | | |
| Swollen tongue | 3 | 3 | | | 3 | 3 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Toothache | | 1 | | 1 | | |
| Vomiting | 11 | 16 | 3 | 8 | 8 | 8 |
| | 60 | 92 | 27 | 56 | 33 | 36 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 52 | 79 | 32 | 58 | 20 | 21 |
| Axillary pain | 2 | 5 | 2 | 5 | | |
| Cardiac death | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 4 | 2 | 4 | | |
| Chest pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Chills | 38 | 53 | 28 | 41 | 10 | 12 |
| Crying | | 1 | | 1 | | |
| Death | 7 | 7 | | | 7 | 7 |
| Decreased activity | | 1 | | 1 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disease progression | 1 | 1 | | | 1 | 1 |
| Disease recurrence | 1 | 2 | | | 1 | 2 |
| Drug ineffective | 23 | 34 | | | 23 | 34 |
| Exercise tolerance decreased | 1 | 1 | 1 | 1 | | |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 10 | 16 | 9 | 15 | 1 | 1 |
| Feeling abnormal | 4 | 8 | 4 | 8 | | |
| Feeling cold | 7 | 9 | 5 | 6 | 2 | 3 |
| Feeling hot | 6 | 7 | 5 | 6 | 1 | 1 |
| Gait disturbance | 1 | 2 | 1 | 2 | | |
| Illness | 1 | 1 | 1 | 1 | | |
| Inflammation | | 2 | | 2 | | |
| Influenza like illness | 3 | 6 | 3 | 6 | | |
| Malaise | 27 | 35 | 23 | 31 | 4 | 4 |
| Nodule | 1 | 1 | 1 | 1 | | |
| Oedema | 1 | 2 | | 1 | 1 | 1 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Pain | 7 | 10 | 5 | 7 | 2 | 3 |
| Peripheral swelling | 1 | 2 | | 1 | 1 | 1 |
| Pyrexia | 79 | 114 | 43 | 74 | 36 | 40 |
| Swelling | | 3 | | 2 | | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Temperature intolerance | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | 1 | 2 | 1 | 2 | | |
| Thirst | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 6 | 10 | 3 | 7 | 3 | 3 |
| Vaccination site extravasation | | 1 | | 1 | | |
| Vaccination site induration | 1 | 3 | 1 | 3 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site macule | | 1 | | 1 | | |
| Vaccination site movement impairment | 1 | 3 | 1 | 3 | | |
| Vaccination site oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site pain | 34 | 72 | 28 | 65 | 6 | 7 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 5 | 1 | 5 | | |
| Vaccination site reaction | 18 | 25 | 2 | 9 | 16 | 16 |
| Vaccination site scab | | 1 | | 1 | | |
| Vaccination site swelling | 6 | 12 | 5 | 11 | 1 | 1 |
| Vaccination site vesicles | | 1 | | 1 | | |
| Vaccination site warmth | 1 | 3 | 1 | 3 | | |
| | 359 | 560 | 216 | 394 | 143 | 166 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 8 | 8 | | | 8 | 8 |
| Anaphylactic shock | 6 | 6 | | | 6 | 6 |
| Hypersensitivity | 5 | 7 | 1 | 3 | 4 | 4 |
| | 19 | 21 | 1 | 3 | 18 | 18 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asymptomatic COVID-19 | 1 | 2 | | | 1 | 2 |
| COVID-19 | 27 | 38 | 5 | 6 | 22 | 32 |
| Cystitis | | 1 | | 1 | | |
| Herpes virus infection | | 3 | | 3 | | |
| Herpes zoster | | 1 | | 1 | | |
| Infection | 1 | 1 | | | 1 | 1 |
| Influenza | | 1 | | 1 | | |
| Nasopharyngitis | 2 | 2 | 2 | 2 | | |
| Parotitis | 1 | 1 | 1 | 1 | | |
| Pneumonia | 1 | 2 | | | 1 | 2 |
| Pulpitis dental | | 1 | | 1 | | |
| Rhinitis | 1 | 1 | | | 1 | 1 |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Sinusitis | | 1 | | 1 | | |
| Suspected COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site infection | | 1 | | 1 | | |
| Viral infection | 1 | 1 | 1 | 1 | | |
| | 38 | 60 | 10 | 20 | 28 | 40 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Brachial plexus injury | 1 | 1 | | | 1 | 1 |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Contusion | 3 | 3 | | | 3 | 3 |
| Exposure during pregnancy | 1 | 2 | 1 | 2 | | |
| Exposure via breast milk | | 7 | | 7 | | |
| Fall | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | | 2 | | 2 | | |
| Incorrect dose administered | | 1 | | 1 | | |
| Incorrect route of product administration | | 2 | | 2 | | |
| Maternal exposure during pregnancy | 1 | 2 | 1 | 2 | | |
| Off label use | 2 | 10 | 2 | 9 | | 1 |
| Poor quality product administered | 4 | 4 | 4 | 4 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product label confusion | | 2 | | 2 | | |
| Product preparation error | 1 | 1 | 1 | 1 | | |
| Product use issue | 3 | 10 | 3 | 9 | | 1 |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| | 18 | 51 | 13 | 44 | 5 | 7 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Antibody test abnormal | 12 | 12 | 12 | 12 | | |
| Blood glucose increased | 1 | 1 | | | 1 | 1 |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 9 | 10 | 1 | 2 | 8 | 8 |
| Blood pressure increased | 6 | 8 | 1 | 1 | 5 | 7 |
| Blood urine present | | 1 | | 1 | | |
| Body temperature increased | 4 | 6 | 3 | 5 | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 3 | 6 | 2 | 3 | 1 | 3 |
| Oxygen saturation decreased | 5 | 7 | | 1 | 5 | 6 |
| SARS-CoV-2 ant body test negative | 3 | 3 | 3 | 3 | | |
| SARS-CoV-2 test negative | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| | 46 | 58 | 23 | 29 | 23 | 29 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 3 | 5 | 2 | 4 | 1 | 1 |
| Electrolyte imbalance | 1 | 1 | 1 | 1 | | |
| | 4 | 6 | 3 | 5 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 27 | 46 | 22 | 40 | 5 | 6 |
| Arthritis | | 1 | | 1 | | |
| Arthropathy | 1 | 2 | 1 | 2 | | |
| Back pain | 8 | 11 | 7 | 10 | 1 | 1 |
| Bone pain | 8 | 12 | 5 | 8 | 3 | 4 |
| Decreased nasolabial fold | 1 | 1 | 1 | 1 | | |
| Joint effusion | 1 | 1 | 1 | 1 | | |
| Joint range of motion decreased | | 1 | | 1 | | |
| Joint swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscle tightness | | 1 | | 1 | | |
| Muscular weakness | 2 | 2 | 2 | 2 | | |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal stiffness | 2 | 4 | 2 | 4 | | |
| Myalgia | 49 | 69 | 35 | 54 | 14 | 15 |
| Neck pain | 6 | 9 | 4 | 6 | 2 | 3 |
| Pain in extremity | 25 | 43 | 18 | 34 | 7 | 9 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Spinal pain | 1 | 3 | | 1 | 1 | 2 |
| | 137 | 212 | 102 | 170 | 35 | 42 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 6 | 8 | 5 | 7 | 1 | 1 |
| Altered state of consciousness | 2 | 2 | | | 2 | 2 |
| Anosmia | 7 | 10 | 6 | 9 | 1 | 1 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Burning sensation | | 2 | | 2 | | |
| Cerebral haematoma | 2 | 2 | | | 2 | 2 |
| Chorea | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 4 | 4 | 3 | 3 | 1 | 1 |
| Dizziness | 15 | 21 | 7 | 13 | 8 | 8 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 3 | 5 | | 2 | 3 | 3 |
| Dysstasia | | 1 | | 1 | | |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Febrile convulsion | 5 | 5 | | | 5 | 5 |
| Formication | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Haemorrhagic stroke | 1 | 1 | | | 1 | 1 |
| Headache | 47 | 74 | 31 | 57 | 16 | 17 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Hyperaesthesia | 2 | 3 | 1 | 1 | 1 | 2 |
| Hypoaesthesia | 14 | 17 | 7 | 9 | 7 | 8 |
| Hypotonic-hyporesponsive episode | 10 | 10 | 3 | 3 | 7 | 7 |
| Loss of consciousness | 13 | 13 | | | 13 | 13 |
| Migraine | | 1 | | 1 | | |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Movement disorder | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 5 | 6 | 3 | 4 | 2 | 2 |
| Paralysis | | 1 | | | | 1 |
| Paraparesis | | 1 | | | | 1 |
| Paresis | | 2 | | 1 | | 1 |
| Parosmia | 3 | 3 | 1 | 1 | 2 | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Poor quality sleep | | 1 | | 1 | | |
| Presyncope | | 1 | | 1 | | |
| Seizure | 10 | 10 | | | 10 | 10 |
| Sinus headache | 1 | 1 | | | 1 | 1 |
| Somnolence | 5 | 8 | 3 | 6 | 2 | 2 |
| Speech disorder | 3 | 3 | 1 | 1 | 2 | 2 |
| Syncope | 15 | 15 | | | 15 | 15 |
| Taste disorder | 3 | 5 | 2 | 4 | 1 | 1 |
| Tension headache | 1 | 1 | 1 | 1 | | |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 4 | 1 | 2 | 1 | 2 |
| Ulnar nerve palsy | 1 | 1 | 1 | 1 | | |
| Visual field defect | 1 | 2 | 1 | 2 | | |
| | 193 | 256 | 80 | 136 | 113 | 120 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Needle issue | | 1 | | 1 |
| Product temperature excursion issue | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | 2 | 4 | 1 | 3 | 1 | 1 |
| Confusional state | 3 | 3 | 1 | 1 | 2 | 2 |
| Delirium | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Helplessness | | 1 | | | | 1 |
| Initial insomnia | | 1 | | 1 | | |
| Insomnia | 7 | 9 | 7 | 9 | | |
| Mental disorder | 1 | 1 | 1 | 1 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Nervousness | 1 | 1 | 1 | 1 | | |
| | 17 | 23 | 12 | 17 | 5 | 6 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Haematuria | 1 | 1 | 1 | 1 |
| Hydronephrosis | 1 | 1 | 1 | 1 |
| Urinary tract inflammation | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adnexa uteri pain | 1 | 1 | 1 | 1 | | |
| Breast pain | 1 | 2 | | 1 | 1 | 1 |
| Prostatitis | 1 | 1 | | | 1 | 1 |
| Suppressed lactation | | 2 | | 1 | | 1 |
| | 3 | 6 | 1 | 3 | 2 | 3 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma | 3 | 3 | | | 3 | 3 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Bronchial oedema | 1 | 1 | | | 1 | 1 |
| Cough | 5 | 8 | 2 | 5 | 3 | 3 |
| Dysphonia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 12 | 14 | 3 | 5 | 9 | 9 |
| Epistaxis | | 2 | | 2 | | |
| Haemoptysis | 1 | 1 | 1 | 1 | | |
| Hypopnoea | 1 | 1 | | | 1 | 1 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Increased upper airway secretion | 1 | 1 | 1 | 1 | | |
| Laryngospasm | 3 | 3 | | | 3 | 3 |
| Lung disorder | 1 | 1 | 1 | 1 | | |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 2 | 5 | | 3 | 2 | 2 |
| Painful respiration | | 1 | | 1 | | |
| Pharyngeal swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory tract oedema | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 4 | 6 | 4 | 6 | | |
| Throat irritation | | 1 | | 1 | | |
| Tonsillar hypertrophy | | 1 | | 1 | | |
| Tracheal oedema | 1 | 1 | | | 1 | 1 |
| | 46 | 61 | 16 | 31 | 30 | 30 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 4 | 4 | | | 4 | 4 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Ecchymosis | 1 | 1 | | | 1 | 1 |
| Erythema | 3 | 4 | 1 | 1 | 2 | 3 |
| Erythema multiforme | 2 | 2 | | | 2 | 2 |
| Hyperhidrosis | 10 | 11 | 6 | 7 | 4 | 4 |
| Lividity | 2 | 2 | | | 2 | 2 |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pain of skin | | 1 | | 1 | | |
| Petechiae | 3 | 3 | 1 | 1 | 2 | 2 |
| Pruritus | 2 | 3 | 1 | 2 | 1 | 1 |
| Rash | 2 | 4 | 1 | 3 | 1 | 1 |
| Rash macular | | 1 | | 1 | | |
| Rash papular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Rash rubelliform | 1 | 1 | | | 1 | 1 |
| Skin hypertrophy | 1 | 1 | 1 | 1 | | |
| Urticaria | 2 | 4 | | 2 | 2 | 2 |
| Yellow skin | 1 | 1 | | | 1 | 1 |
| | 38 | 47 | 14 | 22 | 24 | 25 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Walking disability | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aortic aneurysm rupture | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Flushing | 2 | 2 | 2 | 2 | | |
| Haematoma | | 1 | | 1 | | |
| Hot flush | 1 | 4 | 1 | 3 | | 1 |
| Hypertension | 2 | 3 | | 1 | 2 | 2 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Pallor | 3 | 5 | | 1 | 3 | 4 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Shock symptom | 1 | 1 | | | 1 | 1 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Vein disorder | 1 | 1 | 1 | 1 | | |
| | 15 | 22 | 5 | 10 | 10 | 12 |

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Country Where Event Occurred

PORTUGAL

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukaemoid reaction | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 3 | 4 | | 1 | 3 | 3 |
| Lymphadenopathy | 75 | 83 | 2 | 7 | 73 | 76 |
| Lymph node pain | 1 | 1 | | | 1 | 1 |
| Myelosuppression | 1 | 1 | | | 1 | 1 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| | 82 | 91 | 2 | 8 | 80 | 83 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arrhythmia | 4 | 4 | | | 4 | 4 |
| Bradycardia | 3 | 3 | | | 3 | 3 |
| Cardio-respiratory arrest | 1 | 2 | | | 1 | 2 |
| Myocarditis | 2 | 2 | | | 2 | 2 |
| Palpitations | 5 | 6 | | 1 | 5 | 5 |
| Postural orthostatic tachycardia syndrome | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 1 | 2 | | | 1 | 2 |
| Tachyarrhythmia | 2 | 2 | | | 2 | 2 |
| Tachycardia | 28 | 33 | 1 | 4 | 27 | 29 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| | 48 | 56 | 1 | 5 | 47 | 51 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Autophony | 1 | 1 | 1 | 1 |
| Deafness transitory | 1 | 1 | 1 | 1 |
| Ear pain | 3 | 3 | 3 | 3 |
| Hypoacusis | 1 | 1 | 1 | 1 |
| Tinnitus | 1 | 1 | 1 | 1 |
| Vertigo | 7 | 7 | 7 | 7 |
| Vertigo positional | | 1 | | 1 |
| | 14 | 15 | 14 | 15 |

System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hypothyroidism | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Choroiditis | 1 | 1 | | | 1 | 1 |
| Conjunctival irritation | 1 | 1 | | | 1 | 1 |
| Dry eye | | 1 | | 1 | | |
| Exophthalmos | | 1 | | | | 1 |
| Eye disorder | 1 | 1 | | | 1 | 1 |
| Eye irritation | 2 | 3 | 1 | 2 | 1 | 1 |
| Eyelid myokymia | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 3 | 4 | | | 3 | 4 |
| Eye movement disorder | | 1 | | | | 1 |
| Eye pain | | 1 | | 1 | | |
| Eye paraesthesia | | 1 | | | | 1 |
| Eye pruritus | 1 | 1 | | | 1 | 1 |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | 1 | 1 | | | 1 | 1 |
| Ocular discomfort | | 1 | | 1 | | |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Photophobia | 2 | 3 | | 1 | 2 | 2 |
| Vision blurred | 2 | 3 | | 1 | 2 | 2 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| | 19 | 29 | 1 | 7 | 18 | 22 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 2 | 5 | | 2 | 2 | 3 |
| Abdominal pain | 8 | 9 | | | 8 | 9 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 5 | 6 | 1 | 2 | 4 | 4 |
| Abnormal faeces | 1 | 1 | | | 1 | 1 |
| Aphthous ulcer | 2 | 2 | | | 2 | 2 |
| Crohn's disease | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 27 | 29 | 2 | 4 | 25 | 25 |
| Dry mouth | 3 | 3 | | | 3 | 3 |
| Dyspepsia | 1 | 1 | | | 1 | 1 |
| Dysphagia | 8 | 9 | | | 8 | 9 |
| Eructation | | 2 | | 2 | | |
| Faeces soft | 1 | 1 | | | 1 | 1 |
| Flatulence | 2 | 2 | 1 | 1 | 1 | 1 |
| Functional gastrointestinal disorder | | 1 | | | | 1 |
| Hypoaesthesia oral | 4 | 10 | | 1 | 4 | 9 |
| Lip oedema | 7 | 11 | | | 7 | 11 |
| Lip pruritus | | 1 | | | | 1 |
| Lip swelling | 2 | 2 | | | 2 | 2 |
| Nausea | 84 | 96 | 4 | 11 | 80 | 85 |
| Odynophagia | 10 | 14 | 2 | 3 | 8 | 11 |
| Oedema mouth | 2 | 2 | | | 2 | 2 |
| Oesophageal pain | 1 | 1 | | | 1 | 1 |
| Oesophageal stenosis | 1 | 1 | | | 1 | 1 |
| Oral disorder | | 1 | | | | 1 |
| Oral pain | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 9 | 13 | | 1 | 9 | 12 |
| Stiff tongue | 1 | 1 | | | 1 | 1 |
| Stomatitis | 1 | 3 | | 2 | 1 | 1 |
| Terminal ileitis | 1 | 1 | | | 1 | 1 |
| Tongue coated | 1 | 1 | | | 1 | 1 |
| Tongue discomfort | 2 | 2 | | | 2 | 2 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tongue disorder | | 1 | | 1 | | |
| Tongue dry | 1 | 2 | | 1 | 1 | 2 |
| Tongue eruption | 1 | 2 | | | 1 | 2 |
| Tongue oedema | 9 | 12 | | | 9 | 12 |
| Tongue pruritus | | 1 | | | | 1 |
| Trichoglossia | 1 | 1 | 1 | 1 | | |
| Vomiting | 25 | 28 | 1 | 2 | 24 | 26 |
| | 226 | 281 | 12 | 33 | 214 | 248 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 63 | 64 | 3 | 4 | 60 | 60 |
| Axillary pain | 10 | 10 | | | 10 | 10 |
| Chest discomfort | 8 | 9 | 1 | 1 | 7 | 8 |
| Chest pain | 13 | 16 | | 1 | 13 | 15 |
| Chills | 89 | 96 | 3 | 6 | 86 | 90 |
| Condition aggravated | 2 | 2 | 1 | 1 | 1 | 1 |
| Crying | 1 | 1 | | | 1 | 1 |
| Death | 2 | 4 | | | 2 | 4 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 15 | 31 | | | 15 | 31 |
| Drug interaction | 1 | 1 | | | 1 | 1 |
| Face oedema | 11 | 15 | | 1 | 11 | 14 |
| Fatigue | 65 | 73 | 3 | 8 | 62 | 65 |
| Feeling abnormal | 1 | 2 | 1 | 2 | | |
| Feeling cold | 6 | 6 | | | 6 | 6 |
| Feeling hot | 12 | 13 | | | 12 | 13 |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| General symptom | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 6 | 6 | 1 | 1 | 5 | 5 |
| Illness | 1 | 1 | 1 | 1 | | |
| Inflammation | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | | | 1 | 1 |
| Injected limb mobility decreased | | 1 | | 1 | | |
| Localised oedema | 4 | 5 | | 1 | 4 | 4 |
| Malaise | 33 | 40 | 1 | 6 | 32 | 34 |
| Oedema | 2 | 2 | | | 2 | 2 |
| Oedema mucosal | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 5 | 5 | 1 | 1 | 4 | 4 |
| Pain | 18 | 19 | 1 | 2 | 17 | 17 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pyrexia | 195 | 207 | 3 | 11 | 192 | 196 |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Swelling | 2 | 2 | | | 2 | 2 |
| Vaccination site discomfort | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site erythema | 17 | 20 | | 3 | 17 | 17 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 3 | 3 | | | 3 | 3 |
| Vaccination site inflammation | 6 | 6 | | | 6 | 6 |
| Vaccination site movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 12 | 15 | | 1 | 12 | 14 |
| Vaccination site pain | 105 | 143 | 12 | 43 | 93 | 100 |
| Vaccination site paraesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site pruritus | 8 | 9 | | | 8 | 9 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 10 | 12 | | 2 | 10 | 10 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 6 | 6 | | | 6 | 6 |
| | 750 | 864 | 36 | 102 | 714 | 762 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 1 | 3 | | | 1 | 3 |
| Anaphylactic reaction | 8 | 9 | | | 8 | 9 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anaphylactoid reaction | 2 | 2 | | | 2 | 2 |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 3 | 10 | | 4 | 3 | 6 |
| | 17 | 27 | | 4 | 17 | 23 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asymptomatic COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| COVID-19 | 23 | 39 | 6 | 7 | 17 | 32 |
| Gonorrhoea | 1 | 1 | | | 1 | 1 |
| Influenza | 2 | 2 | | | 2 | 2 |
| Mastitis | 1 | 1 | | | 1 | 1 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Ophthalmic herpes simplex | 1 | 1 | | | 1 | 1 |
| Oral candidiasis | 1 | 1 | | | 1 | 1 |
| Oral herpes | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Rhinitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Sinusitis | 1 | 1 | 1 | 1 | | |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Varicella | 1 | 1 | | | 1 | 1 |
| | 39 | 55 | 9 | 10 | 30 | 45 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chillblains | | 1 | | 1 | | |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Exposure to SARS-CoV-2 | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | 1 | 5 | 1 | 5 | | |
| Fall | 1 | 1 | 1 | 1 | | |
| Inappropriate schedule of product administration | 3 | 4 | 3 | 4 | | |
| Incorrect route of product administration | 14 | 16 | 14 | 16 | | |
| Maternal exposure during pregnancy | 1 | 2 | 1 | 2 | | |
| Occupational exposure to SARS-CoV-2 | 1 | 1 | 1 | 1 | | |
| Off label use | 8 | 11 | 8 | 11 | | |
| Overdose | 1 | 5 | 1 | 5 | | |
| Procedural haemorrhage | 1 | 1 | | | 1 | 1 |
| Product administered at inappropriate site | 1 | 1 | 1 | 1 | | |
| Product use issue | 7 | 9 | 7 | 9 | | |
| Scar | | 1 | | 1 | | |
| Vaccination complication | 1 | 1 | | | 1 | 1 |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Wound | 1 | 1 | 1 | 1 | | |
| | 44 | 63 | 40 | 59 | 4 | 4 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Amylase increased | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 5 | 1 | 1 | 3 | 4 |
| Body temperature increased | 2 | 3 | | 1 | 2 | 2 |
| Heart rate increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Inspiratory capacity decreased | 1 | 1 | | | 1 | 1 |
| Lipase increased | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 5 | 5 | 1 | 1 | 4 | 4 |
| SARS-CoV-2 test positive | 4 | 8 | 1 | 1 | 3 | 7 |
| Thyroid function test abnormal | | 1 | | 1 | | |
| Weight decreased | | 1 | | 1 | | |
| | 21 | 29 | 4 | 7 | 17 | 22 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 10 | 12 | 3 | 5 | 7 | 7 |
| Hyperglycaemia | 3 | 4 | 1 | 1 | 2 | 3 |
| Hypoglycaemia | 3 | 3 | | | 3 | 3 |
| Hypokalaemia | 3 | 3 | | | 3 | 3 |
| Polydipsia | 3 | 3 | | | 3 | 3 |
| | 22 | 25 | 4 | 6 | 18 | 19 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 70 | 70 | 3 | 3 | 67 | 67 |
| Arthritis reactive | | 1 | | | | 1 |
| Back pain | 12 | 12 | 1 | 1 | 11 | 11 |
| Bone pain | | 1 | | 1 | | |
| Groin pain | 1 | 1 | | | 1 | 1 |
| Joint range of motion decreased | 1 | 1 | | | 1 | 1 |
| Limb discomfort | 1 | 1 | | | 1 | 1 |
| Muscle fatigue | 2 | 2 | | | 2 | 2 |
| Muscle spasms | 2 | 2 | | | 2 | 2 |
| Muscle tightness | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 3 | 4 | | | 3 | 4 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 271 | 292 | 12 | 26 | 259 | 266 |
| Myalgia intercostal | 1 | 1 | | | 1 | 1 |
| Neck mass | 1 | 1 | 1 | 1 | | |
| Neck pain | 2 | 2 | | | 2 | 2 |
| Pain in extremity | 19 | 21 | 2 | 3 | 17 | 18 |
| Pain in jaw | | 1 | | | | 1 |
| Rhabdomyolysis | 1 | 1 | | | 1 | 1 |
| Synovial cyst | 4 | 4 | | | 4 | 4 |
| Tenosynovitis | | 1 | | 1 | | |
| Trismus | 1 | 1 | | | 1 | 1 |
| | 395 | 423 | 19 | 36 | 376 | 387 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 2 | 2 | | | 2 | 2 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Amnesia | | 1 | | 1 | | |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Balance disorder | 3 | 4 | | | 3 | 4 |
| Burning sensation | 2 | 2 | | | 2 | 2 |
| Cerebral venous sinus thrombosis | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Dizziness | 55 | 58 | 4 | 6 | 51 | 52 |
| Dysarthria | 4 | 5 | | 1 | 4 | 4 |
| Dysgeusia | 5 | 7 | | 1 | 5 | 6 |
| Dyskinesia | 1 | 1 | | | 1 | 1 |
| Dyslexia | 1 | 1 | | | 1 | 1 |
| Dysstasia | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 5 | 6 | | | 5 | 6 |
| Generalised tonic-clonic seizure | 1 | 2 | | | 1 | 2 |
| Headache | 237 | 258 | 11 | 27 | 226 | 231 |
| Head discomfort | 1 | 1 | | | 1 | 1 |
| Hemianaesthesia | 1 | 1 | | | 1 | 1 |
| Hemidysaesthesia | 1 | 1 | | | 1 | 1 |
| Hemiparaesthesia | 1 | 1 | | | 1 | 1 |
| Hyperaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 6 | 8 | | 2 | 6 | 6 |
| Intercostal neuralgia | 1 | 2 | | 1 | 1 | 1 |
| Migraine | 4 | 8 | 1 | 2 | 3 | 6 |
| Motor dysfunction | 3 | 3 | | | 3 | 3 |
| Muscle contractions involuntary | 1 | 1 | | | 1 | 1 |
| Myoclonus | 1 | 1 | | | 1 | 1 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Nystagmus | 2 | 3 | | | 2 | 3 |
| Paraesthesia | 34 | 40 | 3 | 6 | 31 | 34 |
| Paralysis | 1 | 1 | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Poor quality sleep | 1 | 1 | | | 1 | 1 |
| Presyncope | 17 | 21 | | 3 | 17 | 18 |
| Seizure | 3 | 3 | | | 3 | 3 |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Sensory loss | 4 | 5 | | | 4 | 5 |
| Somnolence | 9 | 15 | | 3 | 9 | 12 |
| Syncope | 10 | 10 | | | 10 | 10 |
| Taste disorder | 5 | 7 | | 2 | 5 | 5 |
| Tremor | 21 | 23 | | 2 | 21 | 21 |
| | 451 | 511 | 20 | 58 | 431 | 453 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | 3 | 4 | | 1 | 3 | 3 |
| Bradyphrenia | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Depressed mood | 1 | 1 | | | 1 | 1 |
| Insomnia | 9 | 9 | 1 | 1 | 8 | 8 |
| L bido decreased | 1 | 1 | 1 | 1 | | |
| Phonophobia | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 2 | 2 | | | 2 | 2 |
| | 19 | 20 | 2 | 3 | 17 | 17 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocyturia | 1 | 1 | 1 | 1 | | |
| Proteinuria | 1 | 1 | 1 | 1 | | |
| Renal colic | 1 | 1 | | | 1 | 1 |
| Renal disorder | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Breast swelling | 1 | 1 | 1 | 1 | | |
| Metrorrhagia | 1 | 1 | | | 1 | 1 |
| Perineal pain | 1 | 1 | | | 1 | 1 |
| Vulvovaginal burning sensation | 1 | 1 | | | 1 | 1 |
| Vulvovaginal swelling | 1 | 1 | | | 1 | 1 |
| | 8 | 8 | 2 | 2 | 6 | 6 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bronchospasm | 4 | 4 | | | 4 | 4 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Cough | 18 | 20 | 5 | 5 | 13 | 15 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dysphonia | 3 | 3 | 1 | 1 | 2 | 2 |
| Dyspnoea | 22 | 22 | 2 | 2 | 20 | 20 |
| Dyspnoea at rest | 2 | 2 | | | 2 | 2 |
| Haemoptysis | 1 | 1 | | | 1 | 1 |
| Laryngeal oedema | 8 | 12 | | | 8 | 12 |
| Nasal congestion | 5 | 5 | 1 | 1 | 4 | 4 |
| Nasal discomfort | 1 | 1 | 1 | 1 | | |
| Nasal dryness | 1 | 1 | 1 | 1 | | |
| Nasal obstruction | | 1 | | | | 1 |
| Oropharyngeal discomfort | 6 | 7 | 1 | 1 | 5 | 6 |
| Oropharyngeal oedema | | 2 | | 1 | | 1 |
| Oropharyngeal pain | 4 | 5 | 1 | 1 | 3 | 4 |
| Painful respiration | 1 | 1 | | | 1 | 1 |
| Pharyngeal erythema | 1 | 1 | | | 1 | 1 |
| Pharyngeal hypoesthesia | | 1 | | | | 1 |
| Pharyngeal inflammation | 2 | 2 | 1 | 1 | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 3 | | | 2 | 3 |
| Pleuritic pain | 2 | 2 | | | 2 | 2 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Productive cough | | 2 | | | | 2 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory tract congestion | | 1 | | | | 1 |
| Rhinorrhoea | 14 | 17 | 3 | 3 | 11 | 14 |
| Tachypnoea | 1 | 2 | | | 1 | 2 |
| Throat irritation | 6 | 9 | | 3 | 6 | 6 |
| Throat tightness | 2 | 3 | | | 2 | 3 |
| Tonsillar hypertrophy | 1 | 1 | | | 1 | 1 |
| Upper-airway cough syndrome | | 1 | | | | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 112 | 137 | 17 | 21 | 95 | 116 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 8 | 8 | | | 8 | 8 |
| Circumoral oedema | | 1 | | | | 1 |
| Cold sweat | 3 | 3 | | | 3 | 3 |
| Cutaneous vasculitis | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | | 1 | | | | 1 |
| Eczema | 2 | 2 | | | 2 | 2 |
| Erythema | 10 | 18 | | 3 | 10 | 15 |
| Hyperhidrosis | 15 | 16 | 1 | 1 | 14 | 15 |
| Macule | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Palmar-plantar erythrodysesthesia syndrome | | 1 | | | | 1 |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Piloerection | 3 | 3 | | | 3 | 3 |
| Pruritus | 20 | 27 | | 2 | 20 | 25 |
| Rash | 29 | 42 | 1 | 8 | 28 | 34 |
| Rash erythematous | 3 | 3 | | | 3 | 3 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 1 | 3 | | 2 | 1 | 1 |
| Rash papular | 2 | 2 | | | 2 | 2 |
| Rash pruritic | 2 | 4 | | 2 | 2 | 2 |
| Skin exfoliation | 1 | 1 | | | 1 | 1 |
| Skin lesion | 1 | 1 | | | 1 | 1 |
| Skin reaction | 1 | 1 | | | 1 | 1 |
| Urticaria | 6 | 9 | | 1 | 6 | 8 |
| Urticaria cholinergic | | 1 | | 1 | | |
| Urticaria papular | 1 | 1 | | | 1 | 1 |
| | 113 | 153 | 2 | 20 | 111 | 133 |

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System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Impaired work ability | 2 | 2 | 1 | 1 | 1 | 1 |
| Loss of personal independence in daily activities | 2 | 2 | 1 | 1 | 1 | 1 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cyanosis | 2 | 2 | | | 2 | 2 |
| Embolism | | 1 | | | | 1 |
| Flushing | 6 | 8 | | | 6 | 8 |
| Haematoma | 1 | 1 | | | 1 | 1 |
| Hot flush | 4 | 4 | | | 4 | 4 |
| Hyperaemia | 1 | 1 | | | 1 | 1 |
| Hypertension | 16 | 16 | | | 16 | 16 |
| Hypertensive crisis | 2 | 2 | | | 2 | 2 |
| Hypoperfusion | 1 | 1 | | | 1 | 1 |
| Hypotension | 13 | 13 | | | 13 | 13 |
| Pallor | 5 | 8 | | 2 | 5 | 6 |
| Peripheral coldness | 2 | 3 | | | 2 | 3 |
| Phlebitis | 1 | 1 | | | 1 | 1 |
| Takayasu's arteritis | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis | 1 | 1 | | | 1 | 1 |
| Vasculitis | 1 | 1 | | | 1 | 1 |
| | 57 | 64 | | 2 | 57 | 62 |

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Country Where Event Occurred

PUERTO RICO

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenitis | 1 | 1 | 1 | 1 |
| Lymphadenopathy | 1 | 3 | 1 | 3 |
| | 2 | 4 | 2 | 4 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Palpitations | | 1 | | 1 | | |
| Sinus arrhythmia | | 1 | | | | 1 |
| Tachycardia | 1 | 2 | 1 | 2 | | |
| | 1 | 4 | 1 | 3 | | 1 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Photophobia | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Abdominal discomfort | 2 | 4 | 2 | 4 |
| Abdominal pain | | 1 | | 1 |
| Diarrhoea | | 3 | | 3 |
| Dry mouth | | 1 | | 1 |
| Dyspepsia | | 1 | | 1 |
| Flatulence | 1 | 1 | 1 | 1 |
| Gingival bleeding | | 1 | | 1 |
| Nausea | 2 | 5 | 2 | 5 |
| | 5 | 17 | 5 | 17 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Asthenia | | 1 | | 1 |
| Axillary pain | | 1 | | 1 |
| Chills | | 4 | | 4 |
| Discomfort | 1 | 1 | 1 | 1 |
| Facial pain | 1 | 1 | 1 | 1 |
| Fatigue | 3 | 11 | 3 | 11 |
| Gait disturbance | | 1 | | 1 |
| Inflammation | | 1 | | 1 |
| Malaise | | 1 | | 1 |
| Nodule | | 1 | | 1 |
| Pain | 3 | 6 | 3 | 6 |
| Puncture site swelling | | 1 | | 1 |
| Pyrexia | 3 | 11 | 3 | 11 |
| Swelling | 1 | 1 | 1 | 1 |
| Swelling face | | 1 | | 1 |
| Thirst | 1 | 1 | 1 | 1 |
| Vaccination site discomfort | | 1 | | 1 |
| Vaccination site erythema | | 1 | | 1 |
| Vaccination site induration | | 1 | | 1 |
| Vaccination site inflammation | | 1 | | 1 |
| Vaccination site pain | 2 | 6 | 2 | 6 |
| Vaccination site swelling | | 2 | | 2 |
| | 15 | 56 | 15 | 56 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 2 | 3 | 2 | 3 |
| Maternal exposure during pregnancy | | 1 | | 1 |
| Off label use | | 2 | | 2 |
| Poor quality product administered | 10 | 10 | 10 | 10 |
| | 12 | 16 | 12 | 16 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Antibody test abnormal | 1 | 1 | 1 | 1 | | |
| Antinuclear antibody positive | 1 | 1 | 1 | 1 | | |
| Blood test abnormal | 1 | 1 | 1 | 1 | | |
| Heart rate decreased | | 1 | | | | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 | | |
| | 4 | 5 | 4 | 4 | | 1 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Decreased appetite | | 1 | | 1 |
| Dehydration | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 3 | 6 | 3 | 6 |
| Back pain | 1 | 1 | 1 | 1 |
| Bone disorder | | 1 | | 1 |
| Bone pain | | 1 | | 1 |
| Joint range of motion decreased | | 1 | | 1 |
| Limb discomfort | | 1 | | 1 |
| Muscle spasms | | 1 | | 1 |
| Muscle twitching | 1 | 1 | 1 | 1 |
| Musculoskeletal stiffness | | 1 | | 1 |
| Myalgia | 4 | 6 | 4 | 6 |
| Neck pain | | 1 | | 1 |
| Pain in extremity | 1 | 6 | 1 | 6 |
| | 10 | 27 | 10 | 27 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Bone neoplasm | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Burning sensation | | 2 | | 2 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dyskinesia | | 1 | | | | 1 |
| Facial paralysis | 1 | 2 | | | 1 | 2 |
| Headache | 7 | 17 | 7 | 17 | | |
| Head discomfort | | 1 | | 1 | | |
| Hypoaesthesia | 1 | 5 | 1 | 5 | | |
| Migraine | | 1 | | | | 1 |
| Movement disorder | | 1 | | 1 | | |
| Neuralgia | | 1 | | 1 | | |
| Paraesthesia | 1 | 3 | 1 | 3 | | |
| Speech disorder | | 1 | | 1 | | |
| Taste disorder | | 2 | | 2 | | |
| | 11 | 38 | 10 | 34 | 1 | 4 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Depression | | 1 | | 1 |
| Stress | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Dysphonia | | 1 | | 1 |
| Dyspnoea | | 1 | | 1 |
| Rhinorrhoea | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | | 1 | | 1 | | |
| Night sweats | | 1 | | | | 1 |
| Pruritus | | 1 | | 1 | | |
| Rash | | 1 | | 1 | | |
| | | 4 | | 3 | | 1 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Haematoma | | 1 | | 1 |
| Hypertension | | 1 | | 1 |
| | | 2 | | 2 |

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Country Where Event Occurred

QATAR

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dyspepsia | 2 | 2 | 2 | 2 | | |
| Nausea | | 1 | | | | 1 |
| | 2 | 3 | 2 | 2 | | 1 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Overdose | | 1 | | 1 |
| Product preparation error | | 1 | | 1 |
| | | 2 | | 2 |

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* AE=Adverse Event
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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Blood pressure decreased | 1 | 1 | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Myalgia | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | 1 | 2 | | | 1 | 2 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| | 4 | 5 | 1 | 1 | 3 | 4 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Mood altered | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dyspnoea | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Erythema | | 1 | | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Peripheral coldness | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

ROMANIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 5 | 14 | | 9 | 5 | 5 |
| Lymph node pain | | 1 | | 1 | | |
| | 6 | 16 | 1 | 11 | 5 | 5 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 1 | 2 | | | 1 | 2 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrioventricular block | 1 | 1 | | | 1 | 1 |
| Cardiac fibrillation | 1 | 1 | | | 1 | 1 |
| Palpitations | | 2 | | | | 2 |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 2 | 2 | | | 2 | 2 |
| Tachycardia | 7 | 12 | 3 | 5 | 4 | 7 |
| Ventricular extrasystoles | | 1 | | 1 | | |
| | 14 | 23 | 3 | 6 | 11 | 17 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear pain | | 1 | | 1 | | |
| Paraesthesia ear | | 1 | | 1 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Vertigo | 6 | 9 | | 2 | 6 | 7 |
| Vestibular disorder | | 1 | | 1 | | |
| | 8 | 14 | 2 | 7 | 6 | 7 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angle closure glaucoma | | 1 | | | | 1 |
| Eyelid oedema | 1 | 2 | | 1 | 1 | 1 |
| Eyelid ptosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| | 5 | 7 | 1 | 2 | 4 | 5 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 3 | 4 | 1 | 2 | 2 | 2 |
| Dry mouth | | 1 | | | | 1 |
| Dysphagia | | 1 | | | | 1 |
| Faeces soft | 1 | 1 | | | 1 | 1 |
| Lip oedema | 3 | 6 | | 2 | 3 | 4 |
| Lip swelling | | 1 | | | | 1 |
| Nausea | 14 | 27 | 5 | 16 | 9 | 11 |
| Odynophagia | | 1 | | 1 | | |
| Oedematous pancreatitis | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | | 1 | | 1 | | |
| Tongue disorder | | 1 | | 1 | | |
| Tongue oedema | | 1 | | | | 1 |
| Tongue spasm | 1 | 1 | | | 1 | 1 |
| Vomiting | 5 | 8 | 1 | 3 | 4 | 5 |
| | 30 | 57 | 8 | 27 | 22 | 30 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Administration site pain | 1 | 1 | | | 1 | 1 |
| Asthenia | 8 | 18 | 3 | 12 | 5 | 6 |
| Axillary pain | 1 | 2 | 1 | 2 | | |
| Chest discomfort | 1 | 3 | | 2 | 1 | 1 |
| Chest pain | 3 | 4 | | | 3 | 4 |
| Chills | 21 | 42 | 8 | 27 | 13 | 15 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Crying | | 1 | | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 30 | 49 | 1 | 1 | 29 | 48 |
| Extensive swelling of vaccinated limb | 1 | 1 | | | 1 | 1 |
| Face oedema | 2 | 2 | | | 2 | 2 |
| Facial pain | | 1 | | 1 | | |
| Fatigue | 7 | 25 | 3 | 19 | 4 | 6 |
| Feeling abnormal | 1 | 2 | | 1 | 1 | 1 |
| Feeling cold | | 2 | | 1 | | 1 |
| Feeling hot | | 2 | | 1 | | 1 |
| Foaming at mouth | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 1 | 2 | 1 | 2 | | |
| Hyperpyrexia | 1 | 1 | | | 1 | 1 |
| Hyperthermia | | 1 | | 1 | | |
| Illness | 1 | 1 | | | 1 | 1 |
| Inflammation | 1 | 2 | 1 | 2 | | |
| Influenza like illness | | 1 | | 1 | | |
| Injected limb mobility decreased | 2 | 5 | 1 | 4 | 1 | 1 |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Malaise | 4 | 9 | 1 | 6 | 3 | 3 |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Oedema | | 1 | | 1 | | |
| Oedema peripheral | | 1 | | | | 1 |
| Pain | 1 | 8 | 1 | 8 | | |
| Pyrexia | 23 | 55 | 8 | 40 | 15 | 15 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling | 1 | 1 | 1 | 1 | | |
| Thirst | | 1 | | | | 1 |
| Vaccination site discomfort | | 3 | | 3 | | |
| Vaccination site erythema | 4 | 19 | 2 | 17 | 2 | 2 |
| Vaccination site induration | 1 | 3 | | 2 | 1 | 1 |
| Vaccination site inflammation | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | | 2 | | 2 | | |
| Vaccination site movement impairment | | 3 | | 3 | | |
| Vaccination site nodule | | 1 | | 1 | | |
| Vaccination site pain | 23 | 74 | 12 | 63 | 11 | 11 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 2 | 1 | 2 | | |
| Vaccination site reaction | 4 | 5 | 4 | 5 | | |
| Vaccination site swelling | 2 | 3 | 2 | 3 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| | 154 | 369 | 54 | 240 | 100 | 129 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | | 1 | | 1 | | |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Hypersensitivity | 3 | 5 | 1 | 3 | 2 | 2 |
| | 6 | 12 | 1 | 4 | 5 | 8 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| COVID-19 | 28 | 39 | 1 | 1 | 27 | 38 |
| Suspected COVID-19 | 2 | 3 | 1 | 1 | 1 | 2 |
| | 31 | 43 | 2 | 2 | 29 | 41 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circumstance or information capable of leading to medication error | | 3 | | 3 | | |
| Exposure during pregnancy | | 1 | | 1 | | |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 2 | 4 | | 2 | 2 | 2 |
| Intercepted medication error | | 1 | | 1 | | |
| Limb injury | | 1 | | | | 1 |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Medication error | | 3 | | 3 | | |
| Off label use | | 3 | | 3 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Product preparation error | | 11 | | 11 | | |
| Product preparation issue | | 6 | | 6 | | |
| Product use issue | | 2 | | 2 | | |
| Underdose | | 1 | | 1 | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | 1 | 14 | 1 | 14 | | |
| | 6 | 54 | 3 | 50 | 3 | 4 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure abnormal | 1 | 2 | | 1 | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 3 | 4 | | 1 | 3 | 3 |
| Body temperature abnormal | 1 | 2 | 1 | 2 | | |
| Body temperature increased | | 1 | | 1 | | |
| Heart rate increased | 6 | 7 | | 1 | 6 | 6 |
| Lipase increased | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Pulse abnormal | 2 | 2 | 1 | 1 | 1 | 1 |
| SARS-CoV-2 ant body test | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test negative | 5 | 5 | 5 | 5 | | |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test negative | | 1 | | 1 | | |
| SARS-CoV-2 test positive | 3 | 10 | 1 | 1 | 2 | 9 |
| Transaminases increased | | 1 | | 1 | | |
| | 27 | 41 | 11 | 18 | 16 | 23 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 1 | 2 | | 1 | 1 | 1 |
| Hypocalcaemia | | 1 | | | | 1 |
| | 1 | 3 | | 1 | 1 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 10 | 24 | 3 | 15 | 7 | 9 |
| Back pain | | 2 | | 2 | | |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Joint ankylosis | | 1 | | | | 1 |
| Muscle swelling | | 1 | | 1 | | |
| Muscular weakness | | 2 | | 2 | | |
| Musculoskeletal chest pain | 1 | 1 | | | 1 | 1 |
| Myalgia | 19 | 45 | 3 | 27 | 16 | 18 |
| Pain in extremity | 1 | 28 | 1 | 27 | | 1 |
| Spinal pain | | 1 | | 1 | | |
| | 33 | 107 | 8 | 76 | 25 | 31 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 3 | | 2 | | 1 |
| Anosmia | | 2 | | 1 | | 1 |
| Balance disorder | | 1 | | | | 1 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 1 | 2 | | 1 | 1 | 1 |
| Dizziness | 11 | 18 | 4 | 11 | 7 | 7 |
| Dysgeusia | | 1 | | | | 1 |
| Facial neuralgia | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 2 | 5 | | | 2 | 5 |
| Headache | 28 | 61 | 9 | 39 | 19 | 22 |
| Horner's syndrome | | 1 | | | | 1 |
| Hypoaesthesia | 4 | 6 | 2 | 3 | 2 | 3 |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Intracranial pressure increased | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Memory impairment | 1 | 1 | | | 1 | 1 |
| Migraine | | 2 | | 1 | | 1 |
| Monoplegia | 1 | 1 | | | 1 | 1 |
| Muscle contractions involuntary | | 1 | | 1 | | |
| Myoclonus | 1 | 1 | | | 1 | 1 |
| Nervous system disorder | 3 | 3 | 3 | 3 | | |
| Nystagmus | | 1 | | 1 | | |
| Paraesthesia | 10 | 18 | 4 | 11 | 6 | 7 |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Paraplegia | 1 | 1 | | | 1 | 1 |
| Parosmia | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 4 | 1 | 4 | | |
| Seizure | | 1 | | | | 1 |
| Sensory loss | 1 | 1 | 1 | 1 | | |
| Somnolence | 3 | 8 | 1 | 6 | 2 | 2 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Syncope | 7 | 8 | | | 7 | 8 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 3 | | 1 | 1 | 2 |
| | 85 | 163 | 29 | 90 | 56 | 73 |

System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product quality issue | | 1 | | 1 |
| Syringe issue | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anxiety | | 6 | | 4 | | 2 |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Emotional distress | | 1 | | 1 | | |
| Fear | | 1 | | 1 | | |
| Insomnia | 1 | 2 | | 1 | 1 | 1 |
| Panic attack | | 2 | | 2 | | |
| | 3 | 14 | 1 | 10 | 2 | 4 |

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System Organ Class

Renal and urinary disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Serious | |
| | | | I | C |
| Nephropathy | 1 | 1 | 1 | 1 |
| Polyuria | 1 | 1 | 1 | 1 |
| Renal pain | 2 | 2 | 2 | 2 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Reproductive system and breast disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast pain | | 1 | | 1 |
| Suppressed lactation | | 1 | | 1 |
| | | 2 | | 2 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Cough | 3 | 6 | | 1 | 3 | 5 |
| Dysphonia | | 1 | | 1 | | |
| Dyspnoea | 7 | 9 | 1 | 1 | 6 | 8 |
| Epiglottic oedema | | 1 | | | | 1 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Laryngeal oedema | | 1 | | | | 1 |
| Nasal discomfort | 1 | 2 | 1 | 2 | | |
| Nasal dryness | 1 | 1 | | | 1 | 1 |
| Nasal oedema | | 1 | | | | 1 |
| Oropharyngeal discomfort | 1 | 2 | | | 1 | 2 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Rhinalgia | 1 | 1 | | | 1 | 1 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| | 21 | 32 | 3 | 6 | 18 | 26 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Circumoral oedema | 1 | 1 | | | 1 | 1 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Drug eruption | 2 | 2 | | | 2 | 2 |
| Erythema | 7 | 17 | 2 | 11 | 5 | 6 |
| Erythema nodosum | 1 | 2 | | 1 | 1 | 1 |
| Hyperhidrosis | 4 | 8 | 2 | 5 | 2 | 3 |
| Pruritus | 5 | 10 | 1 | 5 | 4 | 5 |
| Rash | 3 | 10 | | 7 | 3 | 3 |
| Rash erythematous | 2 | 4 | | | 2 | 4 |
| Rash pruritic | 2 | 3 | | 1 | 2 | 2 |
| Scar pain | | 1 | | 1 | | |
| Skin discolouration | | 1 | | 1 | | |
| Skin irritation | 1 | 1 | | | 1 | 1 |
| Skin plaque | 1 | 1 | | | 1 | 1 |
| Urticaria | 4 | 7 | | 3 | 4 | 4 |
| Urticaria papular | | 1 | | 1 | | |
| | 38 | 74 | 6 | 37 | 32 | 37 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Flushing | | 1 | | 1 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hyperaemia | 1 | 1 | | | 1 | 1 |
| Hypertension | 7 | 12 | 1 | 1 | 6 | 11 |
| Hypertensive crisis | | 1 | | | | 1 |
| Hypotension | 4 | 4 | | | 4 | 4 |
| Pallor | 1 | 1 | 1 | 1 | | |
| Peripheral coldness | | 1 | | 1 | | |
| Raynaud's phenomenon | 1 | 1 | | | 1 | 1 |
| Systolic hypertension | | 1 | | | | 1 |
| | 17 | 26 | 3 | 5 | 14 | 21 |

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Country Where Event Occurred

SAUDI ARABIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Abdominal pain | | 1 | | 1 |
| Mouth ulceration | | 1 | | 1 |
| | | 2 | | 2 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 2 | 2 | 2 | 2 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 6 | 2 | 6 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Injection site pain | | 1 | | 1 | | |
| Malaise | | 1 | | 1 | | |
| Pain | 3 | 4 | 3 | 4 | | |
| Pyrexia | 2 | 5 | 2 | 5 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 4 | 2 | 4 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| | 17 | 30 | 16 | 29 | 1 | 1 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Herpes zoster | | 1 | | 1 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Vaginal infection | | 1 | | 1 | | |
| | 2 | 5 | | 3 | 2 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| C-reactive protein increased | 1 | 1 | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 3 | 2 | 3 | | |
| Mastication disorder | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 4 | 4 | 4 | 4 | | |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | 2 | 4 | 2 | 4 | | |
| Pain in extremity | 3 | 4 | 1 | 2 | 2 | 2 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| | 13 | 18 | 11 | 16 | 2 | 2 |

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* AE=Adverse Event
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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | | 1 | | 1 | | |
| Headache | 2 | 4 | 2 | 4 | | |
| Movement disorder | | 1 | | 1 | | |
| Sciatica | 2 | 2 | 2 | 2 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Syncope | | 1 | | | | 1 |
| | 5 | 10 | 5 | 9 | | 1 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Pollakiuria | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Oropharyngeal pain | 1 | 1 | 1 | 1 |
| Rhinorrhoea | | 1 | | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Hyperhidrosis | 1 | 3 | 1 | 3 |
| Pain of skin | | 1 | | 1 |
| | 1 | 4 | 1 | 4 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypotension | | 1 | | | | 1 |
| Peripheral coldness | 1 | 2 | 1 | 2 | | |
| | 1 | 3 | 1 | 2 | | 1 |

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Country Where Event Occurred
SERBIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenitis | | 1 | | | | 1 |
| Lymphadenopathy | | 2 | | 1 | | 1 |
| | | 3 | | 1 | | 2 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Palpitations | | 1 | | 1 | | |
| Tachycardia | 1 | 2 | 1 | 1 | | 1 |
| | 1 | 3 | 1 | 2 | | 1 |

System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Huntington's disease | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Tinnitus | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Eyelid oedema | 1 | 1 | 1 | 1 |
| Eyelid ptosis | 1 | 1 | 1 | 1 |
| Swelling of eyelid | | 1 | | 1 |
| | 2 | 3 | 2 | 3 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea | | 1 | | 1 | | |
| Dry mouth | | 1 | | 1 | | |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Nausea | 3 | 10 | 1 | 8 | 2 | 2 |
| Pancreatitis acute | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Vomiting | | 2 | | 2 | | |
| | 6 | 17 | 1 | 12 | 5 | 5 |

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 * AE=Adverse Event
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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | | 5 | | 5 | | |
| Axillary pain | | 2 | | 1 | | 1 |
| Chest discomfort | | 1 | | 1 | | |
| Chest pain | | 1 | | 1 | | |
| Chills | 1 | 5 | 1 | 4 | | 1 |
| Disease recurrence | | 1 | | 1 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | | 5 | | 5 | | |
| Feeling cold | | 1 | | 1 | | |
| Influenza like illness | | 1 | | 1 | | |
| Malaise | 5 | 9 | 5 | 9 | | |
| Oedema mucosal | | 1 | | | | 1 |
| Oedema peripheral | | 1 | | 1 | | |
| Pain | 1 | 2 | 1 | 1 | | 1 |
| Peripheral swelling | | 1 | | | | 1 |
| Pyrexia | 10 | 28 | 8 | 25 | 2 | 3 |
| Swelling | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site erythema | 2 | 3 | 2 | 3 | | |
| Vaccination site haematoma | | 1 | | | | 1 |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site oedema | 1 | 2 | 1 | 2 | | |
| Vaccination site pain | 4 | 15 | 4 | 15 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| | 27 | 91 | 24 | 80 | 3 | 11 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Hypersensitivity | | 2 | | 1 | | 1 |
| | | 3 | | 1 | | 2 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abscess | | 1 | | | | 1 |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Herpes zoster | | 1 | | 1 | | |
| | 3 | 5 | 2 | 3 | 1 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fall | | 1 | | 1 |
| Vaccination complication | 2 | 2 | 2 | 2 |
| | 2 | 3 | 2 | 3 |

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System Organ Class

Investigations

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|--------------------------------|--|--|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure increased | | 1 | | 1 | | |
| Body temperature increased | 1 | 5 | 1 | 4 | | 1 |
| Inflammatory marker increased | | 1 | | 1 | | |
| Intraocular pressure increased | | 1 | | | | 1 |
| Monocyte count increased | | 1 | | 1 | | |
| SARS-CoV-2 test positive | | 1 | | 1 | | |
| | 1 | 10 | 1 | 8 | | 2 |

System Organ Class

Metabolism and nutrition disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Decreased appetite | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 5 | 9 | 5 | 9 | | |
| Back pain | | 1 | | 1 | | |
| Bone pain | | 2 | | 2 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Muscular weakness | | 2 | | 2 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 4 | 11 | 3 | 10 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | | 7 | | 7 | | |
| Pain in jaw | | 1 | | 1 | | |
| | 12 | 36 | 11 | 35 | 1 | 1 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 1 | | 1 | | |
| Anosmia | | 1 | | 1 | | |
| Burning sensation | | 1 | | 1 | | |
| Dizziness | | 1 | | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Headache | 8 | 14 | 7 | 13 | 1 | 1 |
| Loss of consciousness | | 1 | | | | 1 |
| Paraesthesia | | 1 | | 1 | | |
| | 9 | 21 | 7 | 18 | 2 | 3 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Anxiety | | 1 | | 1 |
| Confusional state | | 1 | | 1 |
| Fear of death | | 1 | | 1 |
| Insomnia | | 1 | | 1 |
| Sleep disorder | | 1 | | 1 |
| | | 5 | | 5 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asphyxia | | 1 | | | | 1 |
| Bronchospasm | 1 | 2 | 1 | 1 | | 1 |
| Cough | 1 | 2 | 1 | 1 | | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| | 4 | 8 | 3 | 4 | 1 | 4 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | 1 | 4 | 1 | 4 | | |
| Hyperhidrosis | 1 | 3 | 1 | 3 | | |
| Pruritus | | 1 | | 1 | | |
| Rash | | 3 | | 2 | | 1 |
| Rash macular | | 2 | | | | 2 |
| Skin reaction | | 1 | | | | 1 |
| Urticaria | 1 | 2 | 1 | 2 | | |
| | 3 | 16 | 3 | 12 | | 4 |

System Organ Class

SOC Not Yet Coded

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypertension | 1 | 3 | 1 | 2 | | 1 |
| Pallor | 1 | 1 | 1 | 1 | | |
| Phlebitis | | 1 | | | | 1 |
| Superficial vein prominence | | 1 | | 1 | | |
| | 2 | 6 | 2 | 4 | | 2 |

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Country Where Event Occurred
SINGAPORE

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Palpitations | | 2 | | 1 | | 1 |
| | | 2 | | 1 | | 1 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eye swelling | | 1 | | 1 | | |
| Periorbital swelling | | 1 | | | | 1 |
| | | 2 | | 1 | | 1 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | | | 1 |
| Diarrhoea | | 2 | | 1 | | 1 |
| Enlarged uvula | | 2 | | 1 | | 1 |
| Lip swelling | | 2 | | | | 2 |
| Nausea | | 1 | | | | 1 |
| Vomiting | | 1 | | 1 | | |
| | | 9 | | 3 | | 6 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chest discomfort | | 1 | | | | 1 |
| Chills | | 2 | | 2 | | |
| Malaise | | 1 | | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 3 | 8 | 3 | 7 | | 1 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactic reaction | | 2 | | 2 |
| Anaphylactic shock | | 5 | | 5 |
| | | 7 | | 7 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Heart rate increased | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Dizziness | | 1 | | | | 1 |
| Head discomfort | | 1 | | 1 | | |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| | 2 | 4 | 2 | 3 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cough | | 2 | | 1 | | 1 |
| Dysphonia | | 2 | | 1 | | 1 |
| Dyspnoea | | 2 | | 1 | | 1 |
| Throat tightness | | 1 | | | | 1 |
| | | 7 | | 3 | | 4 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | | 2 | | | | 2 |
| Pruritus | | 1 | | | | 1 |
| Rash macular | | 2 | | | | 2 |
| Urticaria | | 3 | | 2 | | 1 |
| | | 8 | | 2 | | 6 |

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* AE=Adverse Event
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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Hypertension | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

SLOVAKIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | | 2 | | 2 |
| | | 2 | | 2 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Myocardial ischaemia | 1 | 1 | | | 1 | 1 |
| Palpitations | 1 | 2 | 1 | 2 | | |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | | 1 | | 1 | | |
| | 4 | 6 | 1 | 3 | 3 | 3 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Tinnitus | 1 | 1 | 1 | 1 |
| Vertigo | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

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* AE=Adverse Event
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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diplopia | | 1 | | 1 | | |
| Eye allergy | 1 | 1 | 1 | 1 | | |
| Eye irritation | 1 | 1 | 1 | 1 | | |
| Eye oedema | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Mydriasis | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| | 7 | 8 | 6 | 7 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Lip oedema | 1 | 1 | 1 | 1 | | |
| Nausea | 6 | 6 | 4 | 4 | 2 | 2 |
| Oral discomfort | 1 | 1 | 1 | 1 | | |
| Vomiting | 2 | 3 | 1 | 2 | 1 | 1 |
| | 17 | 18 | 11 | 12 | 6 | 6 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 13 | 14 | 10 | 11 | 3 | 3 |
| Axillary pain | | 1 | | 1 | | |
| Chest discomfort | 2 | 2 | 2 | 2 | | |
| Chills | 15 | 22 | 12 | 18 | 3 | 4 |
| Drug ineffective | 1 | 3 | | | 1 | 3 |
| Fatigue | 5 | 6 | 5 | 6 | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Malaise | 4 | 4 | 4 | 4 | | |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Oedema | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | 1 | 1 | 1 | 1 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Pyrexia | 11 | 15 | 9 | 13 | 2 | 2 |
| Vaccination site joint movement impairment | | 1 | | 1 | | |
| Vaccination site pain | 13 | 19 | 13 | 18 | | 1 |
| Vaccination site swelling | | 1 | | | | 1 |
| Vaccination site urticaria | | 1 | | 1 | | |
| | 72 | 97 | 63 | 83 | 9 | 14 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactic reaction | 1 | 1 | 1 | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 3 | 7 | | 2 | 3 | 5 |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Rhinitis | | 1 | | 1 | | |
| | 4 | 9 | | 3 | 4 | 6 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Incorrect dose administered | 1 | 1 | 1 | 1 |
| Maternal exposure during pregnancy | | 1 | | 1 |
| Medication error | 1 | 1 | 1 | 1 |
| Product administered at inappropriate site | 1 | 2 | 1 | 2 |
| | 3 | 5 | 3 | 5 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 4 | 1 | 1 | 3 | 3 |
| Body temperature increased | 4 | 6 | 3 | 4 | 1 | 2 |
| SARS-CoV-2 ant body test positive | | 1 | | | | 1 |
| SARS-CoV-2 test positive | | 2 | | 1 | | 1 |
| Tryptase decreased | 1 | 1 | 1 | 1 | | |
| | 10 | 15 | 5 | 7 | 5 | 8 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Insulin resistance | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 3 | 3 | 3 | 3 |
| Limb discomfort | | 1 | | 1 |
| Myalgia | 8 | 9 | 8 | 9 |
| Pain in extremity | 6 | 11 | 6 | 11 |
| Synovitis | 1 | 1 | 1 | 1 |
| | 18 | 25 | 18 | 25 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Burning sensation | 1 | 2 | 1 | 2 | | |
| Dizziness | 6 | 8 | 4 | 6 | 2 | 2 |
| Headache | 11 | 16 | 11 | 15 | | 1 |
| Hypoaesthesia | | 1 | | 1 | | |
| Loss of consciousness | 2 | 2 | | | 2 | 2 |
| Movement disorder | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 4 | 5 | 2 | 2 | 2 | 3 |
| Presyncope | 4 | 4 | 1 | 1 | 3 | 3 |
| Syncope | 2 | 3 | | | 2 | 3 |
| Tremor | 1 | 1 | | | 1 | 1 |
| | 32 | 43 | 20 | 28 | 12 | 15 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal dreams | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Restlessness | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Micturition urgency | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cough | 1 | 3 | 1 | 3 | | |
| Dyspnoea | 2 | 3 | 1 | 2 | 1 | 1 |
| Oropharyngeal pain | | 1 | | 1 | | |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat irritation | 1 | 2 | 1 | 2 | | |
| Throat tightness | | 1 | | 1 | | |
| | 5 | 11 | 3 | 9 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 | 1 | 1 | | |
| Erythema | 3 | 4 | 3 | 3 | | 1 |
| Hyperhidrosis | 4 | 5 | 1 | 2 | 3 | 3 |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Petechiae | 1 | 1 | 1 | 1 | | |
| Pruritus | 3 | 4 | 3 | 3 | | 1 |
| Rash | 2 | 3 | 2 | 3 | | |
| Rash pruritic | | 1 | | 1 | | |
| Urticaria | 1 | 1 | 1 | 1 | | |
| | 17 | 22 | 13 | 16 | 4 | 6 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Axillary vein thrombosis | 1 | 1 | | | 1 | 1 |
| Hot flush | 4 | 4 | 2 | 2 | 2 | 2 |
| Hypertension | 2 | 4 | 1 | 3 | 1 | 1 |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Peripheral coldness | 2 | 2 | 2 | 2 | | |
| Subclavian vein thrombosis | 1 | 1 | | | 1 | 1 |
| Venous thrombosis limb | 1 | 1 | | | 1 | 1 |
| | 13 | 15 | 6 | 8 | 7 | 7 |

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Country Where Event Occurred

SLOVENIA

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 4 | 4 | 4 | 4 | | |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 5 | 5 | 2 | 2 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | | 1 | | | | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrial tachycardia | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | | 1 | | | | 1 |
| Tachycardia | 2 | 2 | 2 | 2 | | |
| | 5 | 7 | 2 | 2 | 3 | 5 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Ear pain | 1 | 1 | 1 | 1 |
| Vertigo | 1 | 2 | 1 | 2 |
| | 2 | 3 | 2 | 3 |

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System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Autoimmune thyroiditis | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Miosis | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 3 | 3 | 3 | 3 | | |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 4 | 4 | 4 | 4 | | |
| Nausea | 3 | 4 | 2 | 2 | 1 | 2 |
| Paraesthesia oral | 2 | 2 | 1 | 1 | 1 | 1 |
| Vomiting | 2 | 3 | 2 | 2 | | 1 |
| | 15 | 17 | 13 | 13 | 2 | 4 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 3 | | 2 | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | 4 | 4 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Disease recurrence | | 1 | | | | 1 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Fatigue | 12 | 13 | 10 | 11 | 2 | 2 |
| Feeling hot | 2 | 2 | 1 | 1 | 1 | 1 |
| Malaise | 5 | 5 | 3 | 3 | 2 | 2 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pyrexia | 5 | 5 | 4 | 4 | 1 | 1 |
| Sudden death | | 1 | | | | 1 |
| Vaccination site erythema | 9 | 10 | 9 | 10 | | |
| Vaccination site oedema | 3 | 4 | 3 | 4 | | |
| Vaccination site pain | 35 | 36 | 32 | 33 | 3 | 3 |
| Vaccination site pruritus | 3 | 3 | 3 | 3 | | |
| | 88 | 96 | 71 | 77 | 17 | 19 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 2 | 2 | 2 | 2 | | |
| Oral herpes | 1 | 1 | | | 1 | 1 |
| | 6 | 6 | 2 | 2 | 4 | 4 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 |
| Wrong technique in product usage process | | 1 | | 1 |
| | 2 | 3 | 2 | 3 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 4 | 4 | 3 | 3 | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | | 1 | | 1 | | |
| | 6 | 7 | 4 | 5 | 2 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Myalgia | 7 | 7 | 6 | 6 | 1 | 1 |
| Pain in extremity | 2 | 2 | 1 | 1 | 1 | 1 |
| | 11 | 11 | 9 | 9 | 2 | 2 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| B-cell lymphoma | 1 | 1 | 1 | 1 |
| B-cell type acute leukaemia | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Aura | 1 | 1 | 1 | 1 | | |
| Cerebral thrombosis | 1 | 1 | | | 1 | 1 |
| Dizziness | 4 | 4 | 2 | 2 | 2 | 2 |
| Dysgeusia | 2 | 2 | 2 | 2 | | |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Headache | 14 | 14 | 12 | 12 | 2 | 2 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hyposmia | 2 | 2 | 2 | 2 | | |
| Neurological symptom | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 2 | 2 | 2 | 2 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sensory disturbance | 1 | 1 | 1 | 1 | | |
| Somnolence | 5 | 5 | 3 | 3 | 2 | 2 |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Syncope | 3 | 3 | | | 3 | 3 |
| Tongue biting | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| | 46 | 46 | 28 | 28 | 18 | 18 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Nightmare | 1 | 1 | 1 | 1 | | |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Thinking abnormal | 1 | 1 | 1 | 1 | | |
| | 4 | 4 | 3 | 3 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | 1 | 1 | 1 | 1 | | |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 2 | 2 | 2 | 2 | | |
| Skin disorder | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 3 | 3 | 2 | 2 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 2 | | | 1 | 2 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| | 4 | 5 | 1 | 1 | 3 | 4 |

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Country Where Event Occurred

SPAIN

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haemorrhagic diathesis | 1 | 1 | | | 1 | 1 |
| Hyperfibrinogenaemia | 1 | 1 | | | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Leukopenia | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 4 | 4 | 1 | 1 | 3 | 3 |
| Lymphadenopathy | 24 | 26 | 2 | 4 | 22 | 22 |
| Lymphopenia | 1 | 1 | 1 | 1 | | |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Pancytopenia | 1 | 1 | | | 1 | 1 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| | 36 | 38 | 4 | 6 | 32 | 32 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Bradycardia | 5 | 5 | | | 5 | 5 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 3 | 3 | | | 3 | 3 |
| Cardiac failure acute | 4 | 4 | | | 4 | 4 |
| Cardio-respiratory arrest | 3 | 3 | | | 3 | 3 |
| Cardio-respiratory distress | | 1 | | | | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Hyperdynamic left ventricle | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Palpitations | 7 | 11 | | 2 | 7 | 9 |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Sinus bradycardia | 1 | 1 | 1 | 1 | | |
| Supraventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Tachyarrhythmia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 33 | 36 | 5 | 6 | 28 | 30 |
| Tachycardia paroxysmal | 1 | 1 | | | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| | 72 | 80 | 6 | 9 | 66 | 71 |

System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Macroglossia | 1 | 1 | 1 | 1 |
| Myoclonic dystonia | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Deafness | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Ear pain | 2 | 2 | | | 2 | 2 |
| Hypoacusis | 2 | 2 | | | 2 | 2 |
| Neurosensory hypoacusis | 1 | 1 | | | 1 | 1 |
| Tinnitus | 2 | 2 | | | 2 | 2 |
| Vertigo | 7 | 7 | 2 | 2 | 5 | 5 |
| | 16 | 16 | 2 | 2 | 14 | 14 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Conjunctival haemorrhage | 5 | 5 | | | 5 | 5 |
| Diplopia | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 4 | 4 | 1 | 1 | 3 | 3 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 2 | 3 | | 1 | 2 | 2 |
| Lacrimation increased | 3 | 3 | | | 3 | 3 |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Periorbital oedema | | 1 | | 1 | | |
| Photophobia | 2 | 2 | | | 2 | 2 |
| Photopsia | 1 | 1 | 1 | 1 | | |
| Vision blurred | 7 | 7 | 2 | 2 | 5 | 5 |
| Visual acuity reduced | 1 | 1 | | | 1 | 1 |
| Vitreous detachment | 2 | 2 | | | 2 | 2 |
| | 31 | 33 | 4 | 6 | 27 | 27 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 2 | | 1 | 1 | 1 |
| Abdominal pain | 4 | 7 | | 2 | 4 | 5 |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 2 | 3 | 1 | 2 | 1 | 1 |
| Anal sphincter atony | 1 | 1 | | | 1 | 1 |
| Angular cheilitis | | 1 | | 1 | | |
| Aphthous ulcer | 1 | 2 | | 1 | 1 | 1 |
| Atrophic glossitis | 1 | 1 | | | 1 | 1 |
| Cheilitis | 3 | 3 | | | 3 | 3 |
| Diarrhoea | 32 | 49 | 7 | 22 | 25 | 27 |
| Diarrhoea haemorrhagic | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 3 | | 1 | 1 | 2 |
| Dysphagia | 3 | 4 | 1 | 1 | 2 | 3 |
| Epigastric discomfort | 1 | 1 | | | 1 | 1 |
| Flatulence | | 1 | | | | 1 |
| Gastroesophageal reflux disease | 2 | 2 | 1 | 1 | 1 | 1 |
| Glossitis | | 1 | | | | 1 |
| Glossodynia | 1 | 1 | | | 1 | 1 |
| Haematochezia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 2 | 3 | 1 | 2 | 1 | 1 |
| Ileus paralytic | 1 | 1 | | | 1 | 1 |
| Inflammatory bowel disease | 1 | 1 | | | 1 | 1 |
| Intestinal ischaemia | | 1 | | | | 1 |
| Intestinal obstruction | 2 | 2 | | | 2 | 2 |
| Lip oedema | 7 | 8 | | 1 | 7 | 7 |
| Lip pruritus | 2 | 3 | | 1 | 2 | 2 |
| Lip swelling | 2 | 2 | | | 2 | 2 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Mouth swelling | 2 | 2 | | | 2 | 2 |
| Nausea | 39 | 52 | 11 | 20 | 28 | 32 |
| Noninfective gingivitis | 1 | 1 | | | 1 | 1 |
| Odynophagia | 6 | 6 | 1 | 1 | 5 | 5 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oedema mouth | 1 | 1 | | | 1 | 1 |
| Oral discomfort | | 1 | | 1 | | |
| Oral dysaesthesia | 1 | 1 | | | 1 | 1 |
| Oral pruritus | 2 | 2 | | | 2 | 2 |
| Palatal oedema | 10 | 11 | | | 10 | 11 |
| Palatal swelling | 2 | 2 | | | 2 | 2 |
| Paraesthesia oral | 8 | 9 | | 1 | 8 | 8 |
| Rectal haemorrhage | 1 | 2 | | | 1 | 2 |
| Stomatitis | | 3 | | 2 | | 1 |
| Swollen tongue | 4 | 4 | | | 4 | 4 |
| Tongue discomfort | | 1 | | 1 | | |
| Tongue eruption | | 1 | | 1 | | |
| Tongue erythema | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 3 | 5 | | 1 | 3 | 4 |
| Tongue pruritus | 2 | 4 | | 1 | 2 | 3 |
| Tongue ulceration | | 1 | | 1 | | |
| Volvulus | 1 | 1 | | | 1 | 1 |
| Vomiting | 33 | 44 | 6 | 14 | 27 | 30 |
| | 191 | 262 | 30 | 81 | 161 | 181 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 31 | 34 | 7 | 10 | 24 | 24 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chest discomfort | 12 | 13 | 1 | 1 | 11 | 12 |
| Chest pain | 13 | 17 | 2 | 4 | 11 | 13 |
| Chills | 26 | 34 | 7 | 15 | 19 | 19 |
| Condition aggravated | 3 | 3 | 1 | 1 | 2 | 2 |
| Death | 2 | 3 | | | 2 | 3 |
| Discomfort | 4 | 7 | 1 | 4 | 3 | 3 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Drowning | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 31 | 37 | | | 31 | 37 |
| Drug interaction | 1 | 2 | | 1 | 1 | 1 |
| Face oedema | 10 | 11 | | | 10 | 11 |
| Fatigue | 21 | 31 | 6 | 13 | 15 | 18 |
| Feeling abnormal | 3 | 4 | | 1 | 3 | 3 |
| Feeling cold | 2 | 3 | | | 2 | 3 |
| Feeling drunk | | 1 | | 1 | | |
| Feeling hot | 8 | 9 | 1 | 2 | 7 | 7 |
| Gait disturbance | 2 | 2 | | | 2 | 2 |
| Gait inability | 1 | 1 | | | 1 | 1 |
| Generalised oedema | 2 | 2 | | | 2 | 2 |
| General physical health deterioration | 2 | 2 | | | 2 | 2 |
| Hypothermia | 3 | 3 | | | 3 | 3 |
| Induration | 1 | 1 | | | 1 | 1 |
| Inflammation | 2 | 2 | | | 2 | 2 |
| Influenza like illness | 2 | 3 | 1 | 2 | 1 | 1 |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Local reaction | 1 | 1 | | | 1 | 1 |
| Malaise | 49 | 64 | 13 | 25 | 36 | 39 |
| Mucosal dryness | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 2 | | | 1 | 2 |
| Necrosis | 1 | 1 | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oedema | 4 | 4 | 2 | 2 | 2 | 2 |
| Oedema peripheral | 6 | 6 | | | 6 | 6 |
| Pain | 8 | 12 | 2 | 6 | 6 | 6 |
| Peripheral swelling | 2 | 4 | 1 | 2 | 1 | 2 |
| Pyrexia | 110 | 157 | 24 | 68 | 86 | 89 |
| Sensation of foreign body | 4 | 4 | | | 4 | 4 |
| Sense of oppression | 1 | 1 | | | 1 | 1 |
| Sudden death | 4 | 7 | | | 4 | 7 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swelling face | 4 | 4 | | | 4 | 4 |
| Temperature regulation disorder | 9 | 11 | 4 | 6 | 5 | 5 |
| Vaccination site erosion | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 6 | 8 | 2 | 4 | 4 | 4 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site induration | 2 | 2 | | | 2 | 2 |
| Vaccination site inflammation | 6 | 13 | 1 | 7 | 5 | 6 |
| Vaccination site joint erythema | 4 | 5 | | 1 | 4 | 4 |
| Vaccination site joint inflammation | 2 | 2 | | | 2 | 2 |
| Vaccination site joint movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site oedema | 2 | 2 | | | 2 | 2 |
| Vaccination site pain | 34 | 60 | 8 | 33 | 26 | 27 |
| Vaccination site paraesthesia | 4 | 4 | 1 | 1 | 3 | 3 |
| Vaccination site pruritus | 4 | 5 | 1 | 2 | 3 | 3 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 3 | 5 | 1 | 3 | 2 | 2 |
| Vaccination site warmth | 4 | 5 | | 1 | 4 | 4 |
| | 472 | 631 | 91 | 222 | 381 | 409 |

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System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hepatic failure | 1 | 1 | 1 | 1 |
| Hepatitis | 1 | 1 | 1 | 1 |
| Hepatitis acute | 2 | 2 | 2 | 2 |
| Hypertransaminaemia | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic oedema | 1 | 1 | | | 1 | 1 |
| Allergic reaction to excipient | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 4 | 4 | | | 4 | 4 |
| Anaphylactic reaction | 31 | 33 | | | 31 | 33 |
| Anaphylactic shock | 2 | 5 | | | 2 | 5 |
| Drug hypersensitivity | 2 | 2 | | | 2 | 2 |
| Haemophagocytic lymphohistiocytosis | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 12 | 13 | 1 | 1 | 11 | 12 |
| Immunisation reaction | | 1 | | 1 | | |
| Reaction to excipient | 1 | 1 | | | 1 | 1 |
| Type IV hypersensitivity reaction | 1 | 1 | | | 1 | 1 |
| | 56 | 63 | 1 | 2 | 55 | 61 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appendicitis | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 7 | 7 | 1 | 1 | 6 | 6 |
| Cellulitis | 4 | 4 | | | 4 | 4 |
| Citrobacter infection | 1 | 1 | | | 1 | 1 |
| COVID-19 | 42 | 47 | 5 | 5 | 37 | 42 |
| COVID-19 pneumonia | 5 | 5 | | | 5 | 5 |
| Ear infection | 1 | 1 | | | 1 | 1 |
| Eczema herpeticum | 1 | 1 | | | 1 | 1 |
| Encephalitis | 2 | 2 | | | 2 | 2 |
| Epiglottitis | 1 | 1 | | | 1 | 1 |
| Gastroenteritis | 1 | 2 | 1 | 1 | | 1 |
| Gingivitis | 1 | 1 | 1 | 1 | | |
| Herpes virus infection | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 17 | 17 | | | 17 | 17 |
| Herpes zoster cutaneous disseminated | 1 | 1 | | | 1 | 1 |
| Herpes zoster oticus | 1 | 1 | | | 1 | 1 |
| Herpes zoster reactivation | 2 | 2 | | | 2 | 2 |
| Infection | 1 | 1 | | | 1 | 1 |
| Influenza | 3 | 3 | | | 3 | 3 |
| Localised infection | 1 | 1 | | | 1 | 1 |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | | 2 | | 2 | | |
| Oral candidiasis | 1 | 1 | | | 1 | 1 |
| Oral herpes | 2 | 2 | | | 2 | 2 |
| Parotitis | 2 | 2 | | | 2 | 2 |
| Pertussis | 2 | 2 | | | 2 | 2 |
| Pharyngotonsillitis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 7 | 8 | | | 7 | 8 |
| Respiratory tract infection | 2 | 2 | | | 2 | 2 |
| Rhinitis | | 1 | | 1 | | |
| Sepsis | | 1 | | | | 1 |

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System Organ Class

Infections and infestations

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-----------------------------------|--|--|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Subcutaneous abscess | 1 | 1 | | | 1 | 1 |
| Tonsillitis | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 2 | 3 | | 1 | 2 | 2 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Vaccination site cellulitis | 2 | 2 | | | 2 | 2 |
| | 120 | 132 | 8 | 12 | 112 | 120 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Brachial plexus injury | 1 | 1 | | | 1 | 1 |
| Circumstance or information capable of leading to medication error | 1 | 1 | 1 | 1 | | |
| Contusion | 3 | 3 | 2 | 2 | 1 | 1 |
| Exposure during pregnancy | | 1 | | 1 | | |
| Exposure via breast milk | 1 | 2 | 1 | 2 | | |
| Facial bones fracture | 1 | 1 | | | 1 | 1 |
| Fall | 2 | 2 | 1 | 1 | 1 | 1 |
| Head injury | 2 | 2 | 1 | 1 | 1 | 1 |
| Inappropriate schedule of product administration | 4 | 5 | 4 | 5 | | |
| Incorrect dose administered | | 1 | | 1 | | |
| Incorrect route of product administration | | 1 | | 1 | | |
| Jaw fracture | 1 | 1 | | | 1 | 1 |
| Off label use | 9 | 11 | 9 | 11 | | |
| Overdose | 1 | 2 | 1 | 2 | | |
| Product use issue | 7 | 9 | 7 | 9 | | |
| Spinal cord injury | 1 | 1 | | | 1 | 1 |
| Underdose | | 1 | | 1 | | |
| Vaccination complication | 2 | 4 | | 1 | 2 | 3 |
| Vaccination failure | 3 | 3 | | | 3 | 3 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 39 | 53 | 27 | 40 | 12 | 13 |

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System Organ Class

Investigations

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| | | Spontaneous | | | |
|--|---|-------------|---|---------|---|
| | | Nonserious | | Serious | |
| | | I | C | I | C |
| Autoantibody negative | 1 | | | 1 | 1 |
| Blood chloride decreased | 1 | 1 | 1 | | |
| Blood fibrinogen increased | 1 | 1 | 1 | | |
| Blood glucose increased | 1 | 1 | 1 | | |
| Blood pressure abnormal | 2 | 1 | 1 | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | | |
| Blood pressure diastolic decreased | 1 | | | 1 | 1 |
| Blood pressure increased | 7 | 6 | 6 | 1 | 2 |
| Blood pressure systolic increased | 1 | 1 | 1 | | |
| Blood sodium decreased | 1 | 1 | 1 | | |
| Body temperature abnormal | 1 | | | 1 | 1 |
| Body temperature increased | | | 1 | | |
| Breath sounds abnormal | 1 | | | 1 | 1 |
| Carotid bruit | 2 | | | 2 | 2 |
| C-reactive protein increased | 3 | 3 | 3 | | |
| Electrocardiogram QRS complex prolonged | 1 | | | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | | | 1 | 1 |
| Electrocardiogram ST-T change | 1 | | | 1 | 1 |
| Fibrin D dimer increased | 1 | | | 1 | 1 |
| Gamma-glutamyltransferase increased | 1 | 1 | 1 | | |
| Haematocrit decreased | 1 | 1 | 1 | | |
| Haemoglobin decreased | 1 | 1 | 1 | | |
| Heart rate increased | 1 | 1 | 1 | | |
| Lymphocyte percentage decreased | 1 | 1 | 1 | | |
| Neutrophil count increased | 2 | 2 | 2 | | |
| Neutrophil percentage increased | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 6 | | | 6 | 6 |
| Platelet count increased | 1 | 1 | 1 | | |
| Prothrombin time prolonged | 1 | 1 | 1 | | |
| Pulse abnormal | 1 | | | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | | |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| SARS-CoV-2 ant body test positive | 3 | 3 | 3 | 3 | | |
| SARS-CoV-2 test positive | 1 | 2 | 1 | 1 | | 1 |
| Transaminases increased | 1 | 1 | | | 1 | 1 |
| Troponin T increased | | 1 | | | | 1 |
| Urinary sediment present | 1 | 1 | 1 | 1 | | |
| White blood cell count decreased | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 2 | 2 | 2 | 2 | | |
| | 56 | 60 | 35 | 36 | 21 | 24 |

System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 3 | 3 | | | 3 | 3 |
| Dehydration | 2 | 2 | 1 | 1 | 1 | 1 |
| Diabetes mellitus | 1 | 1 | | | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | | 1 | | 1 | | |
| Hypernatraemia | 2 | 2 | | | 2 | 2 |
| Hypocalcaemia | 1 | 1 | 1 | 1 | | |
| Hypoglycaemia | 2 | 2 | | | 2 | 2 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypophosphataemia | 1 | 1 | 1 | 1 | | |
| Insulin resistance | | 1 | | 1 | | |
| Iron deficiency | 1 | 1 | 1 | 1 | | |
| | 15 | 17 | 4 | 6 | 11 | 11 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 20 | 26 | 5 | 10 | 15 | 16 |
| Back pain | 8 | 9 | 3 | 4 | 5 | 5 |
| Bursitis | 1 | 1 | | | 1 | 1 |
| Groin pain | 1 | 1 | | | 1 | 1 |
| Haematoma muscle | | 1 | | | | 1 |
| Jaw disorder | | 1 | | 1 | | |
| Joint contracture | | 1 | | 1 | | |
| Joint range of motion decreased | | 1 | | | | 1 |
| Joint swelling | 1 | 1 | | | 1 | 1 |
| Joint warmth | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 3 | 4 | 1 | 1 | 2 | 3 |
| Muscle contracture | 2 | 3 | 2 | 3 | | |
| Muscle rigidity | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscle tightness | | 1 | | 1 | | |
| Muscular weakness | 4 | 6 | 1 | 3 | 3 | 3 |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal discomfort | 3 | 3 | | | 3 | 3 |
| Musculoskeletal pain | 11 | 12 | 2 | 3 | 9 | 9 |
| Musculoskeletal stiffness | | 2 | | 1 | | 1 |
| Myalgia | 42 | 56 | 9 | 23 | 33 | 33 |
| Myositis | 1 | 1 | | | 1 | 1 |
| Neck pain | 1 | 2 | | | 1 | 2 |
| Nuchal rigidity | | 1 | | | | 1 |
| Pain in extremity | 9 | 18 | 3 | 10 | 6 | 8 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| | 113 | 157 | 29 | 64 | 84 | 93 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute leukaemia | 1 | 1 | | | 1 | 1 |
| Neoplasm | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 3 | 3 | | | 3 | 3 |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anosmia | 3 | 3 | | | 3 | 3 |
| Aphasia | 3 | 3 | | | 3 | 3 |
| Autoimmune demyelinating disease | 1 | 1 | | | 1 | 1 |
| Balance disorder | 4 | 5 | | 1 | 4 | 4 |
| Bradykinesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Burning sensation mucosal | | 1 | | 1 | | |
| Cerebrovascular accident | 3 | 3 | | | 3 | 3 |
| Cervicobrachial syndrome | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 12 | 12 | | | 12 | 12 |
| Disturbance in attention | 3 | 3 | | | 3 | 3 |
| Dizziness | 61 | 72 | 12 | 21 | 49 | 51 |
| Dysaesthesia | 2 | 2 | | | 2 | 2 |
| Dysarthria | 2 | 3 | 1 | 2 | 1 | 1 |
| Dysgeusia | 3 | 6 | 1 | 3 | 2 | 3 |
| Dystonia | 1 | 1 | | | 1 | 1 |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Epilepsy | 3 | 3 | | | 3 | 3 |
| Essential tremor | 1 | 1 | | | 1 | 1 |
| Extensor plantar response | 1 | 1 | 1 | 1 | | |
| Extrapyramidal disorder | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 19 | 20 | | | 19 | 20 |
| Febrile convulsion | 1 | 1 | | | 1 | 1 |
| Formication | 1 | 3 | | 2 | 1 | 1 |
| Generalised tonic-clonic seizure | 2 | 2 | | | 2 | 2 |
| Guillain-Barre syndrome | 1 | 1 | | | 1 | 1 |
| Haemorrhagic stroke | 1 | 1 | | | 1 | 1 |
| Headache | 88 | 123 | 21 | 51 | 67 | 72 |
| Hemiparaesthesia | 3 | 3 | | | 3 | 3 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Hypoaesthesia | 12 | 13 |
| Ischaemic stroke | 7 | 7 |
| Leukoencephalopathy | 1 | 1 |
| Loss of consciousness | 4 | 5 |
| Mental impairment | 3 | 3 |
| Migraine | 2 | 4 |
| Migraine with aura | 2 | 2 |
| Mononeuropathy | 1 | 1 |
| Movement disorder | | 1 |
| Muscle contractions involuntary | | 1 |
| Myoclonus | | 1 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 2 | 2 |
| Neuropathy peripheral | 1 | 1 |
| Paraesthesia | 25 | 32 |
| Paraparesis | 2 | 2 |
| Partial seizures | 1 | 1 |
| Petit mal epilepsy | 2 | 2 |
| Presyncope | 8 | 9 |
| Psychomotor hyperactivity | | 1 |
| Seizure | 3 | 3 |
| Sensory loss | 1 | 2 |
| Slow speech | 2 | 2 |
| Somnolence | 6 | 10 |
| Speech disorder | 2 | 3 |
| Status epilepticus | 1 | 1 |
| Syncope | 29 | 29 |
| Tension headache | 2 | 4 |
| Thunderclap headache | 1 | 1 |
| Tonic clonic movements | 1 | 1 |
| Transient global amnesia | 1 | 1 |
| Transient ischaemic attack | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 3 | 10 | 10 |
| | | 7 | 7 |
| | | 1 | 1 |
| | | 4 | 5 |
| | | 3 | 3 |
| | 1 | 2 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 3 | 10 | 22 | 22 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| 2 | 2 | 6 | 7 |
| | 1 | | |
| | | 3 | 3 |
| | 1 | 1 | 1 |
| | | 2 | 2 |
| 2 | 6 | 4 | 4 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| | | 29 | 29 |
| | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 7 | 7 | 1 | 1 | 6 | 6 |
| Trigeminal neuralgia | 1 | 1 | | | 1 | 1 |
| Tunnel vision | 1 | 1 | | | 1 | 1 |
| | 364 | 443 | 48 | 113 | 316 | 330 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | 3 | 5 | 3 | 5 | | |
| Bradyphrenia | 3 | 3 | 1 | 1 | 2 | 2 |
| Bruxism | | 1 | | 1 | | |
| Confusional state | 4 | 5 | 1 | 1 | 3 | 4 |
| Depressed mood | | 2 | | 2 | | |
| Disorientation | 1 | 1 | 1 | 1 | | |
| Euphoric mood | 1 | 2 | | 1 | 1 | 1 |
| Hypersexuality | 1 | 1 | | | 1 | 1 |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Nervousness | | 1 | | 1 | | |
| Panic reaction | 1 | 1 | | | 1 | 1 |
| Persistent depressive disorder | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Tic | 1 | 1 | | | 1 | 1 |
| | 18 | 26 | 8 | 15 | 10 | 11 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 3 | 3 | | | 3 | 3 |
| Haematuria | 1 | 1 | 1 | 1 | | |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Renal impairment | 2 | 2 | | | 2 | 2 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| | 8 | 8 | 1 | 1 | 7 | 7 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast oedema | 1 | 1 | | | 1 | 1 |
| Genital ulceration | 1 | 1 | | | 1 | 1 |
| Pelvic pain | | 1 | | 1 | | |
| Uterine haemorrhage | 2 | 2 | | | 2 | 2 |
| Vaginal haemorrhage | | 1 | | 1 | | |
| | 4 | 6 | | 2 | 4 | 4 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | 2 | 5 | | | 2 | 5 |
| Aphonia | 2 | 2 | | | 2 | 2 |
| Asphyxia | 3 | 3 | | | 3 | 3 |
| Aspiration | | 1 | | | | 1 |
| Asthma | 3 | 3 | | | 3 | 3 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Bronchial hyperreactivity | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 9 | 9 | | | 9 | 9 |
| Catarrh | 1 | 1 | | | 1 | 1 |
| Choking sensation | 2 | 2 | | | 2 | 2 |
| Chronic respiratory failure | 1 | 1 | | | 1 | 1 |
| Cough | 16 | 18 | 3 | 5 | 13 | 13 |
| Dry throat | 1 | 2 | | 1 | 1 | 1 |
| Dysphonia | 3 | 3 | | | 3 | 3 |
| Dyspnoea | 43 | 50 | 1 | 1 | 42 | 49 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Hypoxia | 10 | 11 | | | 10 | 11 |
| Increased bronchial secretion | 1 | 1 | | | 1 | 1 |
| Interstitial lung disease | 1 | 1 | | | 1 | 1 |
| Laryngeal erythema | 1 | 1 | | | 1 | 1 |
| Laryngeal oedema | 5 | 7 | | | 5 | 7 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Lung infiltration | 2 | 2 | 2 | 2 | | |
| Nasal congestion | 5 | 7 | 1 | 3 | 4 | 4 |
| Oropharyngeal discomfort | 3 | 3 | | | 3 | 3 |
| Oropharyngeal oedema | 2 | 2 | | | 2 | 2 |
| Oropharyngeal pain | 1 | 2 | | 1 | 1 | 1 |
| Pharyngeal erythema | 1 | 1 | | | 1 | 1 |
| Pharyngeal inflammation | 1 | 1 | | | 1 | 1 |
| Pharyngeal oedema | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 1 | 1 | | | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|-----|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Pleural effusion | | 1 | | | | 1 | |
| Pleuritic pain | 1 | 1 | | | 1 | | 1 |
| Productive cough | 2 | 2 | 1 | 1 | 1 | | 1 |
| Pulmonary embolism | 2 | 2 | | | 2 | | 2 |
| Pulmonary thrombosis | 1 | 1 | | | 1 | | 1 |
| Respiratory arrest | | 1 | | | | | 1 |
| Respiratory distress | 6 | 8 | | | 6 | | 8 |
| Respiratory failure | 2 | 3 | | | 2 | | 3 |
| Rhinalgia | 1 | 1 | 1 | 1 | | | |
| Rhinorrhoea | 2 | 4 | 1 | 3 | 1 | | 1 |
| Stridor | 1 | 1 | | | 1 | | 1 |
| Suffocation feeling | 1 | 1 | | | 1 | | 1 |
| Tachypnoea | 4 | 4 | 1 | 1 | 3 | | 3 |
| Throat irritation | 8 | 11 | 1 | 4 | 7 | | 7 |
| Throat tightness | 2 | 3 | | | 2 | | 3 |
| Wheezing | 6 | 6 | | | 6 | | 6 |
| | 165 | 196 | 12 | 23 | 153 | | 173 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 20 | 22 | | | 20 | 22 |
| Blister | 1 | 1 | | | 1 | 1 |
| Butterfly rash | 1 | 1 | | | 1 | 1 |
| Circumoral swelling | | 1 | | 1 | | |
| Cold sweat | 3 | 3 | 1 | 1 | 2 | 2 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Dermatitis bullous | 2 | 2 | | | 2 | 2 |
| Ecchymosis | 1 | 1 | | | 1 | 1 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Epidermal necrosis | 1 | 1 | | | 1 | 1 |
| Erythema | 26 | 29 | 1 | 4 | 25 | 25 |
| Erythema nodosum | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 7 | 8 | 1 | 2 | 6 | 6 |
| Lichen planus | 1 | 1 | | | 1 | 1 |
| Lividity | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Panniculitis | 1 | 1 | | | 1 | 1 |
| Petechiae | 2 | 3 | 1 | 2 | 1 | 1 |
| Pruritus | 37 | 43 | 1 | 5 | 36 | 38 |
| Psoriasis | 1 | 1 | | | 1 | 1 |
| Purpura | 1 | 1 | | | 1 | 1 |
| Rash | 21 | 28 | | 7 | 21 | 21 |
| Rash erythematous | 3 | 3 | | | 3 | 3 |
| Rash maculo-papular | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash papular | 2 | 2 | | | 2 | 2 |
| Rash pruritic | 2 | 3 | 1 | 1 | 1 | 2 |
| Skin exfoliation | 1 | 1 | | | 1 | 1 |
| Skin lesion | 1 | 2 | | 1 | 1 | 1 |
| Skin necrosis | 2 | 2 | | | 2 | 2 |
| Skin odour abnormal | 1 | 1 | | | 1 | 1 |
| Skin reaction | 1 | 1 | | | 1 | 1 |
| Skin ulcer | 1 | 1 | | | 1 | 1 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urticaria | 22 | 24 | 2 | 3 | 20 | 21 |
| | 169 | 194 | 9 | 28 | 160 | 166 |

System Organ Class

Surgical and medical procedures

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Limb immobilisation | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aortic dissection | 1 | 1 | | | 1 | 1 |
| Cyanosis | 2 | 2 | | | 2 | 2 |
| Deep vein thrombosis | 2 | 2 | | | 2 | 2 |
| Flushing | 3 | 3 | 1 | 1 | 2 | 2 |
| Haematoma | 3 | 3 | 1 | 1 | 2 | 2 |
| Haemorrhage | 2 | 2 | | | 2 | 2 |
| Hypertension | 22 | 22 | 6 | 6 | 16 | 16 |
| Hypertensive crisis | 12 | 12 | | | 12 | 12 |
| Hypertensive urgency | 1 | 1 | | | 1 | 1 |
| Hypotension | 9 | 14 | 2 | 4 | 7 | 10 |
| Neurogenic shock | 1 | 1 | | | 1 | 1 |
| Pallor | 4 | 4 | 1 | 1 | 3 | 3 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Peripheral ischaemia | 1 | 2 | | | 1 | 2 |
| Phlebitis | 1 | 1 | 1 | 1 | | |
| Raynaud's phenomenon | 1 | 1 | | | 1 | 1 |
| Shock | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis superficial | 1 | 1 | | | 1 | 1 |
| Vasculitis | 1 | 1 | | | 1 | 1 |
| Venous thrombosis limb | 1 | 1 | 1 | 1 | | |
| | 70 | 76 | 13 | 15 | 57 | 61 |

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Country Where Event Occurred

SWEDEN

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 5 | 6 | 5 | 5 | | 1 |
| Lymph node pain | 5 | 5 | 4 | 4 | 1 | 1 |
| Myelosuppression | 1 | 1 | | | 1 | 1 |
| | 12 | 13 | 9 | 9 | 3 | 4 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute left ventricular failure | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 2 | | | 1 | 2 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Atrioventricular block complete | 2 | 2 | | | 2 | 2 |
| Bundle branch block left | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 3 | 7 | | | 3 | 7 |
| Cardiac disorder | | 1 | | | | 1 |
| Cardiac failure | 6 | 7 | | | 6 | 7 |
| Cardiac failure acute | 1 | 2 | | | 1 | 2 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 4 | 5 | | | 4 | 5 |
| Myocardial ischaemia | | 1 | | | | 1 |
| Myocardial rupture | | 1 | | | | 1 |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Palpitations | 8 | 11 | 1 | 4 | 7 | 7 |
| Pericardial haemorrhage | | 1 | | | | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 3 | 4 | 2 | 2 | 1 | 2 |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| | 40 | 57 | 3 | 6 | 37 | 51 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Paraesthesia ear | 1 | 1 | | | 1 | 1 |
| Tinnitus | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vertigo positional | | 1 | | 1 | | |
| | 4 | 5 | 1 | 2 | 3 | 3 |

System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Goitre | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blindness | 1 | 1 | | | 1 | 1 |
| Blindness transient | 1 | 1 | | | 1 | 1 |
| Eye disorder | 2 | 2 | | | 2 | 2 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 2 | 2 | | | 2 | 2 |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | 1 | 1 | | | 1 | 1 |
| Ocular discomfort | 1 | 1 | | | 1 | 1 |
| Periorbital oedema | 1 | 1 | | | 1 | 1 |
| Periorbital pain | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Vision blurred | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual impairment | 2 | 2 | 1 | 1 | 1 | 1 |
| | 18 | 18 | 4 | 4 | 14 | 14 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 7 | 9 | 6 | 8 | 1 | 1 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | | 1 | | 1 | | |
| Ascites | | 1 | | | | 1 |
| Constipation | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 18 | 23 | 11 | 15 | 7 | 8 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dyspepsia | | 1 | | 1 | | |
| Dysphagia | 6 | 7 | 2 | 3 | 4 | 4 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 8 | 9 | 2 | 3 | 6 | 6 |
| Infrequent bowel movements | 1 | 1 | 1 | 1 | | |
| Intestinal haemorrhage | | 1 | | | | 1 |
| Intestinal ischaemia | | 1 | | | | 1 |
| Lip pruritus | 1 | 1 | | | 1 | 1 |
| Lip swelling | 5 | 6 | 1 | 1 | 4 | 5 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Nausea | 42 | 50 | 23 | 30 | 19 | 20 |
| Oral discomfort | 1 | 1 | | | 1 | 1 |
| Oral pain | 1 | 1 | 1 | 1 | | |
| Oral pruritus | 5 | 6 | 3 | 3 | 2 | 3 |
| Paraesthesia oral | 6 | 7 | 2 | 3 | 4 | 4 |
| Swollen tongue | 7 | 7 | | | 7 | 7 |
| Tongue discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Tongue pruritus | 2 | 3 | | | 2 | 3 |
| Upper gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vomiting | 24 | 26 | 6 | 8 | 18 | 18 |
| | 146 | 174 | 62 | 82 | 84 | 92 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 9 | 10 | 4 | 5 | 5 | 5 |
| Axillary pain | 5 | 6 | 3 | 4 | 2 | 2 |
| Chest discomfort | 7 | 7 | 2 | 2 | 5 | 5 |
| Chest pain | 8 | 8 | 4 | 4 | 4 | 4 |
| Chills | 35 | 44 | 23 | 31 | 12 | 13 |
| Condition aggravated | 5 | 6 | 1 | 1 | 4 | 5 |
| Crepitations | 1 | 2 | | 1 | 1 | 1 |
| Death | 21 | 27 | | | 21 | 27 |
| Discomfort | 5 | 5 | 3 | 3 | 2 | 2 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 7 | 8 | | | 7 | 8 |
| Fatigue | 91 | 102 | 53 | 61 | 38 | 41 |
| Feeling abnormal | 4 | 6 | | 2 | 4 | 4 |
| Feeling cold | 9 | 9 | 7 | 7 | 2 | 2 |
| Feeling hot | 15 | 16 | 7 | 8 | 8 | 8 |
| Feeling of body temperature change | 2 | 2 | | | 2 | 2 |
| Gait disturbance | 2 | 2 | | | 2 | 2 |
| Generalised oedema | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 17 | 22 | 4 | 5 | 13 | 17 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 2 | 2 | 2 | 2 | | |
| Injected limb mobility decreased | 1 | 2 | 1 | 2 | | |
| Local reaction | 1 | 1 | 1 | 1 | | |
| Malaise | 26 | 27 | 15 | 16 | 11 | 11 |
| Nodule | 1 | 1 | 1 | 1 | | |
| Pain | 22 | 26 | 12 | 14 | 10 | 12 |
| Peripheral swelling | 3 | 3 | 2 | 2 | 1 | 1 |
| Pyrexia | 109 | 125 | 70 | 81 | 39 | 44 |
| Sensation of foreign body | | 1 | | | | 1 |
| Sudden death | | 2 | | | | 2 |
| Swelling | 2 | 3 | | 1 | 2 | 2 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling face | 6 | 8 | 1 | 3 | 5 | 5 |
| Systemic inflammatory response syndrome | | 1 | | | | 1 |
| Vaccination site discomfort | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 20 | 23 | 13 | 15 | 7 | 8 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site hypoaesthesia | | 1 | | 1 | | |
| Vaccination site induration | 2 | 2 | 2 | 2 | | |
| Vaccination site joint movement impairment | 3 | 3 | 3 | 3 | | |
| Vaccination site movement impairment | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site pain | 77 | 85 | 70 | 77 | 7 | 8 |
| Vaccination site pruritus | 7 | 8 | 5 | 6 | 2 | 2 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site swelling | 23 | 28 | 15 | 19 | 8 | 9 |
| Vaccination site urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 4 | 7 | 4 | 6 | | 1 |
| | 567 | 656 | 333 | 391 | 234 | 265 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 2 | 2 | | | 2 | 2 |
| Anaphylactic reaction | 12 | 13 | | | 12 | 13 |
| Anaphylactic shock | | 1 | | | | 1 |
| Hypersensitivity | 27 | 28 | 4 | 4 | 23 | 24 |
| Immunisation reaction | 1 | 1 | | | 1 | 1 |
| | 42 | 45 | 4 | 4 | 38 | 41 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| COVID-19 | 25 | 26 | 18 | 18 | 7 | 8 |
| Diverticulitis | 1 | 1 | | | 1 | 1 |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Erysipelas | 1 | 2 | | | 1 | 2 |
| Escherichia infection | 1 | 1 | | | 1 | 1 |
| Escherichia sepsis | | 1 | | | | 1 |
| Furuncle | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 4 | 4 | 1 | 1 | 3 | 3 |
| Infection | 4 | 7 | | | 4 | 7 |
| Meningitis herpes | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 3 | 3 | | | 3 | 3 |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Oral herpes | 2 | 2 | 2 | 2 | | |
| Pharyngitis | | 1 | | 1 | | |
| Pneumonia | 3 | 5 | | | 3 | 5 |
| Pneumonia bacterial | | 1 | | | | 1 |
| Pneumonia pneumococcal | 1 | 1 | | | 1 | 1 |
| Pneumonia streptococcal | 1 | 1 | | | 1 | 1 |
| Post viral fatigue syndrome | | 1 | | 1 | | |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Sepsis | 5 | 6 | | | 5 | 6 |
| Streptococcal bacteraemia | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infection | 1 | 2 | | | 1 | 2 |
| Urinary tract infection | 1 | 2 | | | 1 | 2 |
| Urosepsis | 1 | 3 | | | 1 | 3 |
| | 61 | 77 | 22 | 24 | 39 | 53 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circumstance or information capable of leading to medication error | | 29 | | 29 | | |
| Face injury | 1 | 1 | | | 1 | 1 |
| Fall | 2 | 2 | | | 2 | 2 |
| Head injury | 2 | 2 | 1 | 1 | 1 | 1 |
| Incorrect route of product administration | 6 | 6 | 6 | 6 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | | 35 | | 35 | | |
| Postoperative wound complication | 1 | 1 | | | 1 | 1 |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product preparation issue | 4 | 4 | 4 | 4 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Underdose | 3 | 5 | 3 | 5 | | |
| | 22 | 89 | 17 | 84 | 5 | 5 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood glucose increased | 2 | 2 | | | 2 | 2 |
| Blood pressure abnormal | | 1 | | | | 1 |
| Blood pressure decreased | 6 | 7 | 2 | 2 | 4 | 5 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure increased | 3 | 3 | 1 | 1 | 2 | 2 |
| Blood pressure systolic increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Body temperature decreased | 2 | 2 | | | 2 | 2 |
| Body temperature increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 2 | 3 | 2 | 2 | | 1 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Heart rate decreased | 2 | 2 | 2 | 2 | | |
| Heart rate increased | 7 | 8 | 3 | 3 | 4 | 5 |
| Heart rate irregular | 1 | 1 | 1 | 1 | | |
| Oxygen saturation abnormal | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 8 | 12 | | 2 | 8 | 10 |
| Pulse abnormal | 2 | 3 | 2 | 2 | | 1 |
| Pulse pressure decreased | 1 | 1 | 1 | 1 | | |
| Respiratory rate increased | 4 | 5 | | | 4 | 5 |
| Urine output decreased | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| White blood cells urine positive | 1 | 1 | 1 | 1 | | |
| | 51 | 62 | 20 | 23 | 31 | 39 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cachexia | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 9 | 9 | 4 | 4 | 5 | 5 |
| Dehydration | 2 | 3 | | | 2 | 3 |
| Fluid intake reduced | 1 | 1 | | | 1 | 1 |
| Fluid retention | 1 | 1 | | | 1 | 1 |
| Food refusal | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 2 | 2 | | | 2 | 2 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Lactic acidosis | 1 | 1 | | | 1 | 1 |
| | 22 | 23 | 4 | 4 | 18 | 19 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 19 | 23 | 14 | 17 | 5 | 6 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Back pain | 7 | 7 | 5 | 5 | 2 | 2 |
| Bone disorder | 1 | 1 | 1 | 1 | | |
| Fibromyalgia | | 1 | | | | 1 |
| Flank pain | 1 | 1 | 1 | 1 | | |
| Jaw disorder | 1 | 1 | | | 1 | 1 |
| Joint range of motion decreased | | 1 | | 1 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 4 | 4 | | | 4 | 4 |
| Muscle twitching | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 4 | 5 | 2 | 3 | 2 | 2 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 6 | 6 | 4 | 4 | 2 | 2 |
| Myalgia | 39 | 49 | 25 | 33 | 14 | 16 |
| Neck pain | 4 | 5 | 4 | 5 | | |
| Pain in extremity | 38 | 49 | 30 | 41 | 8 | 8 |
| Pain in jaw | 1 | 1 | | | 1 | 1 |
| | 131 | 160 | 88 | 113 | 43 | 47 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Neoplasm progression | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 4 | 4 | 2 | 2 | 2 | 2 |
| Allodynia | 1 | 1 | 1 | 1 | | |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anosmia | 3 | 3 | 2 | 2 | 1 | 1 |
| Areflexia | 1 | 1 | | | 1 | 1 |
| Autonomic nervous system imbalance | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Cerebral infarction | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 5 | 6 | | | 5 | 6 |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 11 | 12 | | | 11 | 12 |
| Disturbance in attention | 2 | 2 | 2 | 2 | | |
| Dizziness | 33 | 37 | 16 | 19 | 17 | 18 |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysgeusia | 5 | 5 | 2 | 2 | 3 | 3 |
| Dysstasia | 1 | 2 | | | 1 | 2 |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Facial neuralgia | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 6 | 7 | | | 6 | 7 |
| Facial paresis | 7 | 8 | | | 7 | 8 |
| Formication | | 1 | | 1 | | |
| Guillain-Barre syndrome | 1 | 1 | | | 1 | 1 |
| Headache | 90 | 104 | 69 | 82 | 21 | 22 |
| Head discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Hemiparesis | 5 | 5 | | | 5 | 5 |
| Hypersomnia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 23 | 25 | 11 | 12 | 12 | 13 |
| Hypokinesia | 2 | 2 | | | 2 | 2 |
| Ischaemic stroke | | 2 | | | | 2 |
| Lethargy | 1 | 1 | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Loss of consciousness | 5 | 6 | | | 5 | 6 |
| Memory impairment | 2 | 3 | 1 | 1 | 1 | 2 |
| Migraine | 1 | 3 | 1 | 3 | | |
| Muscle contractions involuntary | 1 | 1 | | | 1 | 1 |
| Muscle tone disorder | 1 | 1 | | | 1 | 1 |
| Neurological symptom | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 18 | 21 | 4 | 6 | 14 | 15 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Parosmia | 1 | 1 | | | 1 | 1 |
| Presyncope | 3 | 3 | | | 3 | 3 |
| Restless legs syndrome | 1 | 1 | | | 1 | 1 |
| Seizure | 4 | 4 | | | 4 | 4 |
| Seizure like phenomena | 1 | 1 | | | 1 | 1 |
| Sensory disturbance | 2 | 2 | 1 | 1 | 1 | 1 |
| Sleep paralysis | 1 | 1 | | | 1 | 1 |
| Slow speech | 1 | 1 | | | 1 | 1 |
| Somnolence | 5 | 5 | 1 | 1 | 4 | 4 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Syncope | 7 | 7 | | | 7 | 7 |
| Taste disorder | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 3 | 3 | | | 3 | 3 |
| Tremor | 6 | 6 | 1 | 1 | 5 | 5 |
| Vascular dementia | 1 | 1 | | | 1 | 1 |
| Visual field defect | 2 | 2 | | | 2 | 2 |
| | 286 | 321 | 115 | 137 | 171 | 184 |

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System Organ Class

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Product colour issue | | 36 | | 36 |
| | | 36 | | 36 |

System Organ Class

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal behaviour | 1 | 2 | | 1 | 1 | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anxiety | 9 | 10 | 4 | 4 | 5 | 6 |
| Confusional state | 8 | 9 | | | 8 | 9 |
| Delusional disorder, unspecified type | 1 | 1 | | | 1 | 1 |
| Depressed mood | 1 | 1 | | | 1 | 1 |
| Disorganised speech | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Dissociation | 1 | 1 | | | 1 | 1 |
| Hallucination | 3 | 3 | | | 3 | 3 |
| Hallucination, visual | | 1 | | | | 1 |
| Insomnia | 2 | 4 | 2 | 4 | | |
| Mental fatigue | 1 | 1 | | | 1 | 1 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Nightmare | 1 | 1 | | | 1 | 1 |
| Panic reaction | 1 | 1 | | | 1 | 1 |
| Reading disorder | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 1 | 1 | | | 1 | 1 |
| Sleep talking | | 1 | | | | 1 |
| Stress | 1 | 1 | 1 | 1 | | |
| | 37 | 44 | 8 | 11 | 29 | 33 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | | 1 | | | | 1 |
| Incontinence | 1 | 1 | 1 | 1 | | |
| Renal failure | | 1 | | | | 1 |
| Renal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Urinary incontinence | 1 | 1 | | | 1 | 1 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| | 5 | 7 | 2 | 2 | 3 | 5 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Vaginal haemorrhage | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Apnoea | | 1 | | | | 1 | |
| Asthma | 1 | 1 | | | 1 | 1 | |
| Atelectasis | 1 | 1 | | | 1 | 1 | |
| Bronchospasm | 1 | 1 | | | 1 | 1 | |
| Chronic obstructive pulmonary disease | 4 | 5 | | | 4 | 5 | |
| Chronic respiratory failure | | 1 | | | | 1 | |
| Cough | 14 | 17 | 8 | 9 | 6 | 8 | |
| Dysphonia | 4 | 4 | 4 | 4 | | | |
| Dyspnoea | 42 | 49 | 7 | 7 | 35 | 42 | |
| Epistaxis | 1 | 2 | 1 | 2 | | | |
| Haemoptysis | 1 | 1 | | | 1 | 1 | |
| Hiccups | 1 | 1 | | | 1 | 1 | |
| Increased upper airway secretion | 1 | 1 | 1 | 1 | | | |
| Nasal congestion | 6 | 6 | 1 | 1 | 5 | 5 | |
| Obstructive airways disorder | 2 | 2 | | | 2 | 2 | |
| Oropharyngeal discomfort | 1 | 1 | 1 | 1 | | | |
| Oropharyngeal pain | 16 | 18 | 13 | 14 | 3 | 4 | |
| Oropharyngeal spasm | | 1 | | | | 1 | |
| Painful respiration | 1 | 1 | 1 | 1 | | | |
| Pharyngeal disorder | 1 | 1 | | | 1 | 1 | |
| Pharyngeal erythema | 2 | 2 | 1 | 1 | 1 | 1 | |
| Pharyngeal hypoesthesia | 1 | 1 | | | 1 | 1 | |
| Pharyngeal paraesthesia | 2 | 2 | | | 2 | 2 | |
| Pharyngeal swelling | 6 | 7 | | 1 | 6 | 6 | |
| Pleural effusion | 2 | 2 | | | 2 | 2 | |
| Pleurisy | 1 | 1 | | | 1 | 1 | |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 | |
| Productive cough | 1 | 3 | | | 1 | 3 | |
| Pulmonary artery thrombosis | 1 | 1 | | | 1 | 1 | |
| Pulmonary embolism | 3 | 3 | | | 3 | 3 | |
| Pulmonary oedema | 4 | 7 | | | 4 | 7 | |
| Respiratory arrest | 2 | 2 | | | 2 | 2 | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory distress | 7 | 9 | | | 7 | 9 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinalgia | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 11 | 12 | 11 | 12 | | |
| Sinus congestion | 1 | 1 | 1 | 1 | | |
| Sinus disorder | 1 | 1 | 1 | 1 | | |
| Sneezing | 1 | 1 | 1 | 1 | | |
| Tachypnoea | 1 | 2 | | 1 | 1 | 1 |
| Throat irritation | 6 | 7 | 2 | 2 | 4 | 5 |
| Throat tightness | 2 | 3 | 1 | 1 | 1 | 2 |
| Upper respiratory tract congestion | | 1 | | 1 | | |
| Wheezing | 4 | 5 | | 1 | 4 | 4 |
| | 160 | 191 | 56 | 64 | 104 | 127 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acne | 1 | 1 | 1 | 1 | | |
| Angioedema | 4 | 4 | | | 4 | 4 |
| Blister | 1 | 1 | 1 | 1 | | |
| Cold sweat | 4 | 4 | 2 | 2 | 2 | 2 |
| Decubitus ulcer | | 1 | | 1 | | |
| Dermatitis | 1 | 2 | | 1 | 1 | 1 |
| Drug eruption | 1 | 1 | 1 | 1 | | |
| Eczema | 1 | 1 | 1 | 1 | | |
| Erythema | 20 | 21 | 12 | 13 | 8 | 8 |
| Hyperhidrosis | 5 | 5 | 5 | 5 | | |
| Nail discolouration | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Pruritus | 13 | 14 | 6 | 6 | 7 | 8 |
| Psoriasis | 1 | 1 | 1 | 1 | | |
| Rash | 12 | 12 | 6 | 6 | 6 | 6 |
| Rash erythematous | 5 | 5 | 1 | 1 | 4 | 4 |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 3 | 3 | 2 | 2 | 1 | 1 |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Skin discolouration | 1 | 1 | | | 1 | 1 |
| Skin reaction | 1 | 1 | 1 | 1 | | |
| Skin ulcer | 1 | 2 | | | 1 | 2 |
| Skin warm | 1 | 1 | 1 | 1 | | |
| Stevens-Johnson syndrome | 1 | 1 | | | 1 | 1 |
| Toxic epidermal necrolysis | 1 | 1 | | | 1 | 1 |
| Urticaria | 18 | 19 | 9 | 10 | 9 | 9 |
| | 102 | 108 | 53 | 57 | 49 | 51 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arteriosclerosis | | 1 | | | | 1 |
| Blood pressure fluctuation | | 1 | | | | 1 |
| Circulatory collapse | 2 | 4 | | | 2 | 4 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Deep vein thrombosis | 3 | 3 | | | 3 | 3 |
| Flushing | 2 | 2 | | | 2 | 2 |
| Haematoma | 2 | 2 | | | 2 | 2 |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hypertension | 4 | 5 | 3 | 3 | 1 | 2 |
| Hypotension | 8 | 10 | 2 | 2 | 6 | 8 |
| Pallor | 3 | 3 | 1 | 1 | 2 | 2 |
| Peripheral coldness | 2 | 3 | | 1 | 2 | 2 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| | 29 | 37 | 7 | 8 | 22 | 29 |

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Country Where Event Occurred

SWITZERLAND

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | | 1 | | | | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 2 | 1 | 1 | | 1 |
| | 3 | 6 | 1 | 1 | 2 | 5 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Blindness transient | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 2 | | 1 | | 1 |
| Anal haemorrhage | | 1 | | 1 | | |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastric disorder | | 1 | | | | 1 |
| Nausea | 2 | 4 | | 1 | 2 | 3 |
| Swollen tongue | | 1 | | | | 1 |
| Vomiting | 4 | 4 | | | 4 | 4 |
| | 8 | 15 | 1 | 4 | 7 | 11 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Atrophy | | 1 | | | | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 3 | 4 | 1 | 2 | 2 | 2 |
| Death | 1 | 3 | | | 1 | 3 |
| Drug ineffective | 3 | 3 | | | 3 | 3 |
| Drug interaction | 1 | 1 | 1 | 1 | | |
| Fatigue | 2 | 4 | 1 | 3 | 1 | 1 |
| Feeling cold | | 1 | | 1 | | |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 2 | 2 | | | 2 | 2 |
| General physical health deterioration | 1 | 2 | | | 1 | 2 |
| Hyperthermia | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | | | 1 | 1 |
| Malaise | 3 | 5 | 1 | 2 | 2 | 3 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pyrexia | 5 | 6 | 1 | 1 | 4 | 5 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 4 | 1 | 4 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| | 38 | 53 | 13 | 22 | 25 | 31 |

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System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hepatic cirrhosis | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 3 | 4 | | | 3 | 4 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 2 | 2 | 1 | 1 | 1 | 1 |
| Type I hypersensitivity | | 1 | | | | 1 |
| | 6 | 8 | 1 | 1 | 5 | 7 |

System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| COVID-19 | 2 | 2 | 2 | 2 |
| Encephalitis | 1 | 1 | 1 | 1 |
| Pneumonia | | 1 | | 1 |
| Respiratory tract infection | 1 | 1 | 1 | 1 |
| | 4 | 5 | 4 | 5 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fall | | 1 | | | | 1 |
| Underdose | 1 | 1 | 1 | 1 | | |
| Wrong product administered | 1 | 1 | 1 | 1 | | |
| | 2 | 3 | 2 | 2 | | 1 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 2 | 1 | 1 | | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| C-reactive protein increased | | 1 | | | | 1 |
| Heart rate decreased | | 1 | | | | 1 |
| Oxygen saturation decreased | 1 | 2 | | | 1 | 2 |
| Platelet count increased | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 2 | 2 | | | 2 | 2 |
| | 7 | 11 | 4 | 4 | 3 | 7 |

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 * AE=Adverse Event
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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Muscle disorder | 1 | 1 | | | 1 | 1 |
| Myalgia | 2 | 3 | | | 2 | 3 |
| Pain in extremity | | 1 | | 1 | | |
| | 4 | 7 | | 2 | 4 | 5 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphasia | 2 | 3 | | | 2 | 3 |
| Central nervous system lesion | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | | 1 | | | | 1 |
| Coma | 1 | 2 | | | 1 | 2 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Dizziness | 3 | 4 | 1 | 2 | 2 | 2 |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Dysgeusia | | 1 | | 1 | | |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Haemorrhagic stroke | 1 | 1 | | | 1 | 1 |
| Headache | 4 | 4 | 2 | 2 | 2 | 2 |
| Hemiplegia | | 1 | | | | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Pleocytosis | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 4 | | | 2 | 4 |
| | 21 | 29 | 4 | 6 | 17 | 23 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| | 4 | 4 | 2 | 2 | 2 | 2 |

System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Urinary incontinence | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Asthma | 2 | 2 | | | 2 | 2 |
| Chronic obstructive pulmonary disease | | 1 | | | | 1 |
| Dyspnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory failure | | 1 | | | | 1 |
| Tachypnoea | | 1 | | | | 1 |
| | 8 | 11 | 2 | 2 | 6 | 9 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Erythema | 3 | 3 | 1 | 1 | 2 | 2 |
| Pruritus | 3 | 3 | 2 | 2 | 1 | 1 |
| Urticaria | 2 | 3 | 1 | 1 | 1 | 2 |
| | 10 | 11 | 4 | 4 | 6 | 7 |

System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arteriosclerosis | | 1 | | | | 1 |
| Embolism | | 1 | | | | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypertensive emergency | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorder | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | 1 | 1 | 2 | 4 |

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Country Where Event Occurred

TURKS AND CAICOS ISLANDS

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 1 | 1 | 1 |
| Nodule | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Myalgia | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Seizure | 1 | 1 | 1 | 1 |
| Tonic convulsion | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

UNITED ARAB EMIRATES

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphadenopathy | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hypoacusis | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vision blurred | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 2 | 2 | 2 | 2 | | |
| Diarrhoea | | 1 | | 1 | | |
| Nausea | 4 | 5 | 4 | 4 | | 1 |
| Rectal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 8 | 10 | 7 | 8 | 1 | 2 |

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chest pain | | 1 | | | | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 4 | 6 | | | 4 | 6 |
| Fatigue | 1 | 2 | 1 | 2 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Pyrexia | 3 | 5 | 3 | 5 | | |
| Swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 3 | 1 | 3 | | |
| | 16 | 24 | 11 | 16 | 5 | 8 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 4 | 6 | | | 4 | 6 |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| | 5 | 7 | 1 | 1 | 4 | 6 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Off label use | | 1 | | 1 |
| Product use issue | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Blood pressure decreased | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 1 | 2 | 1 | 2 |
| Back pain | 1 | 1 | 1 | 1 |
| | 2 | 3 | 2 | 3 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Depressed level of consciousness | | 1 | | | | 1 |
| Dizziness | 2 | 3 | 2 | 2 | | 1 |
| Facial paralysis | | 1 | | | | 1 |
| Headache | 2 | 4 | 2 | 3 | | 1 |
| Hypoaesthesia | | 1 | | | | 1 |
| Neurotoxicity | 1 | 1 | | | 1 | 1 |
| Sciatica | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| | 7 | 13 | 6 | 7 | 1 | 6 |

System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Depressed mood | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Erectile dysfunction | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Skin and subcutaneous tissue disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Pruritus | 1 | 1 | 1 | 1 |
| Rash | 1 | 1 | 1 | 1 |
| Skin irritation | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Vascular disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-----------------------|--|--|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypertension | | 2 | | 1 | | 1 |
| | | 2 | | 1 | | 1 |

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Country Where Event Occurred

UNITED KINGDOM

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Anaemia | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Anisocytosis | 1 | 1 | | | | | 1 | 1 |
| Autoimmune haemolytic anaemia | 1 | 1 | | | | | 1 | 1 |
| Eosinophilia | | 1 | | | | 1 | | |
| Granulomatous lymphadenitis | 2 | 2 | | | | | 2 | 2 |
| Immune thrombocytopenia | 3 | 4 | | | | | 3 | 4 |
| Increased tendency to bruise | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Lymphadenitis | 10 | 13 | | | 3 | 4 | 7 | 9 |
| Lymphadenopathy | 409 | 744 | 2 | 2 | 58 | 218 | 351 | 526 |
| Lymphatic disorder | | 1 | | | | 1 | | |
| Lymph node pain | 87 | 162 | | | 12 | 52 | 75 | 110 |
| Lymphopenia | 1 | 1 | | | 1 | 1 | | |
| Mast cell activation syndrome | 1 | 2 | | | | | 1 | 2 |
| Monocytosis | 1 | 1 | | | 1 | 1 | | |
| Myelosuppression | 1 | 1 | | | | | 1 | 1 |
| Neutropenia | 6 | 6 | | | | | 6 | 6 |
| Pancytopenia | | 1 | | | | | | 1 |
| Platelet anisocytosis | 1 | 1 | | | | | 1 | 1 |
| Pseudolymphoma | | 1 | | | | | | 1 |
| Splenomegaly | 1 | 1 | | | | | 1 | 1 |
| Thrombocytopenia | 7 | 11 | | | | | 7 | 11 |
| Thrombocytosis | | 1 | | | | | | 1 |
| | 539 | 963 | 2 | 2 | 78 | 281 | 461 | 682 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute cardiac event | | 1 | | | | | | 1 |
| Acute myocardial infarction | 6 | 11 | | | | | 6 | 11 |
| Angina pectoris | 8 | 11 | | | | | 8 | 11 |
| Arrhythmia | 11 | 15 | | | | | 11 | 15 |
| Arrhythmia supraventricular | 2 | 4 | | | | 1 | 2 | 3 |
| Atrial fibrillation | 24 | 43 | | | | | 24 | 43 |
| Atrial flutter | 2 | 2 | | | | | 2 | 2 |
| Atrial tachycardia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Bradycardia | 7 | 17 | | | | | 7 | 17 |
| Bundle branch block right | 2 | 3 | | | | 1 | 2 | 2 |
| Cardiac arrest | 17 | 37 | | | | | 17 | 37 |
| Cardiac disorder | 1 | 2 | | | | | 1 | 2 |
| Cardiac failure | 4 | 6 | | | | | 4 | 6 |
| Cardiac failure congestive | 1 | 2 | | | | | 1 | 2 |
| Cardiac flutter | 12 | 15 | 1 | 1 | | | 12 | 15 |
| Cardiopulmonary failure | | 1 | | | | | | 1 |
| Cardio-respiratory arrest | | 1 | | | | | | 1 |
| Cardiovascular disorder | 1 | 1 | | | | | 1 | 1 |
| Coronary artery disease | 1 | 4 | | | | | 1 | 4 |
| Coronary artery occlusion | 1 | 1 | | | | | 1 | 1 |
| Extrasystoles | 6 | 10 | | | 1 | 3 | 5 | 7 |
| Left ventricular dysfunction | 1 | 1 | | | | | 1 | 1 |
| Left ventricular failure | 1 | 1 | | | | | 1 | 1 |
| Myocardial infarction | 12 | 27 | | | | | 12 | 27 |
| Myocardial ischaemia | 2 | 3 | | | | | 2 | 3 |
| Myocardial oedema | | 1 | | | | | | 1 |
| Myocarditis | 1 | 5 | | | | | 1 | 5 |
| Palpitations | 156 | 249 | | | 13 | 44 | 143 | 205 |
| Pericarditis | 4 | 6 | | | | | 4 | 6 |
| Postural orthostatic tachycardia syndrome | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Pulseless electrical activity | 1 | 2 | | | | | 1 | 2 |
| Right ventricular enlargement | | 1 | | | | 1 | | |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Right ventricular failure | 1 | 1 | | | | | 1 | 1 |
| Sinus bradycardia | | 1 | | | | | | 1 |
| Sinus node dysfunction | 1 | 1 | | | | | 1 | 1 |
| Sinus tachycardia | 8 | 16 | | | 1 | 5 | 7 | 11 |
| Supraventricular tachycardia | 4 | 10 | | | | 1 | 4 | 9 |
| Tachycardia | 94 | 206 | | | 8 | 44 | 86 | 162 |
| Ventricular arrhythmia | 1 | 1 | | | | | 1 | 1 |
| Ventricular extrasystoles | 3 | 6 | | | 1 | 2 | 2 | 4 |
| Ventricular fibrillation | 1 | 5 | | | | | 1 | 5 |
| | 401 | 734 | 1 | 1 | 26 | 104 | 375 | 630 |

System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dysmorphism | 1 | 1 | 1 | 1 |
| Familial hemiplegic migraine | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Auditory disorder | 1 | 1 | | | | | 1 | 1 |
| Auricular swelling | 2 | 3 | | | | | 2 | 3 |
| Deafness | 13 | 17 | | | | | 13 | 17 |
| Deafness neurosensory | 2 | 2 | | | | | 2 | 2 |
| Deafness unilateral | 3 | 3 | | | | | 3 | 3 |
| Ear congestion | | 1 | | | | 1 | | |
| Ear discomfort | 9 | 17 | | | 1 | 7 | 8 | 10 |
| Ear disorder | 2 | 3 | | | | | 2 | 3 |
| Ear haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Ear pain | 58 | 95 | | | 7 | 25 | 51 | 70 |
| Ear pruritus | 1 | 3 | | | | 1 | 1 | 2 |
| Ear swelling | 3 | 4 | | | | | 3 | 4 |
| Eustachian tube disorder | 1 | 1 | | | | | 1 | 1 |
| External ear pain | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Hyperacusis | 7 | 10 | | | 2 | 3 | 5 | 7 |
| Hypoacusis | 6 | 9 | | | 2 | 4 | 4 | 5 |
| Inner ear disorder | 2 | 2 | | | | | 2 | 2 |
| Meniere's disease | 4 | 4 | | | | | 4 | 4 |
| Middle ear inflammation | | 1 | | | | | | 1 |
| Motion sickness | 5 | 9 | | | | 4 | 5 | 5 |
| Sudden hearing loss | 2 | 3 | | | | | 2 | 3 |
| Tinnitus | 63 | 90 | | | 7 | 19 | 56 | 71 |
| Vertigo | 84 | 135 | 1 | 1 | 5 | 17 | 79 | 118 |
| Vertigo labyrinthine | 2 | 2 | | | | | 2 | 2 |
| Vertigo positional | 7 | 9 | | | | | 7 | 9 |
| | 280 | 427 | 1 | 1 | 25 | 82 | 255 | 345 |

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System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Adrenocortical insufficiency acute | 1 | 1 | 1 | 1 |
| Anovulatory cycle | 1 | 1 | 1 | 1 |
| Goitre | 1 | 1 | 1 | 1 |
| Hypothyroidism | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal sensation in eye | 3 | 6 | | | | 1 | 3 | 5 |
| Age-related macular degeneration | | 1 | | | | | | 1 |
| Amblyopia | | 1 | | | | 1 | | |
| Asthenopia | 19 | 23 | | | 1 | 3 | 18 | 20 |
| Autoimmune uveitis | 1 | 1 | | | | | 1 | 1 |
| Binocular eye movement disorder | 1 | 1 | | | | | 1 | 1 |
| Blepharitis | 1 | 2 | | | | 1 | 1 | 1 |
| Blepharospasm | 3 | 5 | | | | | 3 | 5 |
| Blindness | 10 | 12 | | | | | 10 | 12 |
| Blindness transient | 3 | 3 | | | | | 3 | 3 |
| Central vision loss | | 1 | | | | | | 1 |
| Chalazion | 1 | 1 | | | | | 1 | 1 |
| Choroidal neovascularisation | 2 | 2 | | | | | 2 | 2 |
| Conjunctival haemorrhage | 5 | 9 | | | | | 5 | 9 |
| Diplopia | 13 | 21 | | | | 5 | 13 | 16 |
| Dry eye | 11 | 16 | | | 2 | 5 | 9 | 11 |
| Episcleritis | 1 | 3 | | | | 1 | 1 | 2 |
| Erythema of eyelid | 1 | 1 | | | | | 1 | 1 |
| Extraocular muscle paresis | 1 | 1 | | | | | 1 | 1 |
| Eye allergy | | 1 | | | | | | 1 |
| Eye discharge | 3 | 3 | | | | | 3 | 3 |
| Eye disorder | 7 | 17 | | | 2 | 6 | 5 | 11 |
| Eye haematoma | 1 | 1 | | | | | 1 | 1 |
| Eye haemorrhage | 3 | 4 | | | | 1 | 3 | 3 |
| Eye inflammation | 2 | 2 | | | | | 2 | 2 |
| Eye irritation | 8 | 17 | | | 1 | 3 | 7 | 14 |
| Eyelid exfoliation | | 1 | | | | | | 1 |
| Eyelid function disorder | 1 | 2 | | | | | 1 | 2 |
| Eyelid irritation | 1 | 2 | | | | 1 | 1 | 1 |
| Eyelid oedema | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Eyelid pain | 2 | 3 | | | | | 2 | 3 |
| Eyelid ptosis | 2 | 3 | | | 1 | 2 | 1 | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Eyelid rash | 1 | 3 |
| Eyelids pruritus | | 2 |
| Eye movement disorder | 1 | 4 |
| Eye oedema | 1 | 1 |
| Eye pain | 91 | 143 |
| Eye paraesthesia | | 1 |
| Eye pruritus | 14 | 32 |
| Eye swelling | 46 | 74 |
| Foreign body sensation in eyes | 5 | 7 |
| Glaucoma | 1 | 1 |
| Halo vision | 1 | 1 |
| Hypoaesthesia eye | | 1 |
| Iridocyclitis | 3 | 5 |
| Iritis | 1 | 1 |
| Lacrimation increased | 14 | 29 |
| Maculopathy | | 1 |
| Metamorphopsia | | 2 |
| Miosis | 1 | 1 |
| Mydriasis | 1 | 2 |
| Ocular discomfort | 5 | 6 |
| Ocular hyperaemia | 20 | 31 |
| Ophthalmoplegia | 1 | 1 |
| Optic nerve disorder | 1 | 1 |
| Optic neuropathy | 1 | 1 |
| Oscillopsia | | 1 |
| Papilloedema | 1 | 1 |
| Periorbital oedema | 7 | 8 |
| Periorbital swelling | 18 | 23 |
| Photophobia | 32 | 62 |
| Photopsia | 11 | 12 |
| Pupillary disorder | 1 | 1 |
| Pupillary reflex impaired | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 3 |
| | | | 1 | | 1 |
| | | | | 1 | 4 |
| | | 1 | 1 | | |
| 1 | 1 | 12 | 29 | 79 | 114 |
| | | | 1 | | |
| 2 | 2 | 3 | 8 | 11 | 24 |
| 1 | 1 | 4 | 10 | 42 | 64 |
| | | 1 | 1 | 4 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 3 | 5 |
| | | 1 | 1 | | |
| | | 1 | 5 | 13 | 24 |
| | | | | | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 2 | 3 | 3 | 3 |
| | | 2 | 4 | 18 | 27 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 6 | 7 |
| | | 2 | 6 | 16 | 17 |
| | | 4 | 13 | 28 | 49 |
| | | 1 | 2 | 10 | 10 |
| | | | | 1 | 1 |
| | | | | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|---|-----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Pupils unequal | | 2 | | | | | | | 2 |
| Retinal haemorrhage | 2 | 2 | | | | | 2 | | 2 |
| Retinal toxicity | 1 | 1 | | | | | 1 | | 1 |
| Retinal vein occlusion | 2 | 2 | | | | | 2 | | 2 |
| Scleral discolouration | 1 | 1 | | | 1 | 1 | | | |
| Sudden visual loss | 1 | 1 | | | | | 1 | | 1 |
| Swelling of eyelid | 11 | 19 | | | | 3 | 11 | | 16 |
| Ulcerative keratitis | 2 | 2 | | | | | 2 | | 2 |
| Uveitis | 5 | 5 | | | | | 5 | | 5 |
| Vision blurred | 63 | 121 | | | 9 | 34 | 54 | | 87 |
| Visual acuity reduced | 1 | 2 | | | | 1 | 1 | | 1 |
| Visual brightness | | 1 | | | | 1 | | | |
| Visual impairment | 26 | 44 | | | 6 | 9 | 20 | | 35 |
| Vitreous detachment | 1 | 1 | | | | | 1 | | 1 |
| Vitreous floaters | 3 | 5 | | | 1 | 3 | 2 | | 2 |
| | 506 | 837 | 4 | 4 | 60 | 170 | 446 | | 667 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal adhesions | | 1 | | | | | | 1 |
| Abdominal discomfort | 68 | 90 | 2 | 2 | 6 | 15 | 62 | 75 |
| Abdominal distension | 15 | 25 | | | 4 | 9 | 11 | 16 |
| Abdominal pain | 111 | 178 | | | 16 | 46 | 95 | 132 |
| Abdominal pain lower | 10 | 15 | | | 2 | 4 | 8 | 11 |
| Abdominal pain upper | 188 | 266 | | | 18 | 49 | 170 | 217 |
| Abdominal rigidity | 2 | 2 | | | | | 2 | 2 |
| Abdominal tenderness | 1 | 5 | | | | 2 | 1 | 3 |
| Abnormal faeces | | 1 | | | | 1 | | |
| Acute abdomen | 1 | 1 | | | | | 1 | 1 |
| Aerophagia | | 1 | | | | | | 1 |
| Anal haemorrhage | 3 | 4 | | | | | 3 | 4 |
| Anal incontinence | 5 | 6 | 1 | 1 | 2 | 2 | 3 | 4 |
| Anal sphincter atony | 1 | 1 | | | | | 1 | 1 |
| Aphthous ulcer | 1 | 3 | | | | | 1 | 3 |
| Ascites | 2 | 2 | | | | | 2 | 2 |
| Bowel movement irregularity | 1 | 1 | | | | | 1 | 1 |
| Breath odour | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Chapped lips | 2 | 3 | | | | 1 | 2 | 2 |
| Cheilitis | 2 | 3 | | | | | 2 | 3 |
| Colitis | 2 | 2 | | | | | 2 | 2 |
| Colitis microscopic | 1 | 1 | | | | | 1 | 1 |
| Colitis ulcerative | 3 | 4 | | | | | 3 | 4 |
| Constipation | 16 | 21 | | | 1 | 3 | 15 | 18 |
| Crohn's disease | 5 | 5 | | | | | 5 | 5 |
| Defaecation urgency | 1 | 3 | | | | | 1 | 3 |
| Diarrhoea | 505 | 764 | | | 47 | 142 | 458 | 622 |
| Diarrhoea haemorrhagic | 2 | 3 | | | | | 2 | 3 |
| Discoloured vomit | | 2 | | | | 2 | | |
| Dry mouth | 52 | 90 | 1 | 1 | 9 | 26 | 43 | 64 |
| Duodenogastric reflux | 1 | 1 | | | | | 1 | 1 |
| Dyschezia | 1 | 1 | | | | | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------------------|--|--|
| Dyspepsia | 21 | 29 |
| Dysphagia | 29 | 50 |
| Enlarged uvula | 2 | 3 |
| Enteritis | | 1 |
| Epigastric discomfort | 2 | 2 |
| Eructation | 7 | 12 |
| Faeces discoloured | 5 | 8 |
| Faeces pale | 2 | 4 |
| Faeces soft | 1 | 1 |
| Flatulence | 23 | 24 |
| Food poisoning | 1 | 1 |
| Frequent bowel movements | 6 | 11 |
| Functional gastrointestinal disorder | 1 | 1 |
| Gastric antral vascular ectasia | 1 | 1 |
| Gastric disorder | 6 | 8 |
| Gastric haemorrhage | 2 | 2 |
| Gastric varices haemorrhage | 1 | 1 |
| Gastritis | 5 | 8 |
| Gastrointestinal disorder | 1 | 2 |
| Gastrointestinal haemorrhage | 2 | 2 |
| Gastrointestinal motility disorder | | 1 |
| Gastrointestinal pain | 14 | 19 |
| Gastrointestinal sounds abnormal | 3 | 3 |
| Gastroesophageal reflux disease | 11 | 16 |
| Gingival bleeding | | 3 |
| Gingival blister | | 2 |
| Gingival discomfort | 1 | 2 |
| Gingival pain | 8 | 15 |
| Gingival swelling | 1 | 1 |
| Gingivitis ulcerative | 1 | 2 |
| Glossitis | | 1 |
| Glossodynia | 22 | 31 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 7 | 19 | 22 |
| | | 5 | 10 | 24 | 40 |
| | | | 1 | 2 | 2 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 7 | 12 |
| | | 4 | 6 | 1 | 2 |
| | | 1 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | 3 | 3 | 20 | 21 |
| | | | | 1 | 1 |
| | | | 2 | 6 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 4 | 3 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 5 | 7 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | 1 | 14 | 18 |
| | | | | 3 | 3 |
| | | | 1 | 11 | 15 |
| | | | 1 | | 2 |
| | | | 2 | | |
| | | | 1 | 1 | 1 |
| | | 2 | 5 | 6 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | 4 | 9 | 18 | 22 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Haematemesis | 6 | 16 |
| Haematochezia | 6 | 7 |
| Haemorrhoids | 3 | 3 |
| Hyperaesthesia teeth | 1 | 1 |
| Hyperchlorhydria | 3 | 4 |
| Hypoaesthesia oral | 37 | 80 |
| Hypoaesthesia teeth | 1 | 1 |
| Impaired gastric emptying | 1 | 1 |
| Infantile vomiting | 1 | 1 |
| Intestinal ischaemia | 1 | 1 |
| Intestinal obstruction | 1 | 1 |
| Intestinal perforation | 1 | 1 |
| Intestinal pseudo-obstruction | 1 | 1 |
| Irritable bowel syndrome | 6 | 11 |
| Lip blister | 2 | 4 |
| Lip discolouration | | 1 |
| Lip disorder | 1 | 3 |
| Lip dry | 4 | 8 |
| Lip erythema | 1 | 1 |
| Lip exfoliation | 2 | 2 |
| Lip haemorrhage | 1 | 1 |
| Lip oedema | 2 | 3 |
| Lip pain | 1 | 5 |
| Lip pruritus | | 1 |
| Lip scab | 1 | 1 |
| Lip swelling | 79 | 125 |
| Lip ulceration | 1 | 1 |
| Mallory-Weiss syndrome | 1 | 1 |
| Melaena | 3 | 5 |
| Mouth cyst | | 1 |
| Mouth swelling | 9 | 16 |
| Mouth ulceration | 34 | 50 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 6 | 16 |
| | | | | 6 | 7 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | 9 | 33 | 28 | 47 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 2 | 6 | 9 |
| | | | | 2 | 4 |
| | | | | | 1 |
| | | 1 | 3 | | |
| | | 1 | 4 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 2 | 1 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 7 | 22 | 72 | 103 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 3 | 9 | 13 |
| | | 9 | 18 | 25 | 32 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Mucous stools | 1 | 1 |
| Nausea | 1,283 | 2,187 |
| Noninfective gingivitis | 1 | 1 |
| Odynophagia | 5 | 6 |
| Oedema mouth | 1 | 3 |
| Oesophageal pain | 1 | 2 |
| Oesophageal spasm | | 1 |
| Oesophageal stenosis | 1 | 1 |
| Oral blood blister | | 2 |
| Oral discomfort | 10 | 15 |
| Oral disorder | 3 | 3 |
| Oral mucosa erosion | | 1 |
| Oral mucosal blistering | 4 | 7 |
| Oral mucosal eruption | | 1 |
| Oral mucosal erythema | | 1 |
| Oral mucosal exfoliation | 1 | 1 |
| Oral pain | 21 | 27 |
| Oral papule | | 1 |
| Oral pruritus | 3 | 4 |
| Palatal oedema | 1 | 1 |
| Palatal swelling | 3 | 3 |
| Palatal ulcer | 1 | 1 |
| Pancreatitis | 1 | 1 |
| Pancreatitis necrotising | 1 | 1 |
| Paraesthesia oral | 101 | 216 |
| Parotid gland enlargement | | 1 |
| Plicated tongue | | 1 |
| Proctalgia | 1 | 1 |
| Proctitis ulcerative | | 1 |
| Rectal discharge | 1 | 1 |
| Rectal haemorrhage | 14 | 16 |
| Regurgitation | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| 7 | 10 | 156 | 508 | 1127 | 1679 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 4 |
| | | | 1 | 1 | 2 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | 1 | 2 | 9 | 13 |
| | | 2 | 2 | 1 | 1 |
| | | | 1 | | |
| | | 2 | 4 | 2 | 3 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 2 | 21 | 25 |
| | | | | | 1 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 23 | 84 | 78 | 132 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 14 | 16 |
| | | | | | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Retching | 16 | 28 | | | 2 | 6 | 14 | 22 |
| Salivary duct obstruction | 1 | 1 | | | | | 1 | 1 |
| Salivary gland pain | | 1 | | | | | | 1 |
| Salivary hypersecretion | 3 | 11 | | | | 5 | 3 | 6 |
| Small intestinal haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Small intestinal obstruction | | 1 | | | | | | 1 |
| Stiff tongue | | 1 | | | | | | 1 |
| Stomatitis | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 |
| Submaxillary gland enlargement | | 1 | | | | 1 | | |
| Swollen tongue | 59 | 110 | | | 8 | 22 | 51 | 88 |
| Tongue blistering | 1 | 1 | | | 1 | 1 | | |
| Tongue coated | 1 | 1 | | | | | 1 | 1 |
| Tongue discolouration | 1 | 1 | | | | | 1 | 1 |
| Tongue discomfort | 4 | 7 | | | | 2 | 4 | 5 |
| Tongue disorder | 7 | 8 | | | 1 | 1 | 6 | 7 |
| Tongue dry | 1 | 2 | | | | 1 | 1 | 1 |
| Tongue eruption | | 1 | | | | | | 1 |
| Tongue erythema | 1 | 2 | | | | 1 | 1 | 1 |
| Tongue movement disturbance | 1 | 2 | | | 1 | 1 | | 1 |
| Tongue oedema | 10 | 11 | | | | 1 | 10 | 10 |
| Tongue pruritus | 2 | 3 | | | | | 2 | 3 |
| Tongue spasm | 1 | 1 | | | | | 1 | 1 |
| Tongue ulceration | 1 | 4 | | | | 1 | 1 | 3 |
| Toothache | 5 | 11 | | | 1 | 4 | 4 | 7 |
| Upper gastrointestinal haemorrhage | | 2 | | | | | | 2 |
| Vomiting | 389 | 651 | 2 | 3 | 51 | 148 | 338 | 503 |
| Vomiting projectile | 7 | 11 | | | | 1 | 7 | 10 |
| | 3,367 | 5,519 | 15 | 19 | 416 | 1270 | 2951 | 4249 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Administration site joint movement impairment | 1 | 1 | | | | | 1 | 1 |
| Adverse drug reaction | 4 | 6 | | | 1 | 3 | 3 | 3 |
| Adverse event | 1 | 1 | | | | | 1 | 1 |
| Adverse reaction | | | 1 | 1 | | | | |
| Alcohol interaction | 1 | 2 | | | | | 1 | 2 |
| Apparent death | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 267 | 410 | 1 | 1 | 61 | 115 | 206 | 295 |
| Axillary pain | 82 | 160 | | | 21 | 56 | 61 | 104 |
| Chest discomfort | 125 | 219 | | | 17 | 47 | 108 | 172 |
| Chest pain | 201 | 309 | 2 | 2 | 18 | 53 | 183 | 256 |
| Chills | 964 | 1,751 | 4 | 5 | 120 | 405 | 844 | 1346 |
| Chronic fatigue syndrome | 3 | 4 | | | | 1 | 3 | 3 |
| Condition aggravated | 51 | 77 | | | 8 | 17 | 43 | 60 |
| Crying | 10 | 13 | | | | 1 | 10 | 12 |
| Cyst | 1 | 1 | | | | | 1 | 1 |
| Death | 38 | 89 | | | | | 38 | 89 |
| Death neonatal | 1 | 1 | | | | | 1 | 1 |
| Discharge | 1 | 1 | | | | | 1 | 1 |
| Discomfort | 37 | 56 | | | 11 | 21 | 26 | 35 |
| Disease progression | 1 | 1 | | | | | 1 | 1 |
| Disease recurrence | 51 | 62 | | | 3 | 5 | 48 | 57 |
| Drug ineffective | 184 | 425 | 1 | 1 | 1 | 2 | 183 | 423 |
| Drug withdrawal syndrome | 1 | 1 | | | | | 1 | 1 |
| Exercise tolerance decreased | | 1 | | | | | | 1 |
| Eye complication associated with device | 1 | 1 | | | | | 1 | 1 |
| Face oedema | 4 | 4 | | | | | 4 | 4 |
| Facial discomfort | 3 | 6 | | | 2 | 2 | 1 | 4 |
| Facial pain | 22 | 40 | | | 4 | 10 | 18 | 30 |
| Fatigue | 2,047 | 3,224 | 30 | 35 | 299 | 761 | 1748 | 2463 |
| Feeling abnormal | 157 | 252 | 2 | 3 | 32 | 71 | 125 | 181 |
| Feeling cold | 174 | 284 | 1 | 1 | 37 | 84 | 137 | 200 |
| Feeling drunk | 7 | 16 | | | 1 | 3 | 6 | 13 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Feeling hot | 152 | 284 |
| Feeling jittery | 5 | 8 |
| Feeling of body temperature change | 45 | 84 |
| Gait disturbance | 61 | 85 |
| Gait inability | 22 | 31 |
| General physical health deterioration | 3 | 4 |
| Glassy eyes | | 1 |
| Hangover | 6 | 11 |
| Hunger | 2 | 3 |
| Hyperpyrexia | 1 | 3 |
| Hypothermia | 6 | 13 |
| Illness | 182 | 248 |
| Impaired healing | 1 | 1 |
| Induration | 1 | 2 |
| Inflammation | 20 | 36 |
| Influenza like illness | 260 | 463 |
| Injected limb mobility decreased | 5 | 6 |
| Injection site erythema | | 7 |
| Injection site joint movement impairment | 1 | 1 |
| Injection site mass | | 2 |
| Injection site pain | 8 | 35 |
| Injection site pruritus | | 3 |
| Injection site rash | 1 | 3 |
| Injection site swelling | | 5 |
| Injection site warmth | 1 | 4 |
| Injury associated with device | | 1 |
| Localised oedema | 5 | 5 |
| Local reaction | 8 | 15 |
| Loss of control of legs | 2 | 2 |
| Malaise | 702 | 1,193 |
| Mass | 2 | 4 |
| Moaning | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 44 | 118 | 108 | 166 |
| | | | 2 | 5 | 6 |
| | | 7 | 25 | 38 | 59 |
| | | 9 | 17 | 52 | 68 |
| 1 | 1 | 1 | 3 | 21 | 28 |
| | | 1 | 1 | 2 | 3 |
| | | | | | 1 |
| | | 1 | 3 | 5 | 8 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 3 |
| | | | | 6 | 13 |
| 1 | 1 | 19 | 41 | 163 | 207 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 2 | 9 | 18 | 27 |
| | | 40 | 129 | 220 | 334 |
| | | | | 5 | 6 |
| | | | 7 | | |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | 22 | 8 | 13 |
| | | | 3 | | |
| | | | 2 | 1 | 1 |
| | | | 5 | | |
| | | | 3 | 1 | 1 |
| | | | 1 | | |
| | | | | 5 | 5 |
| | | 2 | 5 | 6 | 10 |
| | | | | 2 | 2 |
| 5 | 5 | 114 | 303 | 588 | 890 |
| | | 2 | 3 | | 1 |
| | | | | 1 | 1 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Multiple organ dysfunction syndrome | 1 | 3 |
| No adverse event | 4 | 7 |
| Nodule | 1 | 3 |
| Non-cardiac chest pain | 4 | 4 |
| Oedema | 2 | 5 |
| Oedema peripheral | 9 | 11 |
| Pain | 704 | 1,161 |
| Peripheral swelling | 204 | 323 |
| Physical deconditioning | 1 | 1 |
| Pre-existing condition improved | | 2 |
| Puncture site bruise | 1 | 1 |
| Puncture site discharge | 1 | 1 |
| Pyrexia | 1,362 | 2,557 |
| Screaming | 1 | 1 |
| Secretion discharge | 1 | 2 |
| Sensation of blood flow | 2 | 2 |
| Sensation of foreign body | 7 | 10 |
| Sensitivity to weather change | 1 | 1 |
| Serositis | | 1 |
| Shoulder injury related to vaccine administration | 1 | 1 |
| Sluggishness | 1 | 1 |
| Sudden death | 7 | 14 |
| Suprapubic pain | 1 | 1 |
| Swelling | 137 | 209 |
| Swelling face | 97 | 151 |
| Symptom recurrence | | 1 |
| Systemic inflammatory response syndrome | | 1 |
| Temperature intolerance | 1 | 1 |
| Temperature regulation disorder | 2 | 4 |
| Tenderness | 17 | 37 |
| Therapeutic product effect increased | 1 | 1 |
| Therapeutic response unexpected | 6 | 9 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 3 |
| | | 4 | 7 | | |
| | | | 1 | 1 | 2 |
| | | 1 | 1 | 3 | 3 |
| | | | 1 | 2 | 4 |
| | | 3 | 3 | 6 | 8 |
| 9 | 9 | 148 | 343 | 556 | 818 |
| 1 | 1 | 31 | 74 | 173 | 249 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 6 | 9 | 143 | 548 | 1219 | 2009 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | 7 | 10 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 7 | 14 |
| | | 1 | 1 | | |
| 1 | 1 | 27 | 64 | 110 | 145 |
| | | 15 | 27 | 82 | 124 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 3 |
| 2 | 2 | 4 | 17 | 13 | 20 |
| | | | | 1 | 1 |
| | | 2 | 4 | 4 | 5 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Thirst | 29 | 45 |
| Treatment noncompliance | 1 | 1 |
| Ulcer | 1 | 1 |
| Vaccination site bruising | 22 | 44 |
| Vaccination site coldness | 1 | 1 |
| Vaccination site discolouration | | 6 |
| Vaccination site discomfort | 12 | 29 |
| Vaccination site dryness | 1 | 1 |
| Vaccination site erythema | 118 | 256 |
| Vaccination site haematoma | 1 | 2 |
| Vaccination site haemorrhage | 7 | 11 |
| Vaccination site hyperaesthesia | 2 | 3 |
| Vaccination site hypersensitivity | 2 | 2 |
| Vaccination site hypoaesthesia | 4 | 13 |
| Vaccination site induration | 10 | 23 |
| Vaccination site inflammation | 7 | 24 |
| Vaccination site irritation | 3 | 3 |
| Vaccination site joint erythema | 1 | 1 |
| Vaccination site joint movement impairment | 2 | 12 |
| Vaccination site joint pain | 1 | 9 |
| Vaccination site lymphadenopathy | 6 | 7 |
| Vaccination site macule | | 1 |
| Vaccination site mass | 50 | 79 |
| Vaccination site movement impairment | 19 | 38 |
| Vaccination site necrosis | 2 | 2 |
| Vaccination site nodule | 1 | 1 |
| Vaccination site oedema | 2 | 5 |
| Vaccination site pain | 592 | 1,266 |
| Vaccination site papule | 1 | 1 |
| Vaccination site paraesthesia | 9 | 19 |
| Vaccination site pruritus | 41 | 85 |
| Vaccination site rash | 20 | 46 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 13 | 24 | 32 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | 1 | 6 | 14 | 16 | 30 |
| | | | 2 | | 4 |
| | | 3 | 14 | 9 | 15 |
| | | | | 1 | 1 |
| | | 26 | 102 | 92 | 154 |
| | | | | 1 | 2 |
| | | | 1 | 7 | 10 |
| | | | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | | 4 | 4 | 9 |
| | | 4 | 13 | 6 | 10 |
| | | 2 | 11 | 5 | 13 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 5 | 1 | 7 |
| | | | 3 | 1 | 6 |
| | | 1 | 1 | 5 | 6 |
| | | | 1 | | |
| | | 8 | 23 | 42 | 56 |
| 1 | 1 | 9 | 16 | 10 | 22 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 4 |
| 3 | 7 | 113 | 443 | 479 | 823 |
| | | | | 1 | 1 |
| | | 3 | 8 | 6 | 11 |
| | | 10 | 37 | 31 | 48 |
| | | 4 | 17 | 16 | 29 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|-------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vaccination site reaction | 14 | 28 | | | 5 | 11 | 9 | 17 |
| Vaccination site scab | 1 | 1 | | | | | 1 | 1 |
| Vaccination site scar | 1 | 1 | | | | | 1 | 1 |
| Vaccination site swelling | 139 | 297 | | | 22 | 102 | 117 | 195 |
| Vaccination site ulcer | | 1 | | | | | | 1 |
| Vaccination site urticaria | 2 | 6 | | | | 2 | 2 | 4 |
| Vaccination site vesicles | 3 | 6 | | | 1 | 1 | 2 | 5 |
| Vaccination site warmth | 69 | 152 | | | 16 | 59 | 53 | 93 |
| | 9,718 | 17,039 | 72 | 87 | 1497 | 4362 | 8221 | 12677 |

System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Bile duct stone | | 1 | | 1 |
| Hepatic artery embolism | | 1 | | 1 |
| Hepatic pain | 3 | 4 | 3 | 4 |
| Hepatitis | 1 | 2 | 1 | 2 |
| Jaundice | 1 | 2 | 1 | 2 |
| Liver injury | 1 | 2 | 1 | 2 |
| | 6 | 12 | 6 | 12 |

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System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic oedema | | 1 | | | | 1 |
| Allergic reaction to excipient | 2 | 2 | | | 2 | 2 |
| Allergy to vaccine | 8 | 27 | 1 | 11 | 7 | 16 |
| Anaphylactic reaction | 101 | 169 | | | 101 | 169 |
| Anaphylactic shock | 5 | 7 | | | 5 | 7 |
| Anaphylactoid reaction | 4 | 9 | | | 4 | 9 |
| Anaphylactoid shock | 2 | 2 | | | 2 | 2 |
| Autoimmune disorder | 4 | 4 | | | 4 | 4 |
| Bacille Calmette-Guerin scar reactivation | 1 | 1 | 1 | 1 | | |
| Contrast media reaction | 1 | 1 | | | 1 | 1 |
| Decreased immune responsiveness | 1 | 1 | | | 1 | 1 |
| Drug hypersensitivity | 5 | 8 | 1 | 2 | 4 | 6 |
| Food allergy | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypersensitivity | 65 | 124 | 7 | 26 | 58 | 98 |
| Immune-mediated adverse reaction | 1 | 2 | | 1 | 1 | 1 |
| Immune system disorder | 4 | 5 | | | 4 | 5 |
| Multiple allergies | 1 | 1 | | | 1 | 1 |
| Reaction to excipient | 1 | 1 | | | 1 | 1 |
| Reaction to preservatives | 2 | 3 | | | 2 | 3 |
| Sarcoidosis | 2 | 2 | | | 2 | 2 |
| Seasonal allergy | 2 | 3 | | 1 | 2 | 2 |
| Serum sickness | 1 | 1 | | | 1 | 1 |
| Serum sickness-like reaction | 1 | 1 | | | 1 | 1 |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| Type IV hypersensitivity reaction | 2 | 4 | | | 2 | 4 |
| | 219 | 382 | 11 | 43 | 208 | 339 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abscess | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Abscess oral | 2 | 2 | | | | | 2 | 2 |
| African trypanosomiasis | | 1 | | | | | | 1 |
| Appendicitis | 2 | 3 | | | | | 2 | 3 |
| Arthritis bacterial | 1 | 1 | | | | | 1 | 1 |
| Asymptomatic COVID-19 | 1 | 3 | | | | | 1 | 3 |
| Bacterial diarrhoea | 1 | 1 | | | | | 1 | 1 |
| Bacterial infection | 1 | 1 | | | | | 1 | 1 |
| Biliary sepsis | | 1 | | | | | | 1 |
| Breast abscess | | 1 | | | | | | 1 |
| Bronchitis | 2 | 2 | | | | | 2 | 2 |
| Bronchopulmonary aspergillosis | 1 | 1 | | | | | 1 | 1 |
| Candida infection | 1 | 1 | | | | | 1 | 1 |
| Cellulitis | 33 | 50 | | | | | 33 | 50 |
| Cholecystitis infective | | 1 | | | | | | 1 |
| Clostridium difficile colitis | | 1 | | | | | | 1 |
| Clostridium difficile infection | 1 | 1 | | | | | 1 | 1 |
| Conjunctivitis | 7 | 11 | | | | 1 | 7 | 10 |
| Conjunctivitis bacterial | 2 | 2 | | | | | 2 | 2 |
| Coronavirus infection | | 1 | | | | | | 1 |
| COVID-19 | 137 | 296 | 1 | 1 | 8 | 11 | 129 | 285 |
| COVID-19 pneumonia | 8 | 10 | | | | | 8 | 10 |
| Creutzfeldt-Jakob disease | 1 | 1 | | | | | 1 | 1 |
| Cystitis | 6 | 7 | | | | | 6 | 7 |
| Disseminated varicella zoster virus infection | 1 | 1 | | | | | 1 | 1 |
| Diverticulitis | 1 | 1 | | | | | 1 | 1 |
| Dysentery | 1 | 1 | | | | | 1 | 1 |
| Ear infection | 6 | 10 | | | 1 | 3 | 5 | 7 |
| Ear infection bacterial | 1 | 1 | | | | | 1 | 1 |
| Encephalitis | 4 | 4 | | | | | 4 | 4 |
| Epididymitis | 1 | 1 | | | | | 1 | 1 |
| Epstein-Barr virus infection | 1 | 1 | | | | | 1 | 1 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| External ear cellulitis | 1 | 1 |
| Eye abscess | 1 | 1 |
| Eye infection | 1 | 2 |
| Folliculitis | | 2 |
| Fungal skin infection | 1 | 1 |
| Furuncle | 3 | 4 |
| Gastroenteritis | 7 | 10 |
| Gastroenteritis viral | 1 | 3 |
| Genital herpes | | 1 |
| Gingivitis | 1 | 1 |
| Gonorrhoea | 1 | 1 |
| Herpes ophthalmic | 1 | 1 |
| Herpes simplex | 2 | 3 |
| Herpes virus infection | 2 | 3 |
| Herpes zoster | 76 | 99 |
| Herpes zoster oticus | | 1 |
| Herpes zoster reactivation | 1 | 2 |
| Hordeolum | 1 | 2 |
| Impetigo | 1 | 1 |
| Infected dermal cyst | 1 | 1 |
| Infected skin ulcer | 1 | 1 |
| Infection | 11 | 18 |
| Infectious mononucleosis | 1 | 1 |
| Influenza | 151 | 204 |
| Kidney infection | 2 | 2 |
| Labyrinthitis | 6 | 10 |
| Laryngitis | 1 | 1 |
| Localised infection | 2 | 4 |
| Lower respiratory tract infection | 21 | 33 |
| Lymphangitis | 1 | 1 |
| Mastitis | 2 | 4 |
| Meningitis | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | 7 | 9 |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 2 | 3 |
| | | 4 | 14 | 72 | 85 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 10 | 17 |
| | | | | 1 | 1 |
| | | 18 | 40 | 133 | 164 |
| | | | | 2 | 2 |
| | | | 1 | 6 | 9 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 3 |
| | | | | 21 | 33 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 2 | 2 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Myelitis | | 1 |
| Nasopharyngitis | 73 | 112 |
| Necrotising fasciitis | 1 | 1 |
| Ophthalmic herpes zoster | 2 | 2 |
| Oral candidiasis | 2 | 4 |
| Oral herpes | 16 | 22 |
| Orchitis | 2 | 2 |
| Otitis externa | 1 | 1 |
| Parotitis | 1 | 4 |
| Periorbital cellulitis | 1 | 1 |
| Pharyngitis | 1 | 2 |
| Pharyngitis streptococcal | | 2 |
| Pneumonia | 10 | 18 |
| Pneumonia staphylococcal | 1 | 1 |
| Post viral fatigue syndrome | 1 | 3 |
| Pulpitis dental | 1 | 1 |
| Pustule | 1 | 2 |
| Pyelonephritis | | 1 |
| Q fever | 4 | 5 |
| Rash pustular | 1 | 2 |
| Rhinitis | 7 | 12 |
| Sepsis | 6 | 11 |
| Sialoadenitis | 1 | 1 |
| Sinusitis | 8 | 9 |
| Soft tissue infection | 1 | 1 |
| Sputum purulent | | 1 |
| Subcutaneous abscess | 1 | 1 |
| Suspected COVID-19 | 123 | 205 |
| Sweating fever | 21 | 32 |
| Tonsillitis | 1 | 7 |
| Tonsillitis bacterial | 1 | 2 |
| Urinary tract infection | 27 | 32 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 16 | 36 | 57 | 76 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 2 | 3 |
| | | 4 | 7 | 12 | 15 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | | | 10 | 18 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 4 | 5 |
| | | | | 1 | 2 |
| | | 2 | 5 | 5 | 7 |
| | | 1 | 1 | 5 | 10 |
| | | | | 1 | 1 |
| | | 1 | 1 | 7 | 8 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 23 | 28 | 100 | 177 |
| | | | | 21 | 32 |
| | | | 1 | 1 | 6 |
| | | | | 1 | 2 |
| | | 3 | 3 | 24 | 29 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|---|------|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Urinary tract infection bacterial | | 1 | | | | | | | 1 |
| Urosepsis | 1 | 2 | | | | | 1 | | 2 |
| Vaccination site abscess | 2 | 3 | | | 1 | 1 | 1 | | 2 |
| Vaccination site cellulitis | 9 | 19 | | | 2 | 4 | 7 | | 15 |
| Vaccination site infection | 5 | 9 | | | | 1 | 5 | | 8 |
| Vestibular neuritis | 1 | 3 | | | | | 1 | | 3 |
| Viral infection | 3 | 4 | | | 1 | 2 | 2 | | 2 |
| Viral labyrinthitis | 1 | 2 | | | 1 | 2 | | | |
| Viral pharyngitis | 3 | 4 | | | | | 3 | | 4 |
| Viral rash | 2 | 5 | | | 1 | 2 | 1 | | 3 |
| Viral tonsillitis | | 1 | | | | | | | 1 |
| Viral upper respiratory tract infection | | 1 | | | | | | | 1 |
| Virologic failure | 1 | 1 | | | | | 1 | | 1 |
| Vulval abscess | 1 | 1 | | | | | 1 | | 1 |
| Vulvovaginal candidiasis | 3 | 5 | | | | 1 | 3 | | 4 |
| | 876 | 1,404 | 1 | 1 | 93 | 177 | 783 | | 1227 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Accidental overdose | 3 | 4 | | | 3 | 4 | | |
| Airway burns | 1 | 1 | | | | | 1 | 1 |
| Atypical femur fracture | 1 | 1 | | | | | 1 | 1 |
| Bite | | 1 | | | | | | 1 |
| Bone contusion | 1 | 1 | | | 1 | 1 | | |
| Burn oesophageal | 1 | 1 | | | | | 1 | 1 |
| Burns second degree | 1 | 1 | | | 1 | 1 | | |
| Chest crushing | 1 | 1 | | | | | 1 | 1 |
| Chillblains | | 1 | | | | | | 1 |
| Circumstance or information capable of leading to medication error | 1 | 5 | | | 1 | 5 | | |
| Contraindicated product administered | 1 | 3 | | | 1 | 2 | | 1 |
| Contusion | 35 | 52 | | | 9 | 15 | 26 | 37 |
| Corneal abrasion | 1 | 1 | | | | | 1 | 1 |
| Electric shock | 1 | 1 | | | | | 1 | 1 |
| Epicondylitis | 2 | 2 | | | | | 2 | 2 |
| Expired product administered | | 2 | | | | 2 | | |
| Exposure during pregnancy | 9 | 12 | | | 8 | 11 | 1 | 1 |
| Exposure to SARS-CoV-2 | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Exposure via breast milk | 8 | 12 | | | 6 | 10 | 2 | 2 |
| Eye contusion | 2 | 5 | 1 | 1 | | 1 | 2 | 4 |
| Eye injury | 1 | 2 | | | | | 1 | 2 |
| Face crushing | | 1 | | | | | | 1 |
| Face injury | 1 | 1 | | | 1 | 1 | | |
| Fall | 47 | 72 | | | 12 | 18 | 35 | 54 |
| Femur fracture | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal stoma complication | | 1 | | | | | | 1 |
| Head injury | 10 | 19 | | | 2 | 7 | 8 | 12 |
| Heat illness | | 1 | | | | | | 1 |
| Heat oedema | 1 | 2 | | | | 1 | 1 | 1 |
| Heat stroke | | 1 | | | | 1 | | |
| Inappropriate schedule of product administration | 7 | 20 | | | 6 | 19 | 1 | 1 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Incision site pain | | 1 |
| Incomplete course of vaccination | 1 | 1 |
| Incorrect dose administered | 1 | 2 |
| Incorrect route of product administration | 14 | 34 |
| Infusion related reaction | 2 | 2 |
| Injection related reaction | 6 | 8 |
| Injury | 1 | 1 |
| Injury corneal | | 1 |
| Joint dislocation | 1 | 1 |
| Joint injury | 3 | 3 |
| Ligament sprain | 1 | 2 |
| Limb injury | 3 | 3 |
| Lower limb fracture | 1 | 2 |
| Maternal exposure during pregnancy | 28 | 33 |
| Maternal exposure timing unspecified | 1 | 2 |
| Medication error | 1 | 1 |
| Mouth injury | 1 | 1 |
| Multiple injuries | 1 | 1 |
| Muscle rupture | 1 | 1 |
| Muscle strain | 2 | 4 |
| Nerve injury | 2 | 2 |
| Occupational exposure to product | | 1 |
| Occupational exposure to SARS-CoV-2 | | 2 |
| Off label use | 278 | 331 |
| Overdose | 3 | 10 |
| Periorbital haematoma | 1 | 1 |
| Poisoning | | 1 |
| Poor quality product administered | 2 | 11 |
| Post laminectomy syndrome | 1 | 1 |
| Post lumbar puncture syndrome | | 1 |
| Postoperative ileus | | 1 |
| Post procedural complication | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 13 | 33 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 6 | 7 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 2 |
| | | 22 | 25 | 6 | 8 |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | 2 | | |
| | | 273 | 323 | 5 | 8 |
| | | 2 | 9 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 11 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 2 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Procedural dizziness | 1 | 1 |
| Procedural nausea | 2 | 3 |
| Product administered at inappropriate site | 5 | 7 |
| Product administered to patient of inappropriate age | 33 | 43 |
| Product dose omission issue | 1 | 1 |
| Product label confusion | | 1 |
| Product preparation error | 1 | 4 |
| Product preparation issue | | 2 |
| Product use issue | 270 | 320 |
| Reaction to previous exposure to any vaccine | 1 | 1 |
| Road traffic accident | 2 | 2 |
| Scratch | 3 | 3 |
| Skin abrasion | 4 | 5 |
| Skin laceration | 1 | 2 |
| Skull fracture | 1 | 1 |
| Stoma site discharge | | 1 |
| Stoma site extravasation | | 1 |
| Stoma site haemorrhage | | 1 |
| Sunburn | 1 | 1 |
| Superficial injury of eye | | 1 |
| Synovial rupture | | 1 |
| Tendon injury | 1 | 2 |
| Thermal burn | 3 | 3 |
| Thermal burns of eye | 1 | 1 |
| Tongue injury | 1 | 1 |
| Traumatic haemorrhage | 1 | 1 |
| Ulnar nerve injury | 3 | 3 |
| Underdose | 1 | 6 |
| Upper limb fracture | 3 | 4 |
| Vaccination complication | 4 | 8 |
| Vaccination failure | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | 4 | 4 | 1 | 3 |
| | | 30 | 39 | 3 | 4 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | | 2 | | |
| | | 266 | 313 | 4 | 7 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | 2 | 2 | 2 | 3 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 6 | | |
| | | | | 3 | 4 |
| | | | 2 | 4 | 6 |
| | | | | 2 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Wound | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Wound complication | 1 | 1 | | | | | 1 | 1 |
| Wound secretion | 1 | 1 | | | | | 1 | 1 |
| Wrong product administered | | 1 | | | | 1 | | |
| Wrong technique in product usage process | 1 | 1 | | | 1 | 1 | | |
| | 850 | 1,140 | 1 | 1 | 676 | 891 | 174 | 249 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Alanine aminotransferase increased | 1 | 5 | | | | 1 | 1 | 4 |
| Antibody test abnormal | 2 | 2 | | | 2 | 2 | | |
| Antibody test positive | | 1 | | | | 1 | | |
| Anticoagulation drug level increased | | 1 | | | | | | 1 |
| Aspartate aminotransferase increased | | 1 | | | | | | 1 |
| Bleeding time abnormal | 1 | 1 | | | | | 1 | 1 |
| Blood alkaline phosphatase increased | | 2 | | | | 1 | | 1 |
| Blood creatine phosphokinase increased | | 2 | | | | 1 | | 1 |
| Blood creatinine increased | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Blood electrolytes increased | | 1 | | | | 1 | | |
| Blood glucose | 1 | 1 | | | | | 1 | 1 |
| Blood glucose decreased | 3 | 6 | | | 1 | 1 | 2 | 5 |
| Blood glucose fluctuation | 2 | 2 | | | | | 2 | 2 |
| Blood glucose increased | 8 | 17 | | | | 2 | 8 | 15 |
| Blood growth hormone | | 1 | | | | 1 | | |
| Blood ketone body increased | 1 | 1 | | | | | 1 | 1 |
| Blood ketone body present | | 1 | | | | | | 1 |
| Blood lactic acid increased | 1 | 4 | | | | 1 | 1 | 3 |
| Blood magnesium decreased | 1 | 1 | | | 1 | 1 | | |
| Blood pH increased | 1 | 2 | | | | 1 | 1 | 1 |
| Blood potassium abnormal | | 1 | | | | | | 1 |
| Blood potassium decreased | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Blood pressure abnormal | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Blood pressure decreased | 9 | 17 | | | 2 | 4 | 7 | 13 |
| Blood pressure diastolic decreased | 1 | 1 | | | 1 | 1 | | |
| Blood pressure increased | 55 | 103 | 1 | 1 | 13 | 40 | 42 | 63 |
| Blood pressure orthostatic abnormal | | 1 | | | | | | 1 |
| Blood pressure orthostatic decreased | | 1 | | | | | | 1 |
| Blood pressure systolic decreased | 1 | 2 | | | | | 1 | 2 |
| Blood pressure systolic increased | 3 | 6 | | | 1 | 2 | 2 | 4 |
| Blood sodium decreased | 1 | 2 | | | | 1 | 1 | 1 |
| Blood test abnormal | | 2 | | | | | | 2 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Blood testosterone increased | 1 | 1 |
| Blood urea increased | 1 | 2 |
| Blood urine present | 4 | 6 |
| Blood viscosity increased | 1 | 1 |
| Body temperature | 1 | 4 |
| Body temperature abnormal | 11 | 27 |
| Body temperature decreased | 16 | 21 |
| Body temperature fluctuation | 6 | 12 |
| Body temperature increased | 48 | 100 |
| Breath sounds abnormal | 1 | 1 |
| Cardiac murmur | 1 | 1 |
| Chest X-ray abnormal | 1 | 1 |
| Coagulation time prolonged | 1 | 1 |
| Coma scale abnormal | | 3 |
| Corneal reflex decreased | 1 | 1 |
| Coronavirus test positive | 1 | 1 |
| Cortisol decreased | | 1 |
| C-reactive protein increased | 5 | 7 |
| Culture negative | | 1 |
| Electrocardiogram abnormal | 3 | 3 |
| Electrocardiogram ST segment abnormal | | 1 |
| Electrocardiogram ST segment elevation | | 1 |
| Eosinophil count increased | 1 | 1 |
| Fibrin D dimer increased | 1 | 2 |
| Forced expiratory volume increased | 1 | 1 |
| Full blood count abnormal | 1 | 1 |
| Gamma-glutamyltransferase increased | | 1 |
| Grip strength | 1 | 1 |
| Grip strength decreased | 2 | 5 |
| Haematocrit increased | 1 | 1 |
| Haemoglobin decreased | 2 | 4 |
| Haemoglobin increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | 2 | 4 | 4 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 3 |
| | | 4 | 8 | 7 | 19 |
| | | 2 | 4 | 14 | 17 |
| | | 2 | 5 | 4 | 7 |
| | 1 | 13 | 32 | 35 | 68 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 2 | 3 | 3 | 4 |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 2 | 4 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | | | 1 | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Heart rate | 1 | 1 |
| Heart rate abnormal | 6 | 9 |
| Heart rate decreased | 12 | 16 |
| Heart rate increased | 84 | 156 |
| Heart rate irregular | 10 | 13 |
| Hepatic enzyme increased | | 1 |
| Hormone level abnormal | 1 | 1 |
| Inflammatory marker increased | 2 | 3 |
| International normalised ratio decreased | 3 | 3 |
| International normalised ratio increased | 8 | 12 |
| Intraocular pressure increased | | 1 |
| Liver function test abnormal | 2 | 2 |
| Liver function test increased | 2 | 4 |
| Lymph node palpable | | 1 |
| Mean cell volume decreased | 1 | 1 |
| Oxygen saturation decreased | 21 | 39 |
| Peak expiratory flow rate decreased | 1 | 1 |
| pH urine | 1 | 2 |
| pH urine increased | 1 | 1 |
| Platelet count decreased | 2 | 2 |
| Polymerase chain reaction positive | 2 | 2 |
| Pulse abnormal | 1 | 2 |
| Radial pulse abnormal | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 2 |
| Respiratory rate decreased | 1 | 2 |
| Respiratory rate increased | 13 | 20 |
| SARS-CoV-2 ant body test | 1 | 1 |
| SARS-CoV-2 ant body test negative | 14 | 16 |
| SARS-CoV-2 ant body test positive | | 1 |
| SARS-CoV-2 test | 1 | 1 |
| SARS-CoV-2 test false positive | | 1 |
| SARS-CoV-2 test negative | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 1 | 6 | 8 |
| | | 2 | 2 | 10 | 14 |
| | | 12 | 41 | 72 | 115 |
| | | 1 | 1 | 9 | 12 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | | | 3 | 3 |
| | | | | 8 | 12 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | 1 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 4 | 18 | 35 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 2 | 3 | 11 | 17 |
| | | 1 | 1 | | |
| | | 11 | 13 | 3 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |

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System Organ Class

Investigations

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|----------------------------------|--|--|
| SARS-CoV-2 test positive | 17 | 32 |
| Serum ferritin increased | 1 | 1 |
| Skin temperature | 2 | 2 |
| Sputum abnormal | 2 | 2 |
| Swollen joint count increased | 1 | 1 |
| Tri-iodothyronine decreased | | 1 |
| Troponin increased | 2 | 4 |
| Urine output decreased | | 1 |
| Urine output increased | 1 | 2 |
| Viral test | 1 | 1 |
| Vital capacity | 1 | 1 |
| Weight decreased | 14 | 15 |
| Weight increased | 2 | 2 |
| White blood cell count decreased | 2 | 3 |
| White blood cell count increased | 4 | 4 |
| | 456 | 800 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 4 | 15 | 28 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 2 | 4 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 4 | 11 | 11 |
| | | | | 2 | 2 |
| | | | | 2 | 3 |
| | | 1 | 1 | 3 | 3 |
| 1 | 2 | 97 | 216 | 359 | 584 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal weight gain | 3 | 3 | | | | | 3 | 3 |
| Acidosis | | 2 | | | | 1 | | 1 |
| Appetite disorder | 1 | 2 | | | | | 1 | 2 |
| Decreased appetite | 203 | 319 | 3 | 3 | 41 | 72 | 162 | 247 |
| Dehydration | 18 | 35 | | | 1 | 10 | 17 | 25 |
| Diabetes mellitus | 2 | 2 | | | | | 2 | 2 |
| Diabetes mellitus inadequate control | 1 | 3 | | | | | 1 | 3 |
| Diabetic complication | | 1 | | | | | | 1 |
| Diabetic ketoacidosis | 1 | 4 | | | | | 1 | 4 |
| Eating disorder symptom | 2 | 2 | | | | | 2 | 2 |
| Feeding disorder | 17 | 23 | | | 6 | 11 | 11 | 12 |
| Fluid intake reduced | | 2 | | | | | | 2 |
| Fluid retention | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Food aversion | 2 | 2 | | | | | 2 | 2 |
| Food craving | 1 | 1 | | | | | 1 | 1 |
| Food refusal | 2 | 2 | | | | | 2 | 2 |
| Glucose tolerance impaired | 1 | 1 | | | 1 | 1 | | |
| Gout | 10 | 12 | | | | | 10 | 12 |
| Histamine intolerance | 1 | 1 | | | | | 1 | 1 |
| Hyperglycaemia | 7 | 15 | | | 1 | 2 | 6 | 13 |
| Hyperkalaemia | 1 | 1 | | | | | 1 | 1 |
| Hypoglycaemia | 13 | 21 | | | | 2 | 13 | 19 |
| Hypokalaemic syndrome | 1 | 1 | | | | | 1 | 1 |
| Hyponatraemia | 1 | 3 | | | | | 1 | 3 |
| Hypophagia | 2 | 4 | | | | | 2 | 4 |
| Increased insulin requirement | 1 | 1 | | | | | 1 | 1 |
| Ketoacidosis | 2 | 2 | | | | | 2 | 2 |
| Malnutrition | | 1 | | | | | | 1 |
| Metabolic acidosis | 1 | 1 | | | | | 1 | 1 |
| Postprandial hypoglycaemia | 1 | 1 | | | | | 1 | 1 |
| Salt craving | 1 | 1 | | | | | 1 | 1 |
| Type 1 diabetes mellitus | 2 | 2 | | | | | 2 | 2 |

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| | 301 | 475 | 3 | 3 | 51 | 101 | 250 | 374 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Ankylosing spondylitis | 2 | 3 |
| Arthralgia | 796 | 1,363 |
| Arthritis | 21 | 31 |
| Arthritis reactive | 4 | 6 |
| Arthropathy | 6 | 7 |
| Axillary mass | 7 | 17 |
| Back pain | 234 | 351 |
| Bone pain | 42 | 69 |
| Bone swelling | 1 | 3 |
| Bursitis | 4 | 4 |
| Coccydynia | 1 | 1 |
| Costochondritis | 5 | 7 |
| Crystal arthropathy | 1 | 1 |
| Epiphyses premature fusion | 1 | 1 |
| Facial asymmetry | 1 | 1 |
| Fibromyalgia | 9 | 11 |
| Flank pain | 1 | 4 |
| Groin pain | 11 | 19 |
| Inguinal mass | | 1 |
| Jaw clicking | | 1 |
| Joint effusion | 4 | 7 |
| Joint lock | | 1 |
| Joint noise | | 1 |
| Joint range of motion decreased | 32 | 44 |
| Joint stiffness | 21 | 34 |
| Joint swelling | 45 | 65 |
| Joint warmth | | 2 |
| Limb discomfort | 122 | 217 |
| Limb mass | 8 | 9 |
| Mastication disorder | 1 | 3 |
| Medial tibial stress syndrome | 1 | 1 |
| Mobility decreased | 49 | 77 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 3 |
| 6 | 7 | 93 | 288 | 703 | 1075 |
| | | | 3 | 21 | 28 |
| | | 2 | 2 | 4 | 6 |
| | | | 7 | 7 | 10 |
| 2 | 2 | 30 | 79 | 204 | 272 |
| | | 7 | 20 | 35 | 49 |
| | | 1 | 2 | | 1 |
| | | | | 4 | 4 |
| | | 1 | 1 | | |
| | | 1 | 1 | 4 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 8 | 10 |
| | | | 2 | 1 | 2 |
| 1 | 1 | | 5 | 11 | 14 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 1 | 3 | 6 |
| | | | | | 1 |
| | | | | | 1 |
| 1 | 1 | 6 | 10 | 26 | 34 |
| | | 3 | 6 | 18 | 28 |
| | | 9 | 15 | 36 | 50 |
| | | | 2 | | |
| 1 | 1 | 32 | 82 | 90 | 135 |
| | | 3 | 4 | 5 | 5 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | 20 | 34 | 29 | 43 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Muscle atrophy | 1 | 1 |
| Muscle disorder | 1 | 1 |
| Muscle fatigue | 40 | 55 |
| Muscle rigidity | 4 | 8 |
| Muscle spasms | 72 | 106 |
| Muscle swelling | 2 | 5 |
| Muscle tightness | 9 | 11 |
| Muscle twitching | 19 | 33 |
| Muscular weakness | 102 | 167 |
| Musculoskeletal chest pain | 19 | 28 |
| Musculoskeletal discomfort | 13 | 20 |
| Musculoskeletal disorder | 7 | 10 |
| Musculoskeletal pain | 6 | 17 |
| Musculoskeletal stiffness | 108 | 180 |
| Myalgia | 1,000 | 1,829 |
| Myofascial pain syndrome | 3 | 4 |
| Myositis | | 1 |
| Neck mass | 1 | 4 |
| Neck pain | 177 | 306 |
| Nuchal rigidity | 2 | 2 |
| Osteoarthritis | 3 | 4 |
| Osteoporosis | 1 | 1 |
| Pain in extremity | 959 | 1,591 |
| Pain in jaw | 28 | 45 |
| Periarthritis | 3 | 5 |
| Plantar fasciitis | 1 | 1 |
| Polymyalgia rheumatica | 5 | 6 |
| Polymyositis | 1 | 1 |
| Posture abnormal | | 1 |
| Psoriatic arthropathy | 1 | 2 |
| Rhabdomyolysis | 1 | 4 |
| Rheumatoid arthritis | 9 | 11 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 7 | 36 | 48 |
| | | | | 4 | 8 |
| | | 8 | 21 | 64 | 85 |
| | | 1 | 2 | 1 | 3 |
| | | 1 | 2 | 8 | 9 |
| | | 4 | 12 | 15 | 21 |
| | | 17 | 37 | 85 | 130 |
| | | 2 | 4 | 17 | 24 |
| | | 2 | 7 | 11 | 13 |
| | | | 1 | 7 | 9 |
| | | 1 | 4 | 5 | 13 |
| 2 | 2 | 15 | 41 | 93 | 139 |
| 6 | 9 | 114 | 419 | 886 | 1410 |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 2 | | 2 |
| | | 28 | 86 | 149 | 220 |
| | | | | 2 | 2 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| 17 | 20 | 192 | 479 | 767 | 1112 |
| | | 3 | 11 | 25 | 34 |
| | | | 1 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 5 | 6 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 4 |
| | | | | 9 | 11 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Rotator cuff syndrome | 1 | 1 | | | | | 1 | 1 |
| Sacroiliitis | 1 | 2 | | | 1 | 1 | | 1 |
| Sjogren's syndrome | 1 | 2 | | | | | 1 | 2 |
| Spinal disorder | | 1 | | | | 1 | | |
| Spinal pain | 6 | 10 | | | 1 | 3 | 5 | 7 |
| Symphysiolysis | | 1 | | | | | | 1 |
| Synovial cyst | 2 | 3 | | | | 1 | 2 | 2 |
| Synovitis | 2 | 3 | | | | | 2 | 3 |
| Systemic lupus erythematosus | 1 | 2 | | | | | 1 | 2 |
| Temporomandibular joint syndrome | | 2 | | | | 2 | | |
| Tendonitis | 2 | 3 | | | | | 2 | 3 |
| Tendon pain | 1 | 1 | | | | | 1 | 1 |
| Torticollis | | 1 | | | | | | 1 |
| Trismus | 2 | 3 | | | | | 2 | 3 |
| Weight bearing difficulty | 2 | 2 | | | | | 2 | 2 |
| | 4,049 | 6,859 | 36 | 43 | 607 | 1714 | 3442 | 5145 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Acrochordon | 1 | 1 | 1 | 1 |
| Breast cancer | 1 | 1 | 1 | 1 |
| Leukaemia | | 1 | | 1 |
| Lymphoma | 3 | 3 | 3 | 3 |
| Melanocytic naevus | 1 | 1 | 1 | 1 |
| Metastases to lymph nodes | 5 | 5 | 5 | 5 |
| Neoplasm malignant | 1 | 1 | 1 | 1 |
| Plasma cell myeloma | 1 | 1 | 1 | 1 |
| Sarcoma | 1 | 1 | 1 | 1 |
| Second primary malignancy | 1 | 1 | 1 | 1 |
| Skin cancer | | 1 | | 1 |
| | 15 | 17 | 15 | 17 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ageusia | 34 | 63 | | | 5 | 16 | 29 | 47 |
| Alexia | 1 | 1 | | | 1 | 1 | | |
| Allodynia | | 1 | | | | | | 1 |
| Altered state of consciousness | 2 | 3 | | | | | 2 | 3 |
| Amnesia | 10 | 11 | | | 1 | 2 | 9 | 9 |
| Anosmia | 20 | 37 | | | 2 | 11 | 18 | 26 |
| Anticholinergic syndrome | | 1 | | | | | | 1 |
| Aphasia | 6 | 10 | | | 2 | 2 | 4 | 8 |
| Ataxia | 1 | 1 | | | | | 1 | 1 |
| Aura | | 6 | | | | 3 | | 3 |
| Autonomic nervous system imbalance | 1 | 1 | | | | | 1 | 1 |
| Axonal neuropathy | 1 | 1 | | | | | 1 | 1 |
| Balance disorder | 54 | 79 | | 1 | 8 | 13 | 46 | 66 |
| Bradykinesia | 2 | 2 | | | | | 2 | 2 |
| Brain injury | | 1 | | | | | | 1 |
| Brain oedema | 1 | 1 | | | | | 1 | 1 |
| Brain stem stroke | 1 | 1 | | | | | 1 | 1 |
| Burning sensation | 30 | 57 | | | 5 | 10 | 25 | 47 |
| Carpal tunnel syndrome | 1 | 1 | | | | | 1 | 1 |
| Cataplexy | | 1 | | | | | | 1 |
| Cerebellar infarction | | 2 | | | | | | 2 |
| Cerebellar stroke | | 1 | | | | | | 1 |
| Cerebral disorder | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Cerebral haemorrhage | 8 | 10 | | | | | 8 | 10 |
| Cerebral infarction | 4 | 6 | | | | | 4 | 6 |
| Cerebral venous sinus thrombosis | | 1 | | | | | | 1 |
| Cerebrovascular accident | 30 | 50 | | | | | 30 | 50 |
| Cervicobrachial syndrome | 1 | 1 | | | | | 1 | 1 |
| Chorea | 1 | 1 | | | | | 1 | 1 |
| Clonic convulsion | 2 | 2 | | | | | 2 | 2 |
| Clumsiness | | 1 | | | | | | 1 |
| Cluster headache | 12 | 19 | | | 1 | 2 | 11 | 17 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Cognitive disorder | 8 | 12 |
| Coma | 1 | 1 |
| Consciousness fluctuating | 3 | 4 |
| Coordination abnormal | 14 | 15 |
| Cranial nerve disorder | 1 | 1 |
| Dementia | 2 | 3 |
| Dementia with Lewy bodies | 1 | 1 |
| Depressed level of consciousness | 4 | 8 |
| Diplegia | 1 | 1 |
| Disturbance in attention | 45 | 66 |
| Dizziness | 809 | 1,318 |
| Dizziness exertional | 7 | 8 |
| Dizziness postural | 54 | 93 |
| Dreamy state | 1 | 1 |
| Droling | 3 | 4 |
| Dysaesthesia | 1 | 1 |
| Dysarthria | 19 | 29 |
| Dysgeusia | 83 | 159 |
| Dyskinesia | 7 | 10 |
| Dysstasia | 13 | 21 |
| Dystonia | 3 | 4 |
| Encephalopathy | 1 | 1 |
| Epilepsy | 11 | 17 |
| Essential tremor | 1 | 1 |
| Exertional headache | 1 | 2 |
| Extensor plantar response | 1 | 1 |
| Facial neuralgia | 4 | 5 |
| Facial paralysis | 84 | 122 |
| Facial paresis | 9 | 16 |
| Facial spasm | 3 | 7 |
| Febrile convulsion | 1 | 1 |
| Formication | 4 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 7 | 11 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | 1 | 2 | 13 | 13 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 4 | 8 |
| | | | | 1 | 1 |
| | | 5 | 13 | 40 | 53 |
| 3 | 4 | 99 | 312 | 710 | 1006 |
| | | | 1 | 7 | 7 |
| | | 3 | 12 | 51 | 81 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | 18 | 27 |
| | | 18 | 71 | 65 | 88 |
| | | | 1 | 7 | 9 |
| | | 4 | 7 | 9 | 14 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 11 | 17 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 4 | 4 |
| 1 | 1 | | 2 | 84 | 120 |
| | | 2 | 5 | 7 | 11 |
| | | | 3 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 4 | 6 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Generalised tonic-clonic seizure | 4 | 10 |
| Gliositis | 1 | 1 |
| Guillain-Barre syndrome | 1 | 2 |
| Haemorrhage intracranial | | 2 |
| Haemorrhagic stroke | | 2 |
| Hand-eye coordination impaired | | 1 |
| Headache | 2,311 | 3,925 |
| Head discomfort | 24 | 36 |
| Hemiparaesthesia | | 1 |
| Hemiparesis | 2 | 12 |
| Hemiplegia | 2 | 2 |
| Hemiplegic migraine | 2 | 2 |
| Hyperaesthesia | 10 | 20 |
| Hypergeusia | 1 | 1 |
| Hyperreflexia | 1 | 1 |
| Hypersomnia | 38 | 52 |
| Hypertonia | 1 | 2 |
| Hypoaesthesia | 162 | 266 |
| Hypokinesia | 5 | 8 |
| Hyporeflexia | 1 | 3 |
| Hyporesponsive to stimuli | | 1 |
| Hyposmia | 1 | 5 |
| Hypotonia | 1 | 2 |
| Idiopathic intracranial hypertension | | 1 |
| Illrd nerve paralysis | 2 | 2 |
| Incoherent | 1 | 3 |
| Ischaemic stroke | 3 | 10 |
| Lacunar infarction | | 2 |
| Lacunar stroke | | 1 |
| Lethargy | 219 | 384 |
| Locked-in syndrome | | 1 |
| Long thoracic nerve palsy | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 4 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | | | | 2 |
| | | | | | 1 |
| 17 | 22 | 306 | 937 | 2005 | 2988 |
| 1 | 1 | 6 | 11 | 18 | 25 |
| | | | | | 1 |
| | | | | 2 | 12 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 5 | 10 | 5 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 10 | 15 | 28 | 37 |
| | | | | 1 | 2 |
| 1 | 1 | 34 | 81 | 128 | 185 |
| | | 2 | 3 | 3 | 5 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | | 2 | 1 | 3 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | 2 |
| | | | | 3 | 10 |
| | | | | | 2 |
| | | | | | 1 |
| 3 | 3 | 35 | 95 | 184 | 289 |
| | | | | | 1 |
| | | 1 | 1 | | |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Loss of consciousness | 68 | 101 |
| Medication overuse headache | | 1 |
| Memory impairment | 14 | 19 |
| Mental impairment | 1 | 5 |
| Migraine | 190 | 313 |
| Migraine with aura | 13 | 20 |
| Mononeuropathy | | 1 |
| Monoparesis | 8 | 10 |
| Monoplegia | 9 | 14 |
| Motor dysfunction | 3 | 3 |
| Movement disorder | 18 | 26 |
| Multiple sclerosis | | 2 |
| Multiple sclerosis relapse | 5 | 7 |
| Muscle contractions involuntary | 3 | 5 |
| Muscle tone disorder | | 1 |
| Myasthenia gravis | 2 | 2 |
| Myelitis transverse | 7 | 7 |
| Myoclonus | 2 | 3 |
| Narcolepsy | | 1 |
| Nerve compression | 4 | 4 |
| Nerve degeneration | 1 | 1 |
| Nervous system disorder | 3 | 3 |
| Neuralgia | 24 | 30 |
| Neurological symptom | 3 | 3 |
| Neurologic neglect syndrome | 2 | 2 |
| Neuromyopathy | 1 | 1 |
| Neuropathy peripheral | 13 | 15 |
| Numb chin syndrome | 1 | 1 |
| Occipital neuralgia | 1 | 1 |
| Optic neuritis | 3 | 4 |
| Paraesthesia | 229 | 397 |
| Paralysis | 11 | 17 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 68 | 101 |
| | | | | | 1 |
| | | 2 | 4 | 12 | 15 |
| | | | | 1 | 5 |
| | | 12 | 56 | 178 | 257 |
| | | 1 | 4 | 12 | 16 |
| | | | | | 1 |
| | | 1 | 2 | 7 | 8 |
| | | | | 9 | 14 |
| | | 1 | 1 | 2 | 2 |
| | | 2 | 4 | 16 | 22 |
| | | | | | 2 |
| | | | | 5 | 7 |
| | | 1 | 2 | 2 | 3 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 7 | 7 |
| | | | 1 | 2 | 2 |
| | | | | | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 5 | 6 | 19 | 24 |
| | | 1 | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 13 | 15 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| 1 | 1 | 32 | 120 | 197 | 277 |
| | | | | 11 | 17 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Paraparesis | 1 | 1 |
| Paresis | 1 | 1 |
| Parkinsonism | 2 | 2 |
| Parkinson's disease | 1 | 2 |
| Parosmia | 16 | 21 |
| Partial seizures | | 1 |
| Peripheral sensory neuropathy | 2 | 3 |
| Peroneal nerve palsy | 3 | 4 |
| Persistent postural-perceptual dizziness | 1 | 1 |
| Petit mal epilepsy | 4 | 6 |
| Poor quality sleep | 28 | 40 |
| Posterior reversible encephalopathy syndrome | | 1 |
| Postictal state | 1 | 1 |
| Presyncope | 55 | 105 |
| Primary cough headache | 1 | 3 |
| Primary headache associated with sexual activity | | 1 |
| Psychogenic seizure | 2 | 2 |
| Psychomotor hyperactivity | 2 | 2 |
| Quadrantanopia | 1 | 1 |
| Radiculopathy | | 1 |
| Repetitive speech | 1 | 1 |
| Restless legs syndrome | 6 | 10 |
| Retinal migraine | 3 | 4 |
| Sciatica | 3 | 5 |
| Sedation | 2 | 3 |
| Seizure | 51 | 70 |
| Seizure cluster | 1 | 1 |
| Sensory disturbance | 8 | 19 |
| Sensory loss | 5 | 7 |
| Serotonin syndrome | | 1 |
| Sinus headache | 19 | 30 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | 3 | 5 | 13 | 16 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 4 | 6 |
| | | 6 | 11 | 22 | 29 |
| | | | | | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 13 | 37 | 42 | 68 |
| | | 1 | 1 | | 2 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 8 |
| | | | | 3 | 4 |
| | | 1 | 1 | 2 | 4 |
| | | | 1 | 2 | 2 |
| | | | | 51 | 70 |
| | | | | 1 | 1 |
| | | 3 | 10 | 5 | 9 |
| | | | 1 | 5 | 6 |
| | | | | | 1 |
| | | 4 | 5 | 15 | 25 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|----------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Sleep deficit | | 1 | | | | | | | 1 |
| Sleep paralysis | 2 | 2 | | | 1 | 1 | 1 | 1 | 1 |
| Slow response to stimuli | 1 | 2 | | | | | 1 | 2 | |
| Slow speech | 1 | 1 | | | | | 1 | 1 | |
| Somnolence | 96 | 167 | | | 21 | 49 | 75 | 118 | |
| Speech disorder | 11 | 15 | 1 | 1 | 4 | 4 | 7 | 11 | |
| Status epilepticus | 4 | 4 | | | | | 4 | 4 | |
| Stiff leg syndrome | | 1 | | | | | | 1 | |
| Subarachnoid haemorrhage | 2 | 3 | | | | | 2 | 3 | |
| Syncope | 186 | 286 | 1 | 1 | | | 186 | 286 | |
| Taste disorder | 23 | 38 | | | 7 | 17 | 16 | 21 | |
| Temporal lobe epilepsy | 1 | 1 | | | | | 1 | 1 | |
| Tension headache | 30 | 54 | | | 2 | 8 | 28 | 46 | |
| Thunderclap headache | | 1 | | | | | | 1 | |
| Tongue biting | 1 | 1 | | | | | 1 | 1 | |
| Tonic convulsion | 6 | 6 | | | | | 6 | 6 | |
| Transient global amnesia | 1 | 1 | | | | | 1 | 1 | |
| Transient ischaemic attack | 14 | 20 | | | | | 14 | 20 | |
| Tremor | 202 | 320 | 2 | 2 | 32 | 65 | 170 | 255 | |
| Trigeminal neuralgia | 3 | 4 | | | 1 | 1 | 2 | 3 | |
| Tunnel vision | 3 | 4 | | | | | 3 | 4 | |
| Unresponsive to stimuli | 6 | 22 | | | | | 6 | 22 | |
| Vascular dementia | | 1 | | | | | | 1 | |
| Vascular headache | 2 | 2 | | | 1 | 1 | 1 | 1 | |
| Vestibular migraine | 1 | 2 | | | 1 | 1 | | 1 | |
| Visual field defect | 2 | 4 | | | | 1 | 2 | 3 | |
| Vlth nerve paralysis | 3 | 3 | | | | | 3 | 3 | |
| Writer's cramp | | 1 | | | | | | 1 | |
| | 5,679 | 9,413 | 32 | 39 | 724 | 2078 | 4955 | 7335 | |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|----|
| | | | Serious | |
| | | | I | C |
| Abortion spontaneous | 6 | 8 | 6 | 8 |
| Morning sickness | 2 | 3 | 2 | 3 |
| Premature baby | 2 | 2 | 2 | 2 |
| | 10 | 13 | 10 | 13 |

System Organ Class

Product issues

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-------------------------------------|--|--|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Liquid product physical issue | | 2 | | 2 | | |
| Needle issue | 1 | 1 | | | 1 | 1 |
| Oversensing | 3 | 4 | | 1 | 3 | 3 |
| Product complaint | 1 | 1 | | | 1 | 1 |
| Product packaging quantity issue | | 4 | | 4 | | |
| Product quality issue | 2 | 2 | 2 | 2 | | |
| Product taste abnormal | 1 | 1 | 1 | 1 | | |
| Product temperature excursion issue | | 3 | | 3 | | |
| | 8 | 18 | 3 | 13 | 5 | 5 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal dreams | 6 | 18 | | | 1 | 9 | 5 | 9 |
| Aggression | 3 | 3 | | | | | 3 | 3 |
| Agitation | 10 | 21 | | | 1 | 5 | 9 | 16 |
| Anger | 1 | 2 | | | 1 | 1 | | 1 |
| Anorgasmia | | 1 | | | | | | 1 |
| Anxiety | 57 | 96 | | | 13 | 28 | 44 | 68 |
| Apathy | 4 | 6 | | | 2 | 2 | 2 | 4 |
| Autoscopy | 1 | 1 | | | | | 1 | 1 |
| Behaviour disorder | 1 | 1 | | | | | 1 | 1 |
| Bradypnea | 4 | 5 | | | | | 4 | 5 |
| Catatonia | 1 | 1 | | | | | 1 | 1 |
| Communication disorder | 4 | 5 | | | 2 | 2 | 2 | 3 |
| Confusional state | 104 | 148 | | | 15 | 25 | 89 | 123 |
| Decreased interest | | 2 | | | | 1 | | 1 |
| Delirium | 21 | 37 | | | | | 21 | 37 |
| Delusion | 1 | 2 | | | 1 | 1 | | 1 |
| Depersonalisation/derealisation disorder | | 2 | | | | 1 | | 1 |
| Depressed mood | 21 | 25 | | | 2 | 4 | 19 | 21 |
| Depression | 10 | 14 | | | | | 10 | 14 |
| Derealisation | | 1 | | | | | | 1 |
| Disorganised speech | 1 | 2 | | | | 1 | 1 | 1 |
| Disorientation | 36 | 49 | | | 2 | 5 | 34 | 44 |
| Dissociation | 3 | 5 | | | 1 | 3 | 2 | 2 |
| Dissociative disorder | 1 | 1 | | | 1 | 1 | | |
| Eating disorder | 6 | 7 | | | 3 | 3 | 3 | 4 |
| Emotional disorder | 4 | 4 | | | | | 4 | 4 |
| Emotional distress | 9 | 10 | | | 1 | 2 | 8 | 8 |
| Enuresis | | 3 | | | | 1 | | 2 |
| Euphoric mood | 2 | 3 | | | 2 | 2 | | 1 |
| Fear | 1 | 5 | | | 1 | 2 | | 3 |
| Fear of falling | 1 | 1 | | | | | 1 | 1 |
| Fear of injection | | 1 | | | | 1 | | |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Feeling of despair | 2 | 2 |
| Flashback | 1 | 1 |
| Frustration tolerance decreased | | 1 |
| Hallucination | 29 | 48 |
| Hallucination, auditory | 2 | 2 |
| Hallucination, olfactory | | 1 |
| Hallucinations, mixed | 2 | 2 |
| Hallucination, tactile | | 1 |
| Hallucination, visual | 1 | 6 |
| Head banging | 1 | 1 |
| Hyposomnia | 1 | 1 |
| Indifference | 1 | 2 |
| Initial insomnia | 3 | 5 |
| Insomnia | 166 | 255 |
| Intentional self-injury | | 1 |
| Irritability | 16 | 20 |
| Lack of spontaneous speech | 2 | 2 |
| Laziness | 1 | 1 |
| Listless | 3 | 3 |
| Logorrhoea | 1 | 1 |
| Mental disorder | 1 | 2 |
| Mental fatigue | 18 | 25 |
| Middle insomnia | 11 | 18 |
| Mood altered | 1 | 4 |
| Mood disorder due to a general medical condition | 1 | 1 |
| Mood swings | 5 | 5 |
| Mutism | 2 | 2 |
| Negative thoughts | | 1 |
| Nervousness | 33 | 43 |
| Neuropsychiatric symptoms | 1 | 1 |
| Nightmare | 14 | 22 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 29 | 48 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 6 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 2 | 2 | 3 |
| 1 | 1 | 35 | 79 | 131 | 176 |
| | | | | | 1 |
| | | 4 | 5 | 12 | 15 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 3 | 6 | 15 | 19 |
| | | 4 | 8 | 7 | 10 |
| | | | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | 7 | 10 | 26 | 33 |
| | | 1 | 1 | | |
| | | 3 | 8 | 11 | 14 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Obsessive-compulsive symptom | | 1 |
| Panic attack | 6 | 9 |
| Panic disorder | | 1 |
| Panic reaction | 8 | 8 |
| Paranoia | 1 | 2 |
| Personality change | 1 | 1 |
| Phonophobia | | 1 |
| Psychiatric symptom | 2 | 2 |
| Psychotic behaviour | | 1 |
| Psychotic disorder | 4 | 4 |
| Psychotic symptom | 1 | 1 |
| Restlessness | 14 | 32 |
| Sense of a foreshortened future | 2 | 2 |
| Sleep attacks | | 2 |
| Sleep disorder | 40 | 74 |
| Sleep disorder due to a general medical condition | 2 | 6 |
| Sleep disorder due to general medical condition, insomnia type | 8 | 11 |
| Sleep terror | | 1 |
| Social avoidant behaviour | 1 | 1 |
| Social fear | 1 | 1 |
| Somatic symptom disorder | | 1 |
| Staring | 1 | 1 |
| Stereotypy | 1 | 1 |
| Stress | 4 | 6 |
| Suicidal ideation | 2 | 2 |
| Suicide attempt | 1 | 1 |
| Tachyphrenia | 1 | 1 |
| Tearfulness | 2 | 4 |
| Tension | | 1 |
| Terminal insomnia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 6 | 9 |
| | | | | | 1 |
| | | 2 | 2 | 6 | 6 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | 10 | 14 | 22 |
| | | | | 2 | 2 |
| | | | | | 2 |
| | | 14 | 34 | 26 | 40 |
| | | 1 | 2 | 1 | 4 |
| | | 3 | 5 | 5 | 6 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Thinking abnormal | 4 | 5 | | | | | 4 | 5 |
| Vomiting psychogenic | | 1 | | | | | | 1 |
| | 740 | 1,148 | 1 | 1 | 137 | 289 | 603 | 859 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 5 | 10 | | | 5 | 10 |
| Anuria | | 1 | | | | 1 |
| Bladder discomfort | | 1 | | 1 | | |
| Bladder disorder | 4 | 4 | | | 4 | 4 |
| Bladder irritation | 1 | 1 | | | 1 | 1 |
| Bladder pain | | 1 | | | | 1 |
| Chromaturia | 5 | 9 | 3 | 4 | 2 | 5 |
| Costovertebral angle tenderness | | 1 | | 1 | | |
| Dysuria | 7 | 9 | 2 | 3 | 5 | 6 |
| Genitourinary symptom | 1 | 1 | | | 1 | 1 |
| Haematuria | 4 | 5 | 1 | 2 | 3 | 3 |
| Haemorrhage urinary tract | 2 | 3 | | | 2 | 3 |
| Hypertonic bladder | 1 | 2 | 1 | 2 | | |
| Incontinence | 7 | 10 | 1 | 2 | 6 | 8 |
| Loss of bladder sensation | 1 | 1 | | | 1 | 1 |
| Micturition disorder | 2 | 3 | | | 2 | 3 |
| Micturition urgency | 2 | 3 | | 1 | 2 | 2 |
| Nephritis | 1 | 1 | | | 1 | 1 |
| Nephrotic syndrome | 1 | 2 | | | 1 | 2 |
| Nocturia | | 1 | | 1 | | |
| Oliguria | 1 | 1 | | | 1 | 1 |
| Pollakiuria | 6 | 8 | 1 | 2 | 5 | 6 |
| Polyuria | | 1 | | 1 | | |
| Proteinuria | 1 | 1 | 1 | 1 | | |
| Renal failure | 1 | 3 | | | 1 | 3 |
| Renal impairment | 1 | 1 | | | 1 | 1 |
| Renal pain | 17 | 28 | 3 | 9 | 14 | 19 |
| Urinary incontinence | 12 | 17 | 2 | 3 | 10 | 14 |
| Urinary retention | 12 | 17 | | | 12 | 17 |
| Urinary tract disorder | | 1 | | | | 1 |
| Urinary tract pain | 1 | 1 | | | 1 | 1 |
| Urine abnormality | 1 | 1 | 1 | 1 | | |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urine flow decreased | 1 | 1 | | | 1 | 1 |
| Urine odour abnormal | 1 | 1 | 1 | 1 | | |
| | 99 | 151 | 17 | 35 | 82 | 116 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adnexa uteri pain | 4 | 4 | | | 4 | 4 |
| Breast cyst | 1 | 1 | | | 1 | 1 |
| Breast discomfort | 1 | 2 | | | 1 | 2 |
| Breast enlargement | 1 | 1 | | | 1 | 1 |
| Breast mass | 4 | 5 | 1 | 1 | 3 | 4 |
| Breast pain | 22 | 34 | 3 | 8 | 19 | 26 |
| Breast swelling | 9 | 13 | 3 | 7 | 6 | 6 |
| Breast tenderness | 6 | 6 | 1 | 1 | 5 | 5 |
| Dysmenorrhoea | 7 | 10 | 3 | 5 | 4 | 5 |
| Endometriosis | 1 | 1 | | | 1 | 1 |
| Erectile dysfunction | 4 | 5 | | | 4 | 5 |
| Genital pain | 2 | 2 | | | 2 | 2 |
| Genital ulceration | 1 | 1 | | | 1 | 1 |
| Hypomenorrhoea | 1 | 1 | | | 1 | 1 |
| Infertility | 1 | 1 | | | 1 | 1 |
| Menopausal symptoms | | 2 | | 2 | | |
| Menorrhagia | 12 | 17 | | 2 | 12 | 15 |
| Menstrual disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Menstruation delayed | 9 | 10 | 1 | 2 | 8 | 8 |
| Menstruation irregular | 3 | 5 | 1 | 2 | 2 | 3 |
| Metrorrhagia | 2 | 3 | 1 | 2 | 1 | 1 |
| Nipple pain | 3 | 6 | | 2 | 3 | 4 |
| Nipple swelling | | 2 | | 2 | | |
| Oligomenorrhoea | 1 | 1 | | | 1 | 1 |
| Ovulation pain | 1 | 1 | | | 1 | 1 |
| Pelvic discomfort | 1 | 1 | | | 1 | 1 |
| Pelvic pain | 7 | 8 | 1 | 2 | 6 | 6 |
| Penile swelling | | 1 | | | | 1 |
| Polymenorrhoea | | 2 | | 1 | | 1 |
| Postmenopausal haemorrhage | 1 | 1 | | | 1 | 1 |
| Prostatomegaly | 1 | 2 | 1 | 2 | | |
| Scrotal erythema | | 1 | | | | 1 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Scrotal exfoliation | | 1 | | | | 1 | |
| Scrotal pain | 1 | 3 | | 1 | 1 | 2 | |
| Scrotal swelling | | 1 | | | | 1 | |
| Testicular pain | 1 | 1 | | | 1 | 1 | |
| Testicular torsion | 1 | 1 | | | 1 | 1 | |
| Uterine pain | 1 | 1 | | | 1 | 1 | |
| Vaginal disorder | 1 | 1 | 1 | 1 | | | |
| Vaginal haemorrhage | 9 | 13 | 1 | 1 | 8 | 12 | |
| Vulvovaginal pruritus | | 1 | | 1 | | | |
| | 122 | 175 | 19 | 46 | 103 | 129 | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute pulmonary oedema | | 1 | | | | | | 1 |
| Acute respiratory failure | | 2 | | | | | | 2 |
| Allergic cough | | 2 | | | | | | 2 |
| Allergic sinusitis | 1 | 1 | | | | | 1 | 1 |
| Aphonia | 6 | 11 | | | 1 | 2 | 5 | 9 |
| Apnoea | 1 | 1 | | | | | 1 | 1 |
| Aspiration | 3 | 4 | | | | | 3 | 4 |
| Asthma | 43 | 63 | | | 5 | 11 | 38 | 52 |
| Atelectasis | | 1 | | | | | | 1 |
| Bronchial disorder | 1 | 1 | | | | | 1 | 1 |
| Bronchiectasis | 2 | 2 | | | | | 2 | 2 |
| Bronchospasm | 1 | 4 | | | | | 1 | 4 |
| Catarrh | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Choking | 3 | 4 | | | | | 3 | 4 |
| Choking sensation | 2 | 2 | | | | | 2 | 2 |
| Chronic obstructive pulmonary disease | 3 | 3 | | | | | 3 | 3 |
| Cough | 199 | 341 | 1 | 1 | 27 | 79 | 172 | 262 |
| Dry throat | 16 | 26 | | | 3 | 5 | 13 | 21 |
| Dysphonia | 12 | 25 | | | 2 | 5 | 10 | 20 |
| Dyspnoea | 363 | 577 | | | 34 | 90 | 329 | 487 |
| Dyspnoea at rest | 3 | 3 | | | | | 3 | 3 |
| Dyspnoea exertional | 14 | 24 | | | 3 | 8 | 11 | 16 |
| Epiglottic oedema | 1 | 1 | | | | | 1 | 1 |
| Epistaxis | 40 | 62 | | | 3 | 12 | 37 | 50 |
| Haemoptysis | 8 | 10 | | | | | 8 | 10 |
| Hiccups | 1 | 1 | | | | | 1 | 1 |
| Hypercapnia | 1 | 1 | | | | | 1 | 1 |
| Hypersensitivity pneumonitis | | 1 | | | | | | 1 |
| Hyperventilation | 5 | 6 | | | 3 | 3 | 2 | 3 |
| Hypopnoea | 13 | 15 | | | | | 13 | 15 |
| Hypoxia | 6 | 10 | | | | | 6 | 10 |
| Increased bronchial secretion | 1 | 1 | | | 1 | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Increased upper airway secretion | 1 | 4 |
| Increased viscosity of upper respiratory secretion | 1 | 3 |
| Intranasal hypoaesthesia | | 1 |
| Intranasal paraesthesia | 1 | 1 |
| Irregular breathing | 4 | 4 |
| Laryngeal disorder | 1 | 1 |
| Lung consolidation | | 1 |
| Lung disorder | 1 | 1 |
| Mouth breathing | 2 | 2 |
| Nasal congestion | 25 | 37 |
| Nasal discharge discolouration | | 1 |
| Nasal discomfort | 6 | 9 |
| Nasal disorder | 1 | 1 |
| Nasal dryness | | 1 |
| Nasal obstruction | | 1 |
| Nasal odour | 1 | 2 |
| Nasal oedema | 3 | 4 |
| Nasal pruritus | 2 | 3 |
| Nocturnal dyspnoea | 1 | 1 |
| Obstructive airways disorder | | 1 |
| Oropharyngeal blistering | 4 | 7 |
| Oropharyngeal discomfort | 12 | 17 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 214 | 361 |
| Oropharyngeal spasm | 1 | 1 |
| Orthopnoea | 1 | 2 |
| Painful respiration | 9 | 14 |
| Paranasal sinus discomfort | 4 | 4 |
| Paranasal sinus inflammation | | 1 |
| Pharyngeal erythema | 1 | 2 |
| Pharyngeal haemorrhage | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 3 |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 7 | 14 | 18 | 23 |
| | | | 1 | | |
| | | 1 | 3 | 5 | 6 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 4 | 7 |
| | | 1 | 2 | 11 | 15 |
| | | | | 1 | 1 |
| | | 23 | 93 | 191 | 268 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 2 | 4 | 7 | 10 |
| | | 1 | 1 | 3 | 3 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Pharyngeal hypoaesthesia | 1 | 4 |
| Pharyngeal inflammation | 2 | 6 |
| Pharyngeal oedema | | 4 |
| Pharyngeal paraesthesia | 9 | 15 |
| Pharyngeal swelling | 42 | 64 |
| Pharyngeal ulceration | 4 | 5 |
| Pleural effusion | 1 | 2 |
| Pleurisy | 2 | 4 |
| Pleuritic pain | 2 | 6 |
| Pneumonia aspiration | | 3 |
| Pneumonitis | 6 | 7 |
| Productive cough | 26 | 34 |
| Pulmonary artery thrombosis | 1 | 1 |
| Pulmonary congestion | 3 | 3 |
| Pulmonary embolism | 12 | 14 |
| Pulmonary infarction | 1 | 2 |
| Pulmonary oedema | | 2 |
| Pulmonary pain | 15 | 19 |
| Pulmonary thrombosis | 3 | 4 |
| Rales | 1 | 2 |
| Respiration abnormal | 8 | 12 |
| Respiratory arrest | 2 | 6 |
| Respiratory disorder | 5 | 9 |
| Respiratory distress | 3 | 4 |
| Respiratory failure | 1 | 1 |
| Respiratory symptom | 1 | 1 |
| Respiratory tract irritation | 1 | 2 |
| Respiratory tract oedema | 2 | 3 |
| Reversible airways obstruction | 1 | 1 |
| Rhinalgia | 3 | 3 |
| Rhinitis allergic | 2 | 3 |
| Rhinorrhoea | 56 | 82 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 3 |
| | | | | 2 | 6 |
| | | | | | 4 |
| | | 1 | 2 | 8 | 13 |
| | | 1 | 10 | 41 | 54 |
| | | 1 | 1 | 3 | 4 |
| | | | | 1 | 2 |
| | | | | 2 | 4 |
| | | | | 2 | 6 |
| | | | | | 3 |
| | | | | 6 | 7 |
| | | 7 | 9 | 19 | 25 |
| | | | | 1 | 1 |
| 1 | 1 | | | 3 | 3 |
| | | | | 12 | 14 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | 2 | 4 | 13 | 15 |
| 1 | 1 | | | 3 | 4 |
| | | | | 1 | 2 |
| | | 1 | 2 | 7 | 10 |
| 1 | 1 | 1 | 1 | 1 | 5 |
| | | | 1 | 5 | 8 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| 1 | 1 | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | 1 | 2 |
| 1 | 1 | 5 | 20 | 51 | 62 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Sinonasal obstruction | | 1 | | | | | | 1 |
| Sinus congestion | 5 | 8 | | | 1 | 3 | 4 | 5 |
| Sinus disorder | 1 | 2 | | | | | 1 | 2 |
| Sinus pain | 12 | 24 | | | 1 | 5 | 11 | 19 |
| Sleep apnoea syndrome | 1 | 1 | | | | | 1 | 1 |
| Sneezing | 30 | 50 | | | 4 | 17 | 26 | 33 |
| Snoring | | 1 | | | | | | 1 |
| Stridor | 5 | 6 | | | | | 5 | 6 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 | | |
| Tachypnoea | 4 | 10 | | | 1 | 2 | 3 | 8 |
| Throat clearing | 2 | 4 | | | | | 2 | 4 |
| Throat irritation | 30 | 46 | | | 3 | 9 | 27 | 37 |
| Throat tightness | 41 | 83 | | | 6 | 16 | 35 | 67 |
| Tonsillar disorder | 1 | 1 | | | 1 | 1 | | |
| Tonsillar erythema | 1 | 1 | | | | | 1 | 1 |
| Tonsillar hypertrophy | 5 | 9 | | | | 1 | 5 | 8 |
| Tonsillar inflammation | | 2 | | | | 1 | | 1 |
| Tonsillar ulcer | 1 | 1 | | | | | 1 | 1 |
| Tracheal pain | 1 | 1 | | | 1 | 1 | | |
| Upper-airway cough syndrome | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Upper airway obstruction | 1 | 1 | | | | | 1 | 1 |
| Upper respiratory tract congestion | 1 | 2 | | | 1 | 1 | | 1 |
| Vocal cord disorder | | 1 | | | | | | 1 |
| Wheezing | 51 | 84 | | | 6 | 18 | 45 | 66 |
| Yawning | 3 | 3 | | | 1 | 1 | 2 | 2 |
| | 1,465 | 2,374 | 6 | 6 | 168 | 476 | 1297 | 1898 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acne | 2 | 2 | | | | | 2 | 2 |
| Acute febrile neutrophilic dermatosis | 1 | 1 | | | | | 1 | 1 |
| Alopecia | 6 | 8 | | | 2 | 3 | 4 | 5 |
| Angioedema | 33 | 55 | | | | | 33 | 55 |
| Blister | 22 | 30 | | | 1 | 6 | 21 | 24 |
| Blood blister | 1 | 1 | | | | | 1 | 1 |
| Chronic spontaneous urticaria | 1 | 1 | | | | | 1 | 1 |
| Cold sweat | 66 | 122 | | | 11 | 31 | 55 | 91 |
| Cutaneous symptom | 1 | 1 | | | | | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 | | | | | 1 | 1 |
| Dermatitis | 6 | 12 | | | 1 | 5 | 5 | 7 |
| Dermatitis allergic | 11 | 26 | | | | 7 | 11 | 19 |
| Dermatitis atopic | 1 | 1 | | | | | 1 | 1 |
| Dermatitis bullous | 2 | 3 | | | | | 2 | 3 |
| Dermatitis exfoliative | 1 | 1 | | | | | 1 | 1 |
| Drug eruption | 1 | 4 | | | 1 | 1 | | 3 |
| Dry skin | 7 | 14 | | | 1 | 8 | 6 | 6 |
| Dyshidrotic eczema | 1 | 1 | | | | | 1 | 1 |
| Eczema | 13 | 18 | | | 2 | 3 | 11 | 15 |
| Eczema nummular | 1 | 1 | | | 1 | 1 | | |
| Eczema weeping | 1 | 1 | | | 1 | 1 | | |
| Erythema | 141 | 273 | | | 28 | 99 | 113 | 174 |
| Erythema annulare | 1 | 1 | | | | | 1 | 1 |
| Erythema multiforme | 5 | 7 | | | | | 5 | 7 |
| Erythema nodosum | 2 | 2 | | | | | 2 | 2 |
| Excessive granulation tissue | 1 | 1 | | | | | 1 | 1 |
| Exfoliative rash | 2 | 2 | | | | | 2 | 2 |
| Fixed eruption | | 1 | | | | 1 | | |
| Fracture blisters | 1 | 1 | | | 1 | 1 | | |
| Haemorrhage subcutaneous | 1 | 2 | | | | | 1 | 2 |
| Hair colour changes | | 1 | | | | 1 | | |
| Hyperhidrosis | 220 | 352 | 2 | 2 | 42 | 94 | 178 | 258 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Itching scar | | 1 |
| Livedo reticularis | 7 | 9 |
| Macule | 1 | 1 |
| Mechanical urticaria | | 1 |
| Miliaria | 2 | 6 |
| Nail discolouration | 1 | 3 |
| Night sweats | 52 | 90 |
| Pain of skin | 34 | 49 |
| Papule | 1 | 5 |
| Peau d'orange | | 1 |
| Pemphigoid | 3 | 3 |
| Pemphigus | 1 | 1 |
| Petechiae | 7 | 12 |
| Photosensitivity reaction | 11 | 12 |
| Piloerection | 2 | 5 |
| Pruritus | 250 | 454 |
| Psoriasis | 3 | 4 |
| Purpura | 4 | 7 |
| Pustular psoriasis | 1 | 1 |
| Rash | 241 | 423 |
| Rash erythematous | 84 | 151 |
| Rash macular | 24 | 66 |
| Rash maculo-papular | 6 | 9 |
| Rash morbilliform | 2 | 3 |
| Rash papular | 13 | 28 |
| Rash pruritic | 74 | 125 |
| Rash vesicular | 9 | 13 |
| Red man syndrome | 1 | 1 |
| Rosacea | 1 | 1 |
| Scab | 1 | 1 |
| Scleroderma associated digital ulcer | 1 | 1 |
| Sensitive skin | 15 | 22 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | 7 | 8 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | 2 | 5 |
| | | | | 1 | 3 |
| 3 | 3 | 8 | 26 | 44 | 64 |
| | | 4 | 7 | 30 | 42 |
| | | | 1 | 1 | 4 |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 7 | 11 |
| | | 4 | 4 | 7 | 8 |
| | | | | 2 | 5 |
| 1 | 1 | 46 | 150 | 204 | 304 |
| 1 | 1 | 2 | 2 | 1 | 2 |
| | | | 2 | 4 | 5 |
| | | | | 1 | 1 |
| | | 31 | 121 | 210 | 302 |
| 1 | 1 | 13 | 47 | 71 | 104 |
| | | 6 | 34 | 18 | 32 |
| | | | 1 | 6 | 8 |
| | | | | 2 | 3 |
| | | 1 | 10 | 12 | 18 |
| | | 10 | 28 | 64 | 97 |
| | | 2 | 3 | 7 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 3 | 14 | 19 |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Skin burning sensation | 12 | 27 |
| Skin discolouration | 13 | 21 |
| Skin disorder | 3 | 4 |
| Skin erosion | 3 | 5 |
| Skin exfoliation | 6 | 13 |
| Skin fissures | 1 | 1 |
| Skin induration | | 1 |
| Skin irritation | 12 | 16 |
| Skin laxity | 1 | 1 |
| Skin lesion | 5 | 7 |
| Skin mass | 4 | 7 |
| Skin reaction | 5 | 7 |
| Skin sensitisation | | 2 |
| Skin swelling | 5 | 9 |
| Skin tightness | 4 | 11 |
| Skin ulcer | 1 | 2 |
| Skin warm | 21 | 44 |
| Skin weeping | | 1 |
| Stevens-Johnson syndrome | 2 | 3 |
| Toxic epidermal necrolysis | 1 | 2 |
| Toxic skin eruption | | 1 |
| Urticaria | 120 | 207 |
| Urticaria chronic | 1 | 1 |
| Urticaria papular | 1 | 1 |
| Urticaria thermal | 1 | 1 |
| Vasculitic rash | 2 | 3 |
| Yellow skin | 1 | 2 |
| | 1,630 | 2,856 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 11 | 24 |
| | | 2 | 5 | 11 | 16 |
| | | | 1 | 3 | 3 |
| | | | 1 | 3 | 4 |
| | | 2 | 3 | 4 | 10 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 3 | 11 | 13 |
| | | | | 1 | 1 |
| | | 1 | 3 | 4 | 4 |
| | | | 2 | 4 | 5 |
| | | 1 | 2 | 4 | 5 |
| | | | | | 2 |
| | | 1 | 3 | 4 | 6 |
| | | 2 | 4 | 2 | 7 |
| | | | | 1 | 2 |
| | | 4 | 13 | 17 | 31 |
| | | | | | 1 |
| | | | | 2 | 3 |
| 1 | 1 | | | 1 | 2 |
| | | | | | 1 |
| | | 12 | 56 | 108 | 151 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 2 |
| | | | 1 | 1 | 1 |
| 9 | 9 | 251 | 811 | 1379 | 2045 |

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System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bedridden | 5 | 7 | 1 | 1 | 4 | 6 |
| Immobile | 3 | 4 | | | 3 | 4 |
| Impaired driving ability | 3 | 5 | 1 | 2 | 2 | 3 |
| Impaired work ability | 6 | 6 | 1 | 1 | 5 | 5 |
| Loss of personal independence in daily activities | 28 | 40 | 6 | 8 | 22 | 32 |
| | 45 | 62 | 9 | 12 | 36 | 50 |

System Organ Class

SOC Not Yet Coded

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| | 5 | 14 | 5 | 14 |
| | 5 | 14 | 5 | 14 |

System Organ Class

Surgical and medical procedures

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthma prophylaxis | | 1 | | | | 1 |
| Diabetic diet | 1 | 1 | | | 1 | 1 |
| Limb immobilisation | 1 | 2 | 1 | 2 | | |
| Prophylaxis of nausea and vomiting | 1 | 1 | | | 1 | 1 |
| Weight loss diet | | 1 | | | | 1 |
| | 3 | 6 | 1 | 2 | 2 | 4 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Aortic aneurysm | 1 | 1 | | | | | 1 | 1 |
| Aortic aneurysm rupture | | 1 | | | | | | 1 |
| Aortic stenosis | 1 | 1 | | | | | 1 | 1 |
| Arterial occlusive disease | 1 | 1 | | | | | 1 | 1 |
| Arterial rupture | 1 | 1 | | | | | 1 | 1 |
| Arteritis | 1 | 1 | | | | | 1 | 1 |
| Behcet's syndrome | 2 | 2 | | | | | 2 | 2 |
| Blood pressure fluctuation | 1 | 2 | | | | | 1 | 2 |
| Blue toe syndrome | 2 | 2 | | | | | 2 | 2 |
| Circulatory collapse | 8 | 26 | | | | | 8 | 26 |
| CT hypotension complex | 1 | 1 | | | | | 1 | 1 |
| Cyanosis | 2 | 8 | | | | 2 | 2 | 6 |
| Deep vein thrombosis | 4 | 9 | | | | | 4 | 9 |
| Embolism | 1 | 1 | | | | | 1 | 1 |
| Flushing | 54 | 110 | | | 3 | 30 | 51 | 80 |
| Giant cell arteritis | 2 | 2 | | | | | 2 | 2 |
| Haematoma | 3 | 6 | | | | 1 | 3 | 5 |
| Haemorrhage | 14 | 15 | 1 | 1 | | | 14 | 15 |
| Hot flush | 65 | 117 | | | 9 | 32 | 56 | 85 |
| Hypertension | 65 | 124 | 1 | 1 | 5 | 26 | 60 | 98 |
| Hypertensive crisis | | 1 | | | | | | 1 |
| Hypotension | 45 | 87 | | | 8 | 21 | 37 | 66 |
| Infarction | | 1 | | | | | | 1 |
| Internal haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Labile blood pressure | 2 | 2 | | | | | 2 | 2 |
| Lymphoedema | 6 | 12 | | | | 1 | 6 | 11 |
| Neurogenic shock | 6 | 10 | | | | | 6 | 10 |
| Orthostatic hypertension | 1 | 1 | | | | | 1 | 1 |
| Orthostatic hypotension | 3 | 5 | | | | | 3 | 5 |
| Pallor | 28 | 61 | | | 5 | 17 | 23 | 44 |
| Peripheral circulatory failure | | 2 | | | | | | 2 |
| Peripheral coldness | 40 | 69 | | | 7 | 19 | 33 | 50 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Peripheral ischaemia | | 1 |
| Phlebitis | 1 | 1 |
| Poor peripheral circulation | | 1 |
| Raynaud's phenomenon | 4 | 5 |
| Shock | 4 | 4 |
| Superficial vein prominence | | 1 |
| Systolic hypertension | 2 | 2 |
| Thrombophlebitis | 1 | 1 |
| Thrombosis | 3 | 7 |
| Varicose vein | 1 | 2 |
| Vascular pain | 1 | 1 |
| Vasculitis | 5 | 6 |
| Vasoconstriction | 1 | 1 |
| Vasodilatation | 2 | 4 |
| Vein discolouration | | 1 |
| Vein disorder | 1 | 2 |
| Vein rupture | | 1 |
| Vena cava embolism | | 1 |
| Vena cava thrombosis | | 1 |
| Venous haemorrhage | 1 | 1 |
| | 388 | 727 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----------|------------|------------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 2 | 2 | 3 |
| | | | | 4 | 4 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | | 3 | 7 |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | 5 | 6 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | 41 | 157 |
| | | | | 347 | 570 |

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Country Where Event Occurred

UNITED STATES

System Organ Class

Blood and lymphatic system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemia | 2 | 2 | | | 2 | 2 |
| Autoimmune haemolytic anaemia | 1 | 1 | | | 1 | 1 |
| Blood disorder | | 1 | | 1 | | |
| Coagulopathy | | 1 | | | | 1 |
| Eosinophilia | | 1 | | 1 | | |
| Febrile neutropenia | | 1 | | | | 1 |
| Haemolytic anaemia | 1 | 2 | | | 1 | 2 |
| Immune thrombocytopenia | 8 | 10 | | | 8 | 10 |
| Increased tendency to bruise | 1 | 1 | 1 | 1 | | |
| Leukocytosis | | 3 | | 2 | | 1 |
| Lymphadenitis | 3 | 11 | 3 | 11 | | |
| Lymphadenopathy | 183 | 595 | 176 | 562 | 7 | 33 |
| Lymph node pain | 37 | 125 | 36 | 120 | 1 | 5 |
| Lymphocytosis | 1 | 1 | 1 | 1 | | |
| Neutropenia | 2 | 2 | | | 2 | 2 |
| Normocytic anaemia | 1 | 1 | 1 | 1 | | |
| Pancytopenia | 1 | 2 | | | 1 | 2 |
| Platelet disorder | 1 | 1 | 1 | 1 | | |
| Polycythaemia | 1 | 1 | 1 | 1 | | |
| Splenomegaly | 3 | 3 | 1 | 1 | 2 | 2 |
| Thrombocytopenia | 5 | 9 | | | 5 | 9 |
| Thrombotic thrombocytopenic purpura | 1 | 2 | | | 1 | 2 |
| | 252 | 776 | 221 | 703 | 31 | 73 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | | 3 | | | | 3 |
| Angina pectoris | 6 | 6 | | | 6 | 6 |
| Arrhythmia | 7 | 13 | | | 7 | 13 |
| Arteriospasm coronary | | 1 | | | | 1 |
| Atrial fibrillation | 22 | 29 | | | 22 | 29 |
| Bradycardia | | 1 | | | | 1 |
| Bundle branch block left | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 3 | 11 | | | 3 | 11 |
| Cardiac discomfort | | 1 | | 1 | | |
| Cardiac disorder | 6 | 13 | 2 | 8 | 4 | 5 |
| Cardiac failure | 2 | 2 | | | 2 | 2 |
| Cardiac failure chronic | 1 | 1 | | | 1 | 1 |
| Cardiac failure congestive | 3 | 5 | | | 3 | 5 |
| Cardiac fibrillation | 1 | 1 | | | 1 | 1 |
| Cardiac flutter | 5 | 9 | | | 5 | 9 |
| Cardiac valve sclerosis | | 1 | | | | 1 |
| Cardiomyopathy | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | | 2 | | | | 2 |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Dilatation ventricular | | 1 | | | | 1 |
| Extrasystoles | 3 | 5 | 3 | 5 | | |
| Myocardial infarction | 15 | 25 | | | 15 | 25 |
| Myocarditis | 1 | 2 | | | 1 | 2 |
| Nodal rhythm | | 1 | | 1 | | |
| Palpitations | 82 | 238 | 69 | 185 | 13 | 53 |
| Pericardial disease | | 1 | | | | 1 |
| Pericardial effusion | 2 | 3 | | | 2 | 3 |
| Pericarditis | 3 | 8 | | | 3 | 8 |
| Postural orthostatic tachycardia syndrome | 3 | 4 | | 1 | 3 | 3 |
| Right ventricular dysfunction | | 1 | | | | 1 |
| Sinus tachycardia | 1 | 6 | 1 | 3 | | 3 |
| Supraventricular extrasystoles | | 1 | | | | 1 |

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System Organ Class

Cardiac disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Supraventricular tachycardia | 2 | 7 | | 2 | 2 | 5 |
| Tachycardia | 30 | 190 | 19 | 129 | 11 | 61 |
| Torsade de pointes | 1 | 1 | | | 1 | 1 |
| Ventricular arrhythmia | 1 | 1 | | | 1 | 1 |
| Ventricular extrasystoles | 6 | 12 | 2 | 6 | 4 | 6 |
| Ventricular fibrillation | 2 | 3 | | | 2 | 3 |
| Ventricular tachycardia | | 2 | | | | 2 |
| | 211 | 614 | 97 | 342 | 114 | 272 |

System Organ Class

Congenital, familial and genetic disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hereditary haemorrhagic telangiectasia | 1 | 1 | 1 | 1 | | |
| Macroglossia | 1 | 1 | | | 1 | 1 |
| Von Willebrand's disease | | 1 | | | | 1 |
| | 2 | 3 | 1 | 1 | 1 | 2 |

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System Organ Class

Ear and labyrinth disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Auricular swelling | | 1 | | 1 | | |
| Deafness | 19 | 29 | 1 | 1 | 18 | 28 |
| Deafness neurosensory | 2 | 7 | | | 2 | 7 |
| Deafness unilateral | 4 | 8 | | | 4 | 8 |
| Ear congestion | 1 | 3 | 1 | 2 | | 1 |
| Ear discomfort | 13 | 34 | 13 | 33 | | 1 |
| Ear disorder | 6 | 10 | 2 | 6 | 4 | 4 |
| Ear haemorrhage | 1 | 1 | 1 | 1 | | |
| Ear pain | 21 | 70 | 18 | 65 | 3 | 5 |
| Ear pruritus | 2 | 7 | 2 | 7 | | |
| Ear swelling | 3 | 9 | 2 | 8 | 1 | 1 |
| Eustachian tube disorder | 1 | 1 | 1 | 1 | | |
| Excessive cerumen production | 2 | 2 | 2 | 2 | | |
| External ear pain | | 1 | | 1 | | |
| Hyperacusis | | 5 | | 4 | | 1 |
| Hypoacusis | 12 | 27 | 9 | 24 | 3 | 3 |
| Mastoid disorder | 1 | 1 | | | 1 | 1 |
| Motion sickness | | 4 | | 4 | | |
| Paraesthesia ear | | 1 | | 1 | | |
| Red ear syndrome | 1 | 1 | 1 | 1 | | |
| Sudden hearing loss | 1 | 3 | | | 1 | 3 |
| Tinnitus | 31 | 98 | 22 | 75 | 9 | 23 |
| Vertigo | 50 | 118 | 44 | 108 | 6 | 10 |
| Vertigo positional | | 2 | | 1 | | 1 |
| | 171 | 443 | 119 | 346 | 52 | 97 |

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System Organ Class

Endocrine disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adrenal disorder | 1 | 1 | | | 1 | 1 |
| Adrenocortical insufficiency acute | 2 | 2 | | | 2 | 2 |
| Autoimmune thyroiditis | 2 | 3 | | | 2 | 3 |
| Hypothyroidism | 1 | 3 | | | 1 | 3 |
| Thyroid disorder | 1 | 3 | 1 | 3 | | |
| Thyroid pain | | 1 | | 1 | | |
| | 7 | 13 | 1 | 4 | 6 | 9 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal sensation in eye | | 5 | | 5 | | |
| Anterior chamber cell | 1 | 1 | | | 1 | 1 |
| Asthenopia | 4 | 13 | 4 | 12 | | 1 |
| Blepharitis | 1 | 1 | 1 | 1 | | |
| Blepharochalasis | | 1 | | 1 | | |
| Blepharospasm | 1 | 5 | 1 | 5 | | |
| Blindness | 10 | 14 | | | 10 | 14 |
| Blindness transient | 3 | 4 | | | 3 | 4 |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Cataract | 2 | 2 | | | 2 | 2 |
| Chalazion | | 1 | | 1 | | |
| Ciliary muscle spasm | 1 | 1 | 1 | 1 | | |
| Conjunctival haemorrhage | 1 | 2 | | | 1 | 2 |
| Conjunctival irritation | | 1 | | 1 | | |
| Conjunctival oedema | | 1 | | 1 | | |
| Conjunctivitis allergic | | 2 | | 2 | | |
| Corneal disorder | 1 | 1 | | | 1 | 1 |
| Corneal infiltrates | 1 | 1 | | | 1 | 1 |
| Corneal oedema | | 1 | | 1 | | |
| Diplopia | 3 | 7 | 1 | 4 | 2 | 3 |
| Dry eye | 5 | 9 | 4 | 8 | 1 | 1 |
| Dyschromatopsia | 1 | 1 | 1 | 1 | | |
| Episcleritis | | 2 | | 2 | | |
| Erythema of eyelid | 2 | 7 | | 5 | 2 | 2 |
| Extraocular muscle paresis | 1 | 1 | | | 1 | 1 |
| Eye allergy | | 1 | | 1 | | |
| Eye discharge | 4 | 7 | 4 | 7 | | |
| Eye disorder | 3 | 19 | 3 | 15 | | 4 |
| Eye haemorrhage | 4 | 10 | | | 4 | 10 |
| Eye inflammation | | 6 | | 4 | | 2 |
| Eye irritation | 6 | 25 | 6 | 24 | | 1 |
| Eyelid disorder | 1 | 3 | 1 | 3 | | |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Eyelid function disorder | | 1 |
| Eyelid irritation | 1 | 2 |
| Eyelid oedema | | 2 |
| Eyelid pain | 3 | 5 |
| Eyelid ptosis | 2 | 4 |
| Eyelid sensory disorder | | 1 |
| Eyelids pruritus | | 4 |
| Eye movement disorder | 3 | 6 |
| Eye oedema | 3 | 7 |
| Eye pain | 19 | 68 |
| Eye paraesthesia | | 1 |
| Eye pruritus | 18 | 37 |
| Eye swelling | 28 | 78 |
| Glare | | 1 |
| Glaucoma | 1 | 3 |
| Hypoesthesia eye | 2 | 5 |
| Keratic precipitates | 1 | 1 |
| Lacrimation decreased | 1 | 1 |
| Lacrimation increased | 11 | 22 |
| Mydriasis | | 1 |
| Myopia | | 1 |
| Ocular discomfort | 7 | 16 |
| Ocular hyperaemia | 9 | 33 |
| Periorbital discomfort | | 1 |
| Periorbital oedema | | 1 |
| Periorbital pain | 1 | 1 |
| Periorbital swelling | 11 | 24 |
| Photophobia | 5 | 27 |
| Photopsia | 2 | 6 |
| Pupillary disorder | | 1 |
| Retinal tear | 1 | 1 |
| Scleritis | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 2 | | |
| | 2 | | |
| 2 | 4 | 1 | 1 |
| | 1 | 2 | 3 |
| | 1 | | |
| | 3 | | 1 |
| 2 | 4 | 1 | 2 |
| 3 | 7 | | |
| 16 | 60 | 3 | 8 |
| | | | 1 |
| 17 | 32 | 1 | 5 |
| 18 | 64 | 10 | 14 |
| | 1 | | |
| | | 1 | 3 |
| 2 | 5 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 10 | 20 | 1 | 2 |
| | 1 | | |
| | 1 | | |
| 6 | 12 | 1 | 4 |
| 7 | 30 | 2 | 3 |
| | 1 | | |
| | | 1 | 1 |
| 10 | 21 | 1 | 3 |
| 5 | 26 | | 1 |
| 2 | 5 | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |

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System Organ Class

Eye disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Strabismus | 1 | 1 | | | 1 | 1 |
| Swelling of eyelid | 2 | 24 | 1 | 23 | 1 | 1 |
| Uveitis | | 1 | | 1 | | |
| Vision blurred | 31 | 94 | 26 | 77 | 5 | 17 |
| Visual impairment | 29 | 49 | 23 | 41 | 6 | 8 |
| Vitreous floaters | 3 | 3 | 3 | 3 | | |
| Xanthopsia | 1 | 1 | 1 | 1 | | |
| | 253 | 692 | 182 | 557 | 71 | 135 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 37 | 98 | 37 | 95 | | 3 |
| Abdominal distension | 7 | 21 | 7 | 20 | | 1 |
| Abdominal pain | 27 | 104 | 21 | 92 | 6 | 12 |
| Abdominal pain lower | 2 | 9 | 2 | 6 | | 3 |
| Abdominal pain upper | 55 | 133 | 50 | 122 | 5 | 11 |
| Abdominal rigidity | 2 | 4 | 2 | 3 | | 1 |
| Abdominal symptom | 1 | 1 | 1 | 1 | | |
| Abdominal wall haematoma | 1 | 1 | | | 1 | 1 |
| Abdominal wall haemorrhage | 1 | 1 | | | 1 | 1 |
| Abnormal faeces | 3 | 4 | 3 | 4 | | |
| Anal haemorrhage | 1 | 1 | 1 | 1 | | |
| Anal incontinence | 1 | 2 | 1 | 2 | | |
| Anal skin tags | 1 | 1 | 1 | 1 | | |
| Anorectal discomfort | 1 | 1 | 1 | 1 | | |
| Aphthous ulcer | 1 | 4 | 1 | 4 | | |
| Aptyalism | 1 | 2 | 1 | 2 | | |
| Bowel movement irregularity | 1 | 3 | 1 | 3 | | |
| Breath odour | 1 | 3 | | 2 | 1 | 1 |
| Chapped lips | 1 | 3 | 1 | 3 | | |
| Cheilitis | 1 | 2 | 1 | 2 | | |
| Colitis | 1 | 1 | | | 1 | 1 |
| Colitis ulcerative | | 1 | | | | 1 |
| Constipation | 8 | 12 | 8 | 12 | | |
| Crohn's disease | 3 | 3 | | | 3 | 3 |
| Defaecation urgency | 1 | 2 | 1 | 2 | | |
| Dental paraesthesia | | 2 | | 2 | | |
| Diarrhoea | 188 | 535 | 176 | 509 | 12 | 26 |
| Diarrhoea haemorrhagic | 6 | 7 | | | 6 | 7 |
| Diverticulum intestinal | 1 | 1 | | | 1 | 1 |
| Dry mouth | 19 | 61 | 18 | 55 | 1 | 6 |
| Duodenogastric reflux | 1 | 1 | 1 | 1 | | |
| Dyspepsia | 11 | 32 | 10 | 31 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Dysphagia | 36 | 78 |
| Enlarged uvula | 1 | 5 |
| Eructation | 4 | 5 |
| Faeces discoloured | 2 | 4 |
| Faeces soft | 2 | 3 |
| Flatulence | 5 | 13 |
| Food poisoning | | 1 |
| Frequent bowel movements | 2 | 6 |
| Gastric disorder | 5 | 7 |
| Gastric ulcer | 1 | 1 |
| Gastritis | | 3 |
| Gastrointestinal disorder | 5 | 23 |
| Gastrointestinal haemorrhage | 2 | 2 |
| Gastrointestinal hypomotility | 1 | 1 |
| Gastrointestinal inflammation | 1 | 1 |
| Gastrointestinal motility disorder | 1 | 2 |
| Gastrointestinal pain | 3 | 10 |
| Gastrointestinal sounds abnormal | 1 | 3 |
| Gastrooesophageal reflux disease | 9 | 12 |
| Gastrooesophageal sphincter insufficiency | | 1 |
| Gingival bleeding | 1 | 5 |
| Gingival blister | 1 | 2 |
| Gingival discolouration | | 1 |
| Gingival discomfort | | 1 |
| Gingival disorder | | 1 |
| Gingival erythema | 2 | 4 |
| Gingival pain | 1 | 7 |
| Gingival recession | | 1 |
| Gingival swelling | 4 | 10 |
| Glossitis | | 3 |
| Glossodynia | 8 | 14 |
| Haematochezia | 10 | 17 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 26 | 50 | 10 | 28 |
| 1 | 2 | | 3 |
| 4 | 5 | | |
| 2 | 4 | | |
| 2 | 3 | | |
| 4 | 12 | 1 | 1 |
| | 1 | | |
| 2 | 6 | | |
| 5 | 7 | | |
| | | 1 | 1 |
| | 3 | | |
| 5 | 22 | | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| 3 | 10 | | |
| 1 | 3 | | |
| 9 | 12 | | |
| | | | 1 |
| 1 | 5 | | |
| | 1 | 1 | 1 |
| | | | 1 |
| | 1 | | |
| 2 | 4 | | |
| 1 | 5 | | 2 |
| | 1 | | |
| 4 | 10 | | |
| | 3 | | |
| 7 | 13 | 1 | 1 |
| | | 10 | 17 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Haemorrhoids | 1 | 2 |
| Hyperaesthesia teeth | 2 | 4 |
| Hypoaesthesia oral | 33 | 120 |
| Hypoaesthesia teeth | 2 | 2 |
| Infantile vomiting | | 2 |
| Infrequent bowel movements | | 1 |
| Intestinal ischaemia | 1 | 1 |
| Intestinal obstruction | 1 | 2 |
| Intestinal perforation | 1 | 1 |
| Irritable bowel syndrome | 2 | 4 |
| Lip blister | 3 | 6 |
| Lip discolouration | 1 | 1 |
| Lip disorder | 2 | 5 |
| Lip dry | | 1 |
| Lip erythema | | 3 |
| Lip exfoliation | | 1 |
| Lip oedema | | 4 |
| Lip pain | 1 | 3 |
| Lip pruritus | 6 | 12 |
| Lip swelling | 30 | 95 |
| Mouth haemorrhage | 4 | 4 |
| Mouth swelling | 7 | 15 |
| Mouth ulceration | 1 | 3 |
| Mucous stools | 1 | 2 |
| Nausea | 454 | 1,489 |
| Noninfective gingivitis | 2 | 4 |
| Odynophagia | 6 | 11 |
| Oedema mouth | 1 | 1 |
| Oesophageal pain | 1 | 2 |
| Oral blood blister | 1 | 1 |
| Oral discomfort | 7 | 15 |
| Oral disorder | 5 | 13 |

| Spontaneous | | | |
|-------------|------|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | |
| 2 | 4 | | |
| 27 | 98 | 6 | 22 |
| 2 | 2 | | |
| | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 3 | 1 | 1 |
| 1 | 4 | 2 | 2 |
| | | 1 | 1 |
| 2 | 5 | | |
| | 1 | | |
| | 3 | | |
| | 1 | | |
| | 3 | | 1 |
| 1 | 3 | | |
| 3 | 8 | 3 | 4 |
| 22 | 67 | 8 | 28 |
| 3 | 3 | 1 | 1 |
| 4 | 9 | 3 | 6 |
| 1 | 3 | | |
| 1 | 2 | | |
| 424 | 1392 | 30 | 97 |
| 2 | 4 | | |
| 4 | 8 | 2 | 3 |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| 7 | 14 | | 1 |
| 5 | 12 | | 1 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Oral dysaesthesia | | 1 |
| Oral mucosal blistering | 1 | 5 |
| Oral mucosal eruption | | 5 |
| Oral mucosal erythema | | 3 |
| Oral mucosal exfoliation | 1 | 1 |
| Oral pain | 5 | 14 |
| Oral pruritus | 4 | 11 |
| Palatal disorder | 1 | 2 |
| Palatal swelling | | 3 |
| Pancreatitis | 2 | 3 |
| Pancreatitis acute | 1 | 2 |
| Paraesthesia oral | 47 | 166 |
| Plicated tongue | | 1 |
| Proctalgia | 1 | 1 |
| Rectal discharge | 1 | 1 |
| Rectal haemorrhage | 2 | 3 |
| Rectal tenesmus | 1 | 1 |
| Retching | 9 | 21 |
| Saliva discolouration | 1 | 1 |
| Salivary gland pain | | 1 |
| Salivary hypersecretion | 2 | 4 |
| Small intestinal haemorrhage | 1 | 1 |
| Small intestinal obstruction | 1 | 2 |
| Stiff tongue | | 1 |
| Stomatitis | 2 | 14 |
| Stomatitis haemorrhagic | 1 | 1 |
| Strawberry tongue | | 1 |
| Swollen tongue | 30 | 82 |
| Tongue blistering | | 1 |
| Tongue coated | | 1 |
| Tongue discolouration | 1 | 4 |
| Tongue discomfort | 5 | 16 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 1 | 5 | | |
| | 5 | | |
| | 2 | | 1 |
| 1 | 1 | | |
| 5 | 12 | | 2 |
| 1 | 8 | 3 | 3 |
| | 1 | 1 | 1 |
| | 2 | | 1 |
| | | 2 | 3 |
| | | 1 | 2 |
| 34 | 133 | 13 | 33 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 3 |
| 1 | 1 | | |
| 8 | 19 | 1 | 2 |
| | | 1 | 1 |
| | 1 | | |
| 2 | 4 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| | | | 1 |
| 2 | 13 | | 1 |
| | | 1 | 1 |
| | 1 | | |
| 19 | 49 | 11 | 33 |
| | 1 | | |
| | 1 | | |
| 1 | 4 | | |
| 4 | 14 | 1 | 2 |

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System Organ Class

Gastrointestinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tongue disorder | 4 | 13 | 4 | 11 | | 2 |
| Tongue dry | 1 | 2 | 1 | 2 | | |
| Tongue erythema | | 4 | | 4 | | |
| Tongue haematoma | | 1 | | 1 | | |
| Tongue haemorrhage | | 1 | | 1 | | |
| Tongue movement disturbance | | 1 | | | | 1 |
| Tongue oedema | | 1 | | | | 1 |
| Tongue pruritus | 4 | 12 | 2 | 9 | 2 | 3 |
| Tongue ulceration | 1 | 3 | 1 | 3 | | |
| Toothache | 12 | 26 | 9 | 23 | 3 | 3 |
| Tooth disorder | 2 | 2 | 2 | 2 | | |
| Uvulitis | | 1 | | 1 | | |
| Volvulus | 1 | 1 | | | 1 | 1 |
| Vomiting | 162 | 448 | 145 | 412 | 17 | 36 |
| Vomiting projectile | 2 | 4 | 2 | 4 | | |
| | 1,378 | 4,027 | 1188 | 3571 | 190 | 456 |

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System Organ Class

General disorders and administration site conditions

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Administration site warmth | 1 | 1 |
| Adverse event | 1 | 1 |
| Application site pruritus | 1 | 1 |
| Asthenia | 182 | 510 |
| Axillary pain | 37 | 90 |
| Chest discomfort | 76 | 226 |
| Chest pain | 78 | 191 |
| Chills | 686 | 2,242 |
| Condition aggravated | 44 | 96 |
| Crying | 9 | 22 |
| Cyst | | 2 |
| Death | 27 | 56 |
| Discomfort | 33 | 85 |
| Disease progression | | 1 |
| Disease recurrence | 29 | 55 |
| Drug ineffective | 308 | 1,002 |
| Drug interaction | 3 | 12 |
| Drug intolerance | 1 | 1 |
| Enanthema | | 1 |
| Energy increased | 1 | 3 |
| Extensive swelling of vaccinated limb | | 1 |
| Face oedema | 1 | 3 |
| Facial discomfort | 2 | 5 |
| Facial pain | 11 | 35 |
| Fatigue | 738 | 2,287 |
| Feeling abnormal | 171 | 436 |
| Feeling cold | 58 | 157 |
| Feeling drunk | 5 | 12 |
| Feeling hot | 96 | 277 |
| Feeling jittery | 5 | 18 |
| Feeling of body temperature change | 12 | 32 |
| Gait disturbance | 55 | 107 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 157 | 455 | 25 | 55 |
| | | 37 | 89 | | 1 |
| | | 52 | 159 | 24 | 67 |
| | | 56 | 137 | 22 | 54 |
| | | 651 | 2147 | 35 | 95 |
| | | 30 | 73 | 14 | 23 |
| | | 8 | 20 | 1 | 2 |
| | | | 2 | | |
| | | | | 27 | 56 |
| | | 30 | 78 | 3 | 7 |
| | | | 1 | | |
| | | 17 | 40 | 12 | 15 |
| 2 | 2 | 4 | 23 | 304 | 979 |
| | | 2 | 10 | 1 | 2 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 1 | 2 | | 1 |
| | | 2 | 5 | | |
| | | 10 | 31 | 1 | 4 |
| | | 703 | 2207 | 35 | 80 |
| | | 152 | 400 | 19 | 36 |
| | | 53 | 147 | 5 | 10 |
| | | 4 | 10 | 1 | 2 |
| | | 87 | 247 | 9 | 30 |
| | | 4 | 15 | 1 | 3 |
| | | 12 | 31 | | 1 |
| | | 44 | 88 | 11 | 19 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Gait inability | 19 | 34 |
| General physical health deterioration | | 2 |
| Glassy eyes | 1 | 3 |
| Hangover | 2 | 7 |
| Hunger | | 5 |
| Hyperpyrexia | 1 | 2 |
| Hyperthermia | 1 | 2 |
| Hypothermia | 3 | 4 |
| Idiosyncratic drug reaction | | 1 |
| Ill-defined disorder | | 1 |
| Illness | 58 | 159 |
| Induration | 1 | 4 |
| Inflammation | 9 | 25 |
| Inflammatory pain | | 1 |
| Influenza like illness | 50 | 210 |
| Inhibitory drug interaction | | 1 |
| Injected limb mobility decreased | 1 | 3 |
| Injection site bruising | | 2 |
| Injection site erythema | 3 | 11 |
| Injection site extravasation | 1 | 4 |
| Injection site haemorrhage | | 1 |
| Injection site hypoaesthesia | | 1 |
| Injection site indentation | 1 | 1 |
| Injection site irritation | 1 | 1 |
| Injection site joint pain | | 1 |
| Injection site mass | | 2 |
| Injection site pain | 5 | 41 |
| Injection site pruritus | | 1 |
| Injection site rash | 1 | 4 |
| Injection site reaction | | 1 |
| Injection site swelling | | 7 |
| Injection site urticaria | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 10 | 22 | 9 | 12 |
| | | | | | 2 |
| | | | 2 | 1 | 1 |
| | | 2 | 7 | | |
| | | | 5 | | |
| | | | | 1 | 2 |
| | | 1 | 2 | | |
| | | | | 3 | 4 |
| | | | 1 | | |
| | | | 1 | | |
| | | 57 | 154 | 1 | 5 |
| | | 1 | 3 | | 1 |
| | | 9 | 22 | | 3 |
| | | | 1 | | |
| | | 49 | 205 | 1 | 5 |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | | 2 | | |
| | | 3 | 11 | | |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | 4 | 39 | 1 | 2 |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | | 7 | | |
| | | | 1 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Injection site warmth | 2 | 3 |
| Irritability postvaccinal | | 1 |
| Localised oedema | | 2 |
| Local reaction | | 1 |
| Malaise | 247 | 761 |
| Mass | 6 | 11 |
| Mucosal disorder | 1 | 3 |
| Mucosa vesicle | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 2 |
| No adverse event | 13 | 13 |
| Nodule | 1 | 2 |
| Oedema | 2 | 7 |
| Oedema peripheral | 2 | 9 |
| Pain | 549 | 1,845 |
| Peripheral swelling | 82 | 243 |
| Physical deconditioning | | 1 |
| Pre-existing condition improved | | 1 |
| Pyrexia | 665 | 2,285 |
| Screaming | 1 | 3 |
| Secretion discharge | 1 | 3 |
| Sensation of blood flow | 2 | 2 |
| Sensation of foreign body | 9 | 34 |
| Sensitivity to weather change | 1 | 1 |
| Sluggishness | 5 | 12 |
| Sudden death | | 1 |
| Swelling | 55 | 176 |
| Swelling face | 60 | 150 |
| Systemic inflammatory response syndrome | | 1 |
| Temperature intolerance | 6 | 7 |
| Temperature regulation disorder | 1 | 2 |
| Tenderness | 7 | 25 |
| Therapeutic response unexpected | 13 | 20 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | 232 | 718 | 15 | 43 |
| | | 6 | 11 | | |
| | | | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 13 | 13 | | |
| | | 1 | 2 | | |
| | | 1 | 5 | 1 | 2 |
| | | 2 | 8 | | 1 |
| | | 521 | 1765 | 28 | 80 |
| | | 77 | 232 | 5 | 11 |
| | | | 1 | | |
| | | | 1 | | |
| | | 620 | 2160 | 45 | 125 |
| | | 1 | 2 | | 1 |
| | | 1 | 3 | | |
| | | | | 2 | 2 |
| | | 7 | 24 | 2 | 10 |
| | | 1 | 1 | | |
| | | 5 | 12 | | |
| | | | | | 1 |
| | | 44 | 152 | 11 | 24 |
| | | 44 | 120 | 16 | 30 |
| | | | | | 1 |
| | | 6 | 7 | | |
| | | 1 | 2 | | |
| | | 7 | 25 | | |
| | | 13 | 20 | | |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Thirst | 7 | 26 |
| Thirst decreased | 1 | 1 |
| Ulcer | 1 | 2 |
| Vaccination site bruising | 17 | 41 |
| Vaccination site coldness | 3 | 5 |
| Vaccination site discharge | 1 | 4 |
| Vaccination site discolouration | 8 | 16 |
| Vaccination site discomfort | 11 | 30 |
| Vaccination site erythema | 92 | 319 |
| Vaccination site extravasation | 2 | 5 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site haemorrhage | 15 | 30 |
| Vaccination site hyperaesthesia | | 1 |
| Vaccination site hypersensitivity | | 2 |
| Vaccination site hypoaesthesia | 3 | 16 |
| Vaccination site induration | 10 | 39 |
| Vaccination site inflammation | 5 | 14 |
| Vaccination site injury | 1 | 2 |
| Vaccination site irritation | 1 | 3 |
| Vaccination site joint erythema | 1 | 1 |
| Vaccination site joint movement impairment | 3 | 10 |
| Vaccination site joint pain | 3 | 6 |
| Vaccination site lymphadenopathy | 6 | 12 |
| Vaccination site macule | 1 | 4 |
| Vaccination site mass | 25 | 61 |
| Vaccination site movement impairment | 5 | 38 |
| Vaccination site nodule | 1 | 11 |
| Vaccination site oedema | 1 | 3 |
| Vaccination site pain | 496 | 1,616 |
| Vaccination site pallor | | 1 |
| Vaccination site papule | 1 | 2 |
| Vaccination site paraesthesia | 5 | 22 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 7 | 25 | | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 15 | 38 | 2 | 3 |
| | | 3 | 5 | | |
| | | 1 | 4 | | |
| | | 7 | 15 | 1 | 1 |
| | | 10 | 28 | 1 | 2 |
| | | 87 | 307 | 5 | 12 |
| | | 2 | 5 | | |
| | | | | 1 | 1 |
| | | 13 | 28 | 2 | 2 |
| | | | 1 | | |
| | | | 2 | | |
| | | 2 | 15 | 1 | 1 |
| | | 10 | 38 | | 1 |
| | | 4 | 12 | 1 | 2 |
| | | 1 | 2 | | |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | 3 | 8 | | 2 |
| | | 3 | 5 | | 1 |
| | | 5 | 11 | 1 | 1 |
| | | 1 | 4 | | |
| | | 25 | 57 | | 4 |
| | | 5 | 37 | | 1 |
| | | | 10 | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | 490 | 1591 | 6 | 25 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 5 | 19 | | 3 |

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System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vaccination site pruritus | 52 | 147 | | | 49 | 140 | 3 | 7 |
| Vaccination site rash | 25 | 60 | | | 23 | 58 | 2 | 2 |
| Vaccination site reaction | 4 | 18 | | | 4 | 18 | | |
| Vaccination site scab | 1 | 3 | | | 1 | 3 | | |
| Vaccination site swelling | 115 | 311 | | | 109 | 301 | 6 | 10 |
| Vaccination site ulcer | | 1 | | | | 1 | | |
| Vaccination site urticaria | 4 | 25 | | | 4 | 25 | | |
| Vaccination site vesicles | 2 | 10 | | | 2 | 10 | | |
| Vaccination site warmth | 47 | 137 | | | 42 | 130 | 5 | 7 |
| Vessel puncture site haemorrhage | | 1 | | | | 1 | | |
| Vessel puncture site injury | | 1 | | | | 1 | | |
| | 5,539 | 17,197 | 2 | 2 | 4805 | 15192 | 734 | 2005 |

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System Organ Class

Hepatobiliary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute hepatic failure | | 1 | | | | 1 |
| Cholecystitis | | 1 | | | | 1 |
| Gal bladder disorder | 1 | 3 | 1 | 2 | | 1 |
| Gal bladder polyp | | 1 | | 1 | | |
| Hepatic cirrhosis | 1 | 1 | | | 1 | 1 |
| Hepatic pain | 1 | 2 | 1 | 2 | | |
| Hepatitis | 2 | 2 | | | 2 | 2 |
| Hepatitis acute | 1 | 1 | | | 1 | 1 |
| Hepatomegaly | 1 | 1 | | | 1 | 1 |
| Jaundice | 1 | 3 | | 2 | 1 | 1 |
| Liver disorder | 1 | 1 | 1 | 1 | | |
| Liver injury | | 2 | | | | 2 |
| Liver tenderness | 1 | 1 | 1 | 1 | | |
| | 10 | 20 | 4 | 9 | 6 | 11 |

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

System Organ Class

Immune system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to arthropod sting | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | 18 | 53 | 16 | 40 | 2 | 13 |
| Amyloidosis | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 39 | 134 | 1 | 3 | 38 | 131 |
| Anaphylactic shock | 3 | 7 | | 1 | 3 | 6 |
| Anaphylactoid reaction | | 3 | | | | 3 |
| Autoimmune disorder | 3 | 7 | | | 3 | 7 |
| Contrast media allergy | | 1 | | 1 | | |
| Corneal graft rejection | 1 | 1 | | | 1 | 1 |
| Drug hypersensitivity | 7 | 20 | 4 | 16 | 3 | 4 |
| Food allergy | | 1 | | 1 | | |
| Hypersensitivity | 47 | 140 | 31 | 99 | 16 | 41 |
| Immune system disorder | 3 | 8 | 2 | 5 | 1 | 3 |
| Immunodeficiency | 3 | 5 | | | 3 | 5 |
| Immunosuppression | 1 | 1 | | | 1 | 1 |
| Reaction to excipient | 1 | 4 | | 2 | 1 | 2 |
| Rubber sensitivity | | 1 | | 1 | | |
| Seasonal allergy | 1 | 4 | 1 | 4 | | |
| Sensitisation | | 1 | | 1 | | |
| Serum sickness | | 1 | | | | 1 |
| Systemic immune activation | 1 | 1 | | | 1 | 1 |
| Type III immune complex mediated reaction | | 1 | | | | 1 |
| Type IV hypersensitivity reaction | | 2 | | 2 | | |
| | 130 | 398 | 56 | 177 | 74 | 221 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # | Cumulative Total # |
|----------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Acarodermatitis | 1 | 2 |
| Appendicitis | 3 | 9 |
| Asymptomatic COVID-19 | 4 | 9 |
| Bacterial infection | | 1 |
| Bronchitis | 3 | 8 |
| Candida infection | 1 | 1 |
| Cellulitis | 9 | 14 |
| Coccidioidomycosis | 1 | 1 |
| Conjunctivitis | 3 | 7 |
| Conjunctivitis viral | | 1 |
| COVID-19 | 285 | 773 |
| COVID-19 pneumonia | 6 | 9 |
| Cystitis | 5 | 6 |
| Diabetic foot infection | 1 | 1 |
| Diverticulitis | 6 | 6 |
| Dysentery | 2 | 2 |
| Ear infection | 3 | 5 |
| Encephalitis | 4 | 4 |
| Escherichia infection | | 1 |
| Eye infection | 2 | 3 |
| Folliculitis | 2 | 2 |
| Fungal infection | 2 | 5 |
| Furuncle | | 1 |
| Gastritis bacterial | 1 | 1 |
| Gastroenteritis viral | 1 | 2 |
| Gastrointestinal infection | 1 | 1 |
| Gastrointestinal viral infection | | 1 |
| Genital herpes | 1 | 1 |
| Gingivitis | 1 | 1 |
| Haemorrhagic varicella syndrome | 1 | 1 |
| Helicobacter infection | 1 | 1 |
| Herpes simplex | 3 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 1 |
| | | | | 3 | 9 |
| | | | | 4 | 9 |
| | | | | | 1 |
| | | 2 | 6 | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 9 | 14 |
| | | | | 1 | 1 |
| | | 3 | 7 | | |
| | | | 1 | | |
| 2 | 2 | 17 | 50 | 268 | 723 |
| | | | | 6 | 9 |
| | | 4 | 4 | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 6 | 6 |
| | | | | 2 | 2 |
| | | 2 | 4 | 1 | 1 |
| | | | | 4 | 4 |
| | | | | | 1 |
| | | 2 | 3 | | |
| | | 2 | 2 | | |
| | | 2 | 5 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 6 | 1 | 1 |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Herpes simplex reactivation | 2 | 2 |
| Herpes virus infection | 2 | 7 |
| Herpes zoster | 31 | 72 |
| Hordeolum | 1 | 5 |
| Infection | 3 | 7 |
| Infection parasitic | | 1 |
| Influenza | 17 | 52 |
| Kidney infection | 5 | 6 |
| Labyrinthitis | | 1 |
| Laryngitis | 1 | 3 |
| Lip infection | | 1 |
| Localised infection | 1 | 3 |
| Lower respiratory tract infection | 1 | 2 |
| Lymphangitis | 1 | 1 |
| Lymph gland infection | 1 | 2 |
| Mastitis | | 1 |
| Meningitis | | 1 |
| Meningitis aseptic | 1 | 1 |
| Meningitis viral | 2 | 4 |
| Nasopharyngitis | 39 | 101 |
| Ophthalmic herpes simplex | 1 | 1 |
| Oral candidiasis | | 2 |
| Oral herpes | 9 | 25 |
| Oral viral infection | | 1 |
| Orchitis | | 1 |
| Periorbital cellulitis | 1 | 1 |
| Pertussis | | 1 |
| Pharyngitis | 2 | 3 |
| Pharyngitis streptococcal | 2 | 3 |
| Pneumonia | 18 | 29 |
| Pustule | 2 | 5 |
| Rash pustular | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 2 | | |
| | | 2 | 7 | | |
| | | 23 | 63 | 8 | 9 |
| | | | 4 | 1 | 1 |
| | | 2 | 5 | 1 | 2 |
| | | | 1 | | |
| | | 16 | 49 | 1 | 3 |
| | | | | 5 | 6 |
| | | | | | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | 39 | 99 | | 2 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 9 | 24 | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 2 | 3 | | |
| | | | | 18 | 29 |
| | | 2 | 4 | | 1 |
| | | | 1 | | |

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System Organ Class

Infections and infestations

| Preferred Term | Interval Total # | Cumulative Total # |
|---|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Respiratory tract infection | 2 | 3 |
| Retinitis | 1 | 1 |
| Rhinitis | 1 | 4 |
| Rhinovirus infection | | 1 |
| Sepsis | 4 | 7 |
| Sialoadenitis | 1 | 1 |
| Sinusitis | 7 | 24 |
| Staphylococcal infection | 1 | 2 |
| Staphylococcal skin infection | | 1 |
| Streptococcal infection | 1 | 2 |
| Subcutaneous abscess | 1 | 1 |
| Suspected COVID-19 | 6 | 42 |
| Tonsillitis | | 1 |
| Tooth abscess | 1 | 1 |
| Tooth infection | | 1 |
| Tracheitis | 1 | 1 |
| Tuberculosis | | 2 |
| Upper respiratory tract infection | 4 | 8 |
| Urinary tract infection | 22 | 32 |
| Urinary tract infection bacterial | 2 | 2 |
| Vaccination site cellulitis | 5 | 9 |
| Vaccination site infection | 1 | 6 |
| Vaginal infection | | 1 |
| Varicella | | 2 |
| Varicella zoster virus infection | | 1 |
| Viral infection | 2 | 4 |
| Viral rash | | 1 |
| Viral upper respiratory tract infection | 1 | 1 |
| Vulvovaginal mycotic infection | | 1 |
| | 560 | 1,396 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | | | 4 | 7 |
| | | | | 1 | 1 |
| | | 7 | 23 | | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 7 | 5 | 35 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | | 2 |
| | | 4 | 8 | | |
| | | 13 | 22 | 9 | 10 |
| | | | | 2 | 2 |
| | | 1 | 3 | 4 | 6 |
| | | 1 | 6 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | | 2 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| 2 | 2 | 176 | 463 | 384 | 933 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accidental exposure to product | 13 | 29 | 13 | 28 | | 1 |
| Accidental overdose | 5 | 33 | 4 | 31 | 1 | 2 |
| Accidental underdose | 1 | 3 | 1 | 3 | | |
| Animal bite | | 1 | | 1 | | |
| Arthropod bite | 1 | 5 | 1 | 5 | | |
| Back injury | 2 | 3 | 1 | 2 | 1 | 1 |
| Booster dose missed | | 2 | | 2 | | |
| Burn oral cavity | | 1 | | | | 1 |
| Cartilage injury | | 1 | | 1 | | |
| Chest injury | 1 | 1 | | | 1 | 1 |
| Chillblains | | 1 | | 1 | | |
| Circumstance or information capable of leading to medication error | 27 | 99 | 27 | 99 | | |
| Contraindicated product administered | | 2 | | 2 | | |
| Contusion | 25 | 47 | 24 | 46 | 1 | 1 |
| Dental restoration failure | | 2 | | 2 | | |
| Epicondylitis | | 2 | | 2 | | |
| Expired product administered | 1 | 2 | 1 | 2 | | |
| Exposure during pregnancy | 8 | 22 | 8 | 21 | | 1 |
| Exposure to SARS-CoV-2 | 11 | 53 | 10 | 42 | 1 | 11 |
| Exposure via breast milk | 10 | 80 | 10 | 80 | | |
| Exposure via eye contact | | 2 | | 2 | | |
| Exposure via skin contact | 12 | 25 | 12 | 24 | | 1 |
| Eye contusion | | 4 | | 4 | | |
| Face injury | 1 | 5 | 1 | 4 | | 1 |
| Fall | 38 | 62 | 23 | 40 | 15 | 22 |
| Foreign body aspiration | | 1 | | | | 1 |
| Foreign body in throat | 1 | 1 | | | 1 | 1 |
| Frostbite | | 1 | | 1 | | |
| Gastrointestinal stoma complication | 1 | 1 | 1 | 1 | | |
| Head injury | 3 | 9 | 1 | 4 | 2 | 5 |
| Hip fracture | 2 | 2 | | | 2 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Inappropriate schedule of product administration | 148 | 439 |
| Incision site haemorrhage | | 1 |
| Incomplete course of vaccination | 1 | 9 |
| Incorrect dosage administered | 5 | 5 |
| Incorrect dose administered | 5 | 18 |
| Incorrect route of product administration | 14 | 83 |
| Injury | | 1 |
| Intentional overdose | 1 | 1 |
| Intentional product misuse | | 1 |
| Intercepted medication error | 1 | 1 |
| Joint dislocation | 2 | 4 |
| Joint injury | 1 | 2 |
| Ligament injury | | 2 |
| Ligament sprain | 1 | 2 |
| Limb injury | 6 | 11 |
| Lip injury | | 2 |
| Maternal exposure during breast feeding | | 1 |
| Maternal exposure during pregnancy | 11 | 86 |
| Maternal exposure timing unspecified | 1 | 3 |
| Mouth injury | 1 | 1 |
| Muscle rupture | 1 | 1 |
| Muscle strain | 2 | 5 |
| Nasal injury | | 2 |
| Neck injury | | 1 |
| Nerve injury | 3 | 5 |
| Occupational exposure to product | 2 | 3 |
| Occupational exposure to SARS-CoV-2 | 1 | 7 |
| Off label use | 129 | 386 |
| Overdose | 25 | 67 |
| Peripheral nerve injury | 2 | 2 |
| Phrenic nerve injury | 1 | 1 |
| Poor quality product administered | 39 | 232 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 148 | 439 | | |
| | | | 1 |
| 1 | 9 | | |
| 5 | 5 | | |
| 4 | 16 | 1 | 2 |
| 14 | 80 | | 3 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 2 | 4 |
| 1 | 2 | | |
| | 2 | | |
| 1 | 2 | | |
| 6 | 11 | | |
| | 1 | | 1 |
| | 1 | | |
| 11 | 85 | | 1 |
| 1 | 3 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 4 | 1 | 1 |
| | 2 | | |
| | 1 | | |
| 2 | 4 | 1 | 1 |
| 2 | 3 | | |
| | 5 | 1 | 2 |
| 125 | 381 | 4 | 5 |
| 24 | 65 | 1 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 39 | 232 | | |

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System Organ Class

Injury, poisoning and procedural complications

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Post procedural haemorrhage | | 1 |
| Procedural pain | | 3 |
| Procedural site reaction | 1 | 1 |
| Product administered at inappropriate site | 8 | 45 |
| Product administered to patient of inappropriate age | 3 | 9 |
| Product administration error | 5 | 16 |
| Product communication issue | 1 | 1 |
| Product confusion | | 1 |
| Product dose omission issue | 3 | 5 |
| Product preparation error | 17 | 99 |
| Product preparation issue | 12 | 69 |
| Product prescribing error | 2 | 7 |
| Product storage error | 3 | 3 |
| Product use issue | 117 | 370 |
| Scar | 2 | 3 |
| Scratch | 2 | 6 |
| Skeletal injury | 1 | 1 |
| Skin injury | | 2 |
| Skin laceration | 3 | 6 |
| Soft tissue injury | 1 | 1 |
| Stoma site haemorrhage | 1 | 1 |
| Subdural haemorrhage | 1 | 1 |
| Sunburn | | 2 |
| Suture related complication | | 1 |
| Thermal burn | | 1 |
| Tongue injury | | 1 |
| Underdose | 49 | 156 |
| Upper limb fracture | | 1 |
| Vaccination complication | | 2 |
| Vaccination error | | 2 |
| Vaccination failure | 3 | 4 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | 2 | | 1 |
| | | 1 | 1 |
| 8 | 44 | | 1 |
| 3 | 9 | | |
| 3 | 14 | 2 | 2 |
| 1 | 1 | | |
| | 1 | | |
| 3 | 5 | | |
| 17 | 98 | | 1 |
| 11 | 67 | 1 | 2 |
| 2 | 7 | | |
| 3 | 3 | | |
| 113 | 364 | 4 | 6 |
| | 1 | 2 | 2 |
| 2 | 4 | | 2 |
| 1 | 1 | | |
| | 2 | | |
| 2 | 4 | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| 49 | 156 | | |
| | | | 1 |
| | 2 | | |
| | 2 | | |
| | | 3 | 4 |

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System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Wound | 1 | 3 | 1 | 3 | | |
| Wound haemorrhage | 1 | 2 | 1 | 1 | | 1 |
| Wrong product administered | 7 | 18 | 7 | 18 | | |
| Wrong schedule | | 1 | | 1 | | |
| Wrong technique in device usage process | 2 | 2 | 2 | 2 | | |
| Wrong technique in product usage process | 14 | 62 | 13 | 60 | 1 | 2 |
| | 826 | 2,796 | 769 | 2685 | 57 | 111 |

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System Organ Class

Investigations

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| | | Spontaneous | | | |
|---|----|-------------|----|---------|----|
| | | Nonserious | | Serious | |
| | | I | C | I | C |
| Activated partial thromboplastin time prolonged | 1 | 1 | 1 | | |
| Alanine aminotransferase increased | 2 | 2 | 2 | | 1 |
| Anion gap abnormal | 1 | 1 | 1 | | |
| Antibody test abnormal | 3 | 3 | 3 | | |
| Antibody test negative | 1 | 1 | 2 | | |
| Aspartate aminotransferase increased | 1 | 1 | 2 | | |
| Bilirubin urine present | | | 1 | | |
| Blood albumin decreased | | | 1 | | |
| Blood bilirubin increased | 3 | 3 | 2 | 1 | 1 |
| Blood calcium decreased | | | 1 | | |
| Blood chloride decreased | 1 | 2 | 1 | 2 | |
| Blood chloride increased | | | 1 | | |
| Blood cholesterol increased | 2 | 2 | 2 | 2 | |
| Blood count abnormal | 2 | 3 | 2 | 3 | |
| Blood creatine increased | | | 1 | | |
| Blood creatinine increased | 2 | 3 | 2 | 3 | |
| Blood glucose abnormal | 2 | 4 | 1 | 3 | 1 |
| Blood glucose decreased | 7 | 12 | 5 | 9 | 2 |
| Blood glucose fluctuation | | | 1 | 1 | |
| Blood glucose increased | 11 | 23 | 8 | 18 | 3 |
| Blood immunoglobulin G decreased | 1 | 2 | 1 | 2 | |
| Blood immunoglobulin G increased | | | | 2 | |
| Blood iron decreased | 3 | 4 | 1 | 2 | 2 |
| Blood ketone body increased | 1 | 1 | | | 1 |
| Blood lactic acid increased | 1 | 1 | | | 1 |
| Blood potassium decreased | | | | 4 | 1 |
| Blood potassium increased | 1 | 1 | 1 | 1 | |
| Blood pressure abnormal | 3 | 7 | 2 | 6 | 1 |
| Blood pressure decreased | 13 | 25 | 11 | 19 | 2 |
| Blood pressure diastolic decreased | | | | 1 | |
| Blood pressure diastolic increased | | | | | 1 |
| Blood pressure increased | 69 | 170 | 39 | 101 | 30 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Blood pressure systolic increased | 2 | 9 |
| Blood sodium decreased | 1 | 3 |
| Blood test abnormal | 1 | 1 |
| Blood testosterone decreased | | 1 |
| Blood thyroid stimulating hormone increased | | 3 |
| Blood triglycerides increased | | 1 |
| Blood urine present | 6 | 11 |
| Body height decreased | 8 | 15 |
| Body temperature abnormal | 6 | 14 |
| Body temperature decreased | 3 | 10 |
| Body temperature fluctuation | 1 | 2 |
| Body temperature increased | 29 | 74 |
| Capillary nail refill test abnormal | | 1 |
| Chest X-ray abnormal | 1 | 1 |
| Computerised tomogram normal | 1 | 1 |
| Corneal reflex decreased | 1 | 1 |
| Coronavirus test positive | | 1 |
| C-reactive protein increased | 2 | 9 |
| Crystal urine | | 1 |
| CSF protein increased | 1 | 1 |
| Culture urine positive | | 1 |
| Ejection fraction abnormal | | 1 |
| Ejection fraction decreased | 2 | 2 |
| Electrocardiogram abnormal | 2 | 5 |
| Electrocardiogram QT prolonged | 1 | 2 |
| Electrocardiogram T wave peaked | 1 | 1 |
| Eosinophil count decreased | 1 | 1 |
| Eosinophil count increased | 1 | 3 |
| Epinephrine increased | | 1 |
| Fibrin D dimer increased | 1 | 4 |
| Gastric pH decreased | | 1 |
| Glomerular filtration rate decreased | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | 2 | 7 |
| | 2 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | 1 |
| | | | 1 |
| 4 | 9 | 2 | 2 |
| 7 | 14 | 1 | 1 |
| 6 | 14 | | |
| 3 | 9 | | 1 |
| 1 | 2 | | |
| 28 | 73 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| 1 | 7 | 1 | 2 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 2 |
| 1 | 4 | 1 | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | 2 |
| | 1 | | |
| 1 | 3 | | 1 |
| | 1 | | |
| | 1 | | |

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System Organ Class

Investigations

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|--|--|--|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Glycosylated haemoglobin increased | 1 | 2 | | | 1 | 2 |
| Grip strength decreased | | 2 | | 2 | | |
| Haematocrit decreased | 1 | 3 | | 2 | 1 | 1 |
| Haematocrit increased | | 1 | | 1 | | |
| Haemoglobin decreased | 3 | 6 | 1 | 3 | 2 | 3 |
| Haemoglobin increased | | 1 | | 1 | | |
| Heart rate abnormal | 4 | 8 | 3 | 7 | 1 | 1 |
| Heart rate decreased | 7 | 14 | 4 | 9 | 3 | 5 |
| Heart rate increased | 109 | 359 | 85 | 285 | 24 | 74 |
| Heart rate irregular | 10 | 19 | 9 | 17 | 1 | 2 |
| Hepatic enzyme increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Histamine level increased | | 1 | | | | 1 |
| Hormone level abnormal | 2 | 2 | 1 | 1 | 1 | 1 |
| Influenza B virus test positive | | 1 | | 1 | | |
| Inspiratory capacity decreased | 1 | 1 | 1 | 1 | | |
| International normalised ratio decreased | 1 | 2 | | 1 | 1 | 1 |
| International normalised ratio increased | | 3 | | 2 | | 1 |
| Intraocular pressure increased | 1 | 2 | | 1 | 1 | 1 |
| Laboratory test abnormal | | 1 | | | | 1 |
| Laboratory test normal | 1 | 1 | 1 | 1 | | |
| Lipids increased | | 1 | | 1 | | |
| Liver function test abnormal | | 1 | | | | 1 |
| Liver function test increased | 1 | 1 | 1 | 1 | | |
| Lumbar puncture abnormal | 1 | 1 | | | 1 | 1 |
| Lymph node palpable | | 1 | | 1 | | |
| Lymphocyte count abnormal | 1 | 1 | 1 | 1 | | |
| Lymphocyte count decreased | | 1 | | 1 | | |
| Mean cell volume increased | | 1 | | 1 | | |
| Monocyte count increased | | 1 | | 1 | | |
| Myocardial necrosis marker increased | 1 | 3 | | | 1 | 3 |
| Neurological examination normal | 1 | 1 | 1 | 1 | | |
| Neutrophil count decreased | 2 | 3 | 1 | 2 | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| | 2 | | |
| | 2 | 1 | 1 |
| | 1 | | |
| 1 | 3 | 2 | 3 |
| | 1 | | |
| 3 | 7 | 1 | 1 |
| 4 | 9 | 3 | 5 |
| 85 | 285 | 24 | 74 |
| 9 | 17 | 1 | 2 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| | 2 | | 1 |
| | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 3 | | |
| | | 1 | 3 |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |

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System Organ Class

Investigations

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neutrophil count increased | 1 | 2 | 1 | 1 | | 1 |
| Orthostatic heart rate response increased | | 1 | | 1 | | |
| Oxygen consumption | | 1 | | 1 | | |
| Oxygen saturation abnormal | 2 | 2 | 2 | 2 | | |
| Oxygen saturation decreased | 18 | 33 | 5 | 14 | 13 | 19 |
| Physical examination abnormal | 1 | 1 | | | 1 | 1 |
| Platelet count abnormal | 1 | 1 | | | 1 | 1 |
| Platelet count decreased | 11 | 14 | 3 | 4 | 8 | 10 |
| Platelet count increased | 1 | 6 | 1 | 4 | | 2 |
| PO2 decreased | | 2 | | 1 | | 1 |
| Prothrombin time prolonged | 1 | 1 | | | 1 | 1 |
| Pulse abnormal | 5 | 14 | 2 | 8 | 3 | 6 |
| Pulse absent | 1 | 1 | | | 1 | 1 |
| Red blood cell count decreased | | 2 | | 2 | | |
| Red blood cell sedimentation rate abnormal | 1 | 1 | 1 | 1 | | |
| Red blood cell sedimentation rate increased | 1 | 3 | | 2 | 1 | 1 |
| Red blood cells urine positive | | 1 | | 1 | | |
| Respiratory rate decreased | | 1 | | | | 1 |
| Respiratory rate increased | 6 | 12 | 4 | 7 | 2 | 5 |
| SARS-CoV-1 test positive | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 19 | 31 | 17 | 29 | 2 | 2 |
| SARS-CoV-2 ant body test positive | 3 | 10 | 3 | 9 | | 1 |
| SARS-CoV-2 test false positive | | 2 | | 2 | | |
| SARS-CoV-2 test positive | 40 | 263 | 10 | 33 | 30 | 230 |
| Sinus rhythm | | 1 | | 1 | | |
| Streptococcus test positive | 1 | 2 | 1 | 2 | | |
| Troponin increased | 2 | 4 | | | 2 | 4 |
| Tryptase decreased | | 1 | | 1 | | |
| Tryptase increased | | 1 | | 1 | | |
| Tuberculin test positive | 1 | 1 | 1 | 1 | | |
| Urine analysis abnormal | | 1 | | | 1 | |
| Urine output increased | 1 | 2 | 1 | 2 | | |

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System Organ Class

Investigations

Preferred Term

*Interval Total #
Spontaneous AE* *Cumulative Total #
Spontaneous AE*

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| 10 | 23 | | 4 |
| | 5 | | |
| 4 | 5 | 1 | 1 |
| 4 | 5 | 2 | 6 |
| 324 | 868 | 169 | 524 |

Vitamin B12 decreased

1 1

Vitamin D decreased

1 1

Weight decreased

10 27

Weight increased

5 5

White blood cell count decreased

5 6

White blood cell count increased

6 11

493 1,392 324 868 169 524

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System Organ Class

Metabolism and nutrition disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Acetonaemia | | 1 | | 1 | | | |
| Appetite disorder | 1 | 2 | 1 | 2 | | | |
| Decreased appetite | 60 | 157 | 58 | 148 | 2 | 9 | |
| Dehydration | 15 | 41 | 11 | 32 | 4 | 9 | |
| Diabetes mellitus | 4 | 9 | | | 4 | 9 | |
| Diabetes mellitus inadequate control | 4 | 4 | | | 4 | 4 | |
| Diet refusal | | 1 | | | | 1 | |
| Feeding disorder | 8 | 19 | 8 | 17 | | 2 | |
| Fluid imbalance | | 1 | | | | 1 | |
| Fluid intake reduced | | 1 | | 1 | | | |
| Fluid retention | 2 | 2 | 1 | 1 | 1 | 1 | |
| Food aversion | | 1 | | 1 | | | |
| Gout | 4 | 9 | 3 | 8 | 1 | 1 | |
| Hyperglycaemia | 1 | 4 | 1 | 2 | | 2 | |
| Hyperlipidaemia | 1 | 1 | | | 1 | 1 | |
| Hypocalcaemia | | 1 | | | | 1 | |
| Hypoglycaemia | 2 | 6 | 2 | 6 | | | |
| Hypokalaemia | 1 | 2 | | | 1 | 2 | |
| Hypomagnesaemia | | 1 | | | | 1 | |
| Hypophagia | | 3 | | 2 | | 1 | |
| Increased appetite | | 2 | | 2 | | | |
| Malnutrition | | 1 | | 1 | | | |
| Oligodipsia | | 1 | | | | 1 | |
| Overweight | 1 | 2 | 1 | 2 | | | |
| Polydipsia | | 2 | | 2 | | | |
| Poor feeding infant | | 1 | | 1 | | | |
| Tetany | | 2 | | | | 2 | |
| Type 1 diabetes mellitus | 1 | 1 | | | 1 | 1 | |
| Type 2 diabetes mellitus | 1 | 1 | | | 1 | 1 | |
| Weight fluctuation | 2 | 2 | 2 | 2 | | | |
| | 108 | 281 | 88 | 231 | 20 | 50 | |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 327 | 979 | 318 | 942 | 9 | 37 |
| Arthritis | 12 | 30 | 12 | 29 | | 1 |
| Arthropathy | 7 | 15 | 6 | 14 | 1 | 1 |
| Axillary mass | 2 | 12 | 2 | 10 | | 2 |
| Back disorder | 5 | 5 | 5 | 5 | | |
| Back pain | 103 | 285 | 90 | 260 | 13 | 25 |
| Bone pain | 16 | 54 | 14 | 47 | 2 | 7 |
| Bone swelling | 1 | 6 | 1 | 6 | | |
| Bursitis | | 1 | | 1 | | |
| Chondritis | 1 | 1 | 1 | 1 | | |
| Costochondritis | 1 | 2 | 1 | 1 | | 1 |
| Extremity contracture | | 1 | | 1 | | |
| Facet joint syndrome | | 1 | | 1 | | |
| Facial asymmetry | | 1 | | 1 | | |
| Fasciitis | 2 | 2 | | | 2 | 2 |
| Fibromyalgia | 2 | 3 | 2 | 2 | | 1 |
| Flank pain | 7 | 11 | 6 | 10 | 1 | 1 |
| Foot deformity | 2 | 2 | 2 | 2 | | |
| Groin pain | 3 | 6 | 2 | 5 | 1 | 1 |
| Immune-mediated arthritis | | 1 | | | | 1 |
| Intervertebral disc protrusion | 1 | 2 | | 1 | 1 | 1 |
| Jaw disorder | 2 | 2 | 2 | 2 | | |
| Joint effusion | 2 | 3 | 2 | 3 | | |
| Joint instability | | 2 | | | | 2 |
| Joint noise | | 1 | | 1 | | |
| Joint range of motion decreased | 15 | 38 | 15 | 35 | | 3 |
| Joint stiffness | 5 | 17 | 4 | 15 | 1 | 2 |
| Joint swelling | 21 | 52 | 20 | 48 | 1 | 4 |
| Joint warmth | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 24 | 96 | 23 | 87 | 1 | 9 |
| Limb mass | 3 | 5 | 3 | 4 | | 1 |
| Mastication disorder | 1 | 1 | 1 | 1 | | |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Mixed connective tissue disease | | 1 |
| Mobility decreased | 17 | 39 |
| Muscle atrophy | | 1 |
| Muscle discomfort | 2 | 7 |
| Muscle disorder | 1 | 3 |
| Muscle fatigue | 5 | 11 |
| Muscle rigidity | 1 | 1 |
| Muscle spasms | 39 | 120 |
| Muscle swelling | 1 | 3 |
| Muscle tightness | 14 | 51 |
| Muscle twitching | 13 | 30 |
| Muscular weakness | 49 | 116 |
| Musculoskeletal chest pain | 8 | 27 |
| Musculoskeletal discomfort | 6 | 26 |
| Musculoskeletal disorder | 3 | 9 |
| Musculoskeletal pain | 4 | 13 |
| Musculoskeletal stiffness | 53 | 131 |
| Myalgia | 323 | 1,137 |
| Myositis | 1 | 3 |
| Neck mass | 4 | 9 |
| Neck pain | 84 | 252 |
| Nuchal rigidity | 1 | 3 |
| Osteoarthritis | 2 | 3 |
| Osteochondritis | | 1 |
| Pain in extremity | 525 | 1,506 |
| Pain in jaw | 12 | 45 |
| Periarthritis | | 3 |
| Polyarthritis | 1 | 1 |
| Polychondritis | 1 | 1 |
| Polymyalgia rheumatica | 2 | 3 |
| Posture abnormal | | 1 |
| Psoriatic arthropathy | | 1 |

| Spontaneous | | | |
|-------------|------|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 12 | 31 | 5 | 8 |
| | 1 | | |
| 2 | 7 | | |
| 1 | 3 | | |
| 5 | 11 | | |
| | | 1 | 1 |
| 34 | 107 | 5 | 13 |
| | 2 | 1 | 1 |
| 13 | 48 | 1 | 3 |
| 12 | 28 | 1 | 2 |
| 35 | 89 | 14 | 27 |
| 7 | 26 | 1 | 1 |
| 6 | 25 | | 1 |
| 1 | 5 | 2 | 4 |
| 4 | 11 | | 2 |
| 49 | 123 | 4 | 8 |
| 308 | 1086 | 15 | 51 |
| 1 | 1 | | 2 |
| 4 | 9 | | |
| 69 | 228 | 15 | 24 |
| | 2 | 1 | 1 |
| 2 | 3 | | |
| | 1 | | |
| 503 | 1463 | 22 | 43 |
| 9 | 40 | 3 | 5 |
| | 2 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | 1 | | |
| | | | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rheumatoid arthritis | 5 | 7 | | | 5 | 7 |
| Rotator cuff syndrome | 1 | 1 | 1 | 1 | | |
| Sinus tarsi syndrome | | 1 | | 1 | | |
| Sjogren's syndrome | 1 | 1 | | | 1 | 1 |
| Spinal disorder | 1 | 2 | 1 | 2 | | |
| Spinal pain | 10 | 21 | 10 | 20 | | 1 |
| Spinal stenosis | 1 | 1 | 1 | 1 | | |
| Synovial cyst | 1 | 1 | 1 | 1 | | |
| Synovitis | 1 | 1 | 1 | 1 | | |
| Systemic lupus erythematosus | | 1 | | | | 1 |
| Systemic scleroderma | | 1 | | | | 1 |
| Tendonitis | 1 | 4 | 1 | 3 | | 1 |
| Tendon pain | | 2 | | 2 | | |
| Tenosynovitis | 1 | 2 | 1 | 2 | | |
| Trismus | 1 | 4 | | 3 | 1 | 1 |
| Undifferentiated connective tissue disease | | 1 | | | | 1 |
| Winged scapula | 1 | 1 | 1 | 1 | | |
| | 1,763 | 5,248 | 1628 | 4927 | 135 | 321 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myeloid leukaemia | 2 | 2 | | | 2 | 2 |
| Breast cancer | 1 | 1 | | | 1 | 1 |
| Cardiac neoplasm unspecified | | 1 | | | | 1 |
| Chronic myeloid leukaemia recurrent | 1 | 1 | | | 1 | 1 |
| Colon cancer | 1 | 1 | | | 1 | 1 |
| Ear neoplasm | | 1 | | 1 | | |
| Good syndrome | 1 | 1 | | | 1 | 1 |
| Leukaemia | 1 | 1 | | | 1 | 1 |
| Lung carcinoma cell type unspecified stage I | 1 | 1 | | | 1 | 1 |
| Lung neoplasm malignant | | 1 | | | | 1 |
| Lymphoma | 2 | 2 | | | 2 | 2 |
| Metastases to meninges | | 1 | | | | 1 |
| Neoplasm malignant | 1 | 1 | | | 1 | 1 |
| Neoplasm skin | 1 | 2 | 1 | 2 | | |
| Paraganglion neoplasm | 1 | 1 | | | 1 | 1 |
| Thyroid cancer | 1 | 1 | | | 1 | 1 |
| | 14 | 19 | 1 | 3 | 13 | 16 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Acoustic neuritis | | 1 | | | | 1 | |
| Acute disseminated encephalomyelitis | | 1 | | | | 1 | |
| Ageusia | 35 | 104 | 31 | 91 | 4 | 13 | |
| Allodynia | | 1 | | 1 | | | |
| Altered state of consciousness | 2 | 3 | | | 2 | 3 | |
| Amnesia | 7 | 13 | 5 | 9 | 2 | 4 | |
| Anaesthesia | | 2 | | 2 | | | |
| Anosmia | 29 | 100 | 25 | 85 | 4 | 15 | |
| Aphasia | 5 | 13 | 2 | 7 | 3 | 6 | |
| Areflexia | 1 | 1 | | | 1 | 1 | |
| Ataxia | 1 | 2 | 1 | 1 | | 1 | |
| Aura | | 1 | | 1 | | | |
| Autonomic nervous system imbalance | 1 | 2 | 1 | 1 | | 1 | |
| Balance disorder | 22 | 54 | 20 | 48 | 2 | 6 | |
| Basal ganglia haemorrhage | | 2 | | | | 2 | |
| Basal ganglia stroke | 2 | 2 | | | 2 | 2 | |
| Brachial plexopathy | | 2 | | 1 | | 1 | |
| Bradykinesia | | 1 | | 1 | | | |
| Brain injury | | 2 | | | | 2 | |
| Brain oedema | | 2 | | | | 2 | |
| Brain stem haemorrhage | 1 | 1 | | | 1 | 1 | |
| Brain stem syndrome | 2 | 2 | | | 2 | 2 | |
| Burning sensation | 50 | 110 | 42 | 94 | 8 | 16 | |
| Carpal tunnel syndrome | 1 | 1 | 1 | 1 | | | |
| Central nervous system lesion | 1 | 2 | | 1 | 1 | 1 | |
| Cerebral disorder | | 2 | | 2 | | | |
| Cerebral haemorrhage | 3 | 6 | | | 3 | 6 | |
| Cerebral infarction | 1 | 1 | | | 1 | 1 | |
| Cerebral thrombosis | 1 | 1 | | | 1 | 1 | |
| Cerebrovascular accident | 34 | 51 | | | 34 | 51 | |
| Clumsiness | 1 | 2 | 1 | 2 | | | |
| Cluster headache | 2 | 3 | 2 | 3 | | | |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Cognitive disorder | 7 | 12 |
| Coma | 2 | 3 |
| Coordination abnormal | | 2 |
| Cranial nerve disorder | 1 | 1 |
| Dementia | 7 | 7 |
| Demyelinating polyneuropathy | | 1 |
| Depressed level of consciousness | 1 | 4 |
| Disturbance in attention | 15 | 39 |
| Dizziness | 401 | 1,173 |
| Dizziness exertional | | 2 |
| Dizziness postural | 11 | 23 |
| Drooling | 1 | 2 |
| Dysaesthesia | 4 | 6 |
| Dysarthria | 10 | 18 |
| Dysgeusia | 46 | 159 |
| Dyskinesia | 2 | 7 |
| Dyslexia | | 1 |
| Dysstasia | 17 | 27 |
| Dystonia | | 1 |
| Encephalopathy | | 1 |
| Facial nerve disorder | 1 | 2 |
| Facial neuralgia | 1 | 1 |
| Facial paralysis | 68 | 135 |
| Facial paresis | 2 | 7 |
| Facial spasm | 1 | 1 |
| Febrile convulsion | 1 | 2 |
| Fine motor skill dysfunction | 1 | 5 |
| Formication | 2 | 5 |
| Freezing phenomenon | | 1 |
| Generalised tonic-clonic seizure | 2 | 2 |
| Guillain-Barre syndrome | 9 | 12 |
| Haemorrhage intracranial | | 1 |

| Spontaneous | | | |
|-------------|------|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 6 | 4 | 6 |
| | | 2 | 3 |
| | 1 | | 1 |
| | | 1 | 1 |
| | | 7 | 7 |
| | | | 1 |
| | | 1 | 4 |
| 11 | 31 | 4 | 8 |
| 351 | 1031 | 50 | 142 |
| | 2 | | |
| 10 | 20 | 1 | 3 |
| | 1 | 1 | 1 |
| 3 | 5 | 1 | 1 |
| 4 | 10 | 6 | 8 |
| 44 | 153 | 2 | 6 |
| 1 | 4 | 1 | 3 |
| | 1 | | |
| 10 | 16 | 7 | 11 |
| | | | 1 |
| | | | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 67 | 134 |
| | 2 | 2 | 5 |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 5 | | |
| 2 | 5 | | |
| | 1 | | |
| | | 2 | 2 |
| | | 9 | 12 |
| | | | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Haemorrhagic stroke | 1 | 2 |
| Hand-eye coordination impaired | | 1 |
| Headache | 884 | 2,995 |
| Head discomfort | 24 | 59 |
| Head titubation | 1 | 2 |
| Hemiparesis | 1 | 4 |
| Hemiplegia | 3 | 4 |
| Hyperaesthesia | 3 | 19 |
| Hyperreflexia | 1 | 1 |
| Hypersomnia | 15 | 45 |
| Hypertonia | | 1 |
| Hypoaesthesia | 132 | 406 |
| Hypogeusia | 3 | 9 |
| Hypokinesia | 3 | 9 |
| Hyporeflexia | 1 | 1 |
| Hyporesponsive to stimuli | 1 | 1 |
| Hyposmia | | 5 |
| Hypotonia | 1 | 3 |
| Illrd nerve paralysis | 1 | 1 |
| Incoherent | 2 | 3 |
| Infant irritability | | 3 |
| Intracranial aneurysm | 1 | 1 |
| Intracranial pressure increased | | 1 |
| Irregular sleep wake rhythm disorder | 1 | 2 |
| Ischaemic stroke | 4 | 4 |
| Lacunar infarction | 1 | 1 |
| Lethargy | 37 | 104 |
| Loss of consciousness | 65 | 104 |
| Loss of proprioception | | 1 |
| Memory impairment | 9 | 22 |
| Meningeal disorder | 1 | 1 |
| Meningism | | 1 |

| Spontaneous | | | |
|-------------|------|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| | | | 1 |
| 825 | 2839 | 59 | 156 |
| 21 | 53 | 3 | 6 |
| 1 | 2 | | |
| | | 1 | 4 |
| | | 3 | 4 |
| 3 | 18 | | 1 |
| 1 | 1 | | |
| 14 | 42 | 1 | 3 |
| | 1 | | |
| 110 | 339 | 22 | 67 |
| 3 | 9 | | |
| 3 | 9 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 5 | | |
| | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 2 |
| | 3 | | |
| | | 1 | 1 |
| | | | 1 |
| 1 | 2 | | |
| | | 4 | 4 |
| | | 1 | 1 |
| 34 | 98 | 3 | 6 |
| 1 | 1 | 64 | 103 |
| | | | 1 |
| 6 | 15 | 3 | 7 |
| | | 1 | 1 |
| | 1 | | |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Meningitis noninfective | 1 | 1 |
| Mental impairment | 16 | 30 |
| Migraine | 52 | 157 |
| Migraine with aura | 5 | 7 |
| Mononeuropathy | | 1 |
| Monoplegia | 4 | 4 |
| Motor dysfunction | 1 | 4 |
| Movement disorder | 19 | 42 |
| Muscle contractions involuntary | 1 | 2 |
| Muscle spasticity | 1 | 1 |
| Myelitis transverse | 1 | 2 |
| Myoclonus | 1 | 1 |
| Narcolepsy | 1 | 1 |
| Nerve compression | 2 | 8 |
| Nervous system disorder | 5 | 7 |
| Neuralgia | 15 | 41 |
| Neuralgic amyotrophy | 3 | 3 |
| Neuritis | | 1 |
| Neurological symptom | 3 | 4 |
| Neuropathy peripheral | 8 | 20 |
| Noninfective encephalitis | 3 | 4 |
| Nystagmus | 1 | 3 |
| Occipital neuralgia | 1 | 2 |
| Optic neuritis | | 1 |
| Paraesthesia | 147 | 468 |
| Paraesthesia mucosal | | 1 |
| Paralysis | 6 | 11 |
| Parkinson's disease | 1 | 1 |
| Parosmia | 10 | 28 |
| Peroneal nerve palsy | 1 | 3 |
| Polyneuropathy | | 2 |
| Poor quality sleep | 9 | 29 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 16 | 30 |
| 48 | 146 | 4 | 11 |
| 5 | 7 | | |
| | | | 1 |
| | | 4 | 4 |
| 1 | 2 | | 2 |
| 14 | 36 | 5 | 6 |
| 1 | 1 | | 1 |
| 1 | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 8 | | |
| 5 | 5 | | 2 |
| 12 | 37 | 3 | 4 |
| 2 | 2 | 1 | 1 |
| | 1 | | |
| 2 | 2 | 1 | 2 |
| | | 8 | 20 |
| | | 3 | 4 |
| 1 | 2 | | 1 |
| | 1 | 1 | 1 |
| | | | 1 |
| 126 | 403 | 21 | 65 |
| | 1 | | |
| | | 6 | 11 |
| | | 1 | 1 |
| 10 | 27 | | 1 |
| | 1 | 1 | 2 |
| | | | 2 |
| 9 | 29 | | |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Post herpetic neuralgia | 1 | 1 |
| Postictal state | | 1 |
| Post-traumatic neuralgia | 1 | 1 |
| Presyncope | 35 | 82 |
| Psychomotor hyperactivity | | 2 |
| Radiculitis brachial | | 1 |
| Reduced facial expression | 1 | 2 |
| Restless legs syndrome | | 2 |
| Ruptured cerebral aneurysm | 1 | 1 |
| Sciatica | 5 | 7 |
| Sedation | 1 | 3 |
| Seizure | 18 | 30 |
| Seizure like phenomena | | 1 |
| Sensorimotor disorder | | 1 |
| Sensory disturbance | 6 | 13 |
| Sensory loss | 3 | 10 |
| Serotonin syndrome | | 1 |
| Sinus headache | 9 | 16 |
| Sleep paralysis | 1 | 2 |
| Slow response to stimuli | | 1 |
| Somnolence | 46 | 144 |
| Speech disorder | 23 | 45 |
| Spinal cord disorder | 2 | 2 |
| Subarachnoid haemorrhage | 2 | 2 |
| Syncope | 59 | 99 |
| Taste disorder | 14 | 41 |
| Tension headache | 4 | 10 |
| Tonic clonic movements | 1 | 1 |
| Transient global amnesia | | 1 |
| Transient ischaemic attack | 4 | 8 |
| Tremor | 68 | 201 |
| Trigeminal nerve disorder | 1 | 2 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 28 | 64 | 7 | 18 |
| | 1 | | 1 |
| | 1 | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |
| 3 | 5 | 2 | 2 |
| 1 | 3 | | |
| | | 18 | 30 |
| | | | 1 |
| | | | 1 |
| 6 | 12 | | 1 |
| | 6 | 3 | 4 |
| | | | 1 |
| 9 | 16 | | |
| 1 | 2 | | |
| | 1 | | |
| 43 | 135 | 3 | 9 |
| 14 | 31 | 9 | 14 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 59 | 99 |
| 13 | 39 | 1 | 2 |
| 4 | 10 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 4 | 8 |
| 54 | 164 | 14 | 37 |
| | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Trigeminal neuralgia | 4 | 6 | 3 | 4 | 1 | 2 |
| Trigeminal neuritis | | 1 | | 1 | | |
| Tunnel vision | 4 | 8 | | | 4 | 8 |
| Unresponsive to stimuli | 8 | 12 | | 1 | 8 | 11 |
| Vascular dementia | 1 | 1 | | | 1 | 1 |
| Visual field defect | 3 | 4 | 3 | 4 | | |
| Vlth nerve paralysis | 2 | 2 | | | 2 | 2 |
| Vocal cord paralysis | | 1 | | 1 | | |
| White matter lesion | 1 | 1 | | | 1 | 1 |
| | 2,658 | 7,630 | 2020 | 6309 | 638 | 1321 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abortion spontaneous | 7 | 12 | | | 7 | 12 |
| Foetal death | 1 | 1 | | | 1 | 1 |
| Premature rupture of membranes | | 1 | | | | 1 |
| Uterine contractions during pregnancy | | 1 | | 1 | | |
| | 8 | 15 | | 1 | 8 | 14 |

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System Organ Class

Product issues

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Device breakage | | 1 | | | | 1 |
| Liquid product physical issue | 3 | 8 | 3 | 8 | | |
| Needle issue | 1 | 7 | 1 | 7 | | |
| Product colour issue | 2 | 2 | 2 | 2 | | |
| Product complaint | | 1 | | 1 | | |
| Product container issue | 2 | 2 | 2 | 2 | | |
| Product formulation issue | | 1 | | | | 1 |
| Product leakage | 2 | 11 | 2 | 11 | | |
| Product lot number issue | 1 | 1 | 1 | 1 | | |
| Product packaging quantity issue | | 4 | | 4 | | |
| Product quality issue | 2 | 5 | 2 | 5 | | |
| Product supply issue | 1 | 2 | 1 | 2 | | |
| Product temperature excursion issue | 24 | 129 | 24 | 129 | | |
| Syringe issue | 1 | 2 | 1 | 2 | | |
| | 39 | 176 | 39 | 174 | | 2 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal behaviour | 3 | 4 | 3 | 3 | | 1 |
| Abnormal dreams | 8 | 18 | 7 | 17 | 1 | 1 |
| Aggression | | 2 | | 2 | | |
| Agitation | 2 | 9 | 2 | 9 | | |
| Anger | 2 | 6 | 1 | 5 | 1 | 1 |
| Anxiety | 50 | 124 | 42 | 110 | 8 | 14 |
| Apathy | 3 | 3 | 3 | 3 | | |
| Autoscopy | 1 | 1 | 1 | 1 | | |
| Behaviour disorder | 1 | 1 | | | 1 | 1 |
| Belligerence | 1 | 1 | | | 1 | 1 |
| Bradyphrenia | 1 | 2 | | | 1 | 2 |
| Bruxism | 1 | 1 | 1 | 1 | | |
| Claustrophobia | | 1 | | 1 | | |
| Communication disorder | | 1 | | 1 | | |
| Confusional state | 28 | 52 | 19 | 40 | 9 | 12 |
| Daydreaming | 1 | 1 | 1 | 1 | | |
| Decreased interest | 1 | 1 | 1 | 1 | | |
| Delirium | 7 | 11 | | | 7 | 11 |
| Delusional perception | | 3 | | 2 | | 1 |
| Depersonalisation/derealisation disorder | | 1 | | 1 | | |
| Depressed mood | 4 | 13 | 3 | 11 | 1 | 2 |
| Depression | 2 | 7 | 2 | 5 | | 2 |
| Disorientation | 14 | 24 | 9 | 16 | 5 | 8 |
| Dissociation | 2 | 4 | 2 | 3 | | 1 |
| Dysphemia | 2 | 3 | 1 | 2 | 1 | 1 |
| Eating disorder | 6 | 17 | 5 | 14 | 1 | 3 |
| Emotional disorder | | 5 | | 5 | | |
| Emotional distress | 1 | 2 | 1 | 1 | | 1 |
| Euphoric mood | 1 | 2 | 1 | 2 | | |
| Fear | 5 | 15 | 5 | 14 | | 1 |
| Frustration tolerance decreased | 2 | 4 | 2 | 4 | | |
| Hallucination | 14 | 16 | | | 14 | 16 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Hallucination, auditory | | 2 |
| Hallucination, visual | 4 | 6 |
| Hydrophobia | | 1 |
| Hypervigilance | | 1 |
| Illness anxiety disorder | | 1 |
| Impulsive behaviour | | 1 |
| Initial insomnia | 1 | 4 |
| Insomnia | 68 | 178 |
| Intrusive thoughts | | 1 |
| Irritability | 4 | 14 |
| Laziness | | 2 |
| Major depression | 1 | 1 |
| Mania | 1 | 2 |
| Mental disorder | 3 | 10 |
| Mental fatigue | 1 | 2 |
| Mental status changes | 1 | 2 |
| Middle insomnia | 7 | 24 |
| Mood swings | 1 | 1 |
| Mutism | | 1 |
| Near death experience | 4 | 4 |
| Nervousness | 28 | 63 |
| Nightmare | 9 | 16 |
| Panic attack | 4 | 11 |
| Panic disorder | 1 | 1 |
| Panic reaction | 3 | 8 |
| Paranoia | | 2 |
| Personality change | 1 | 1 |
| Post-traumatic stress disorder | | 2 |
| Posturing | | 1 |
| Pressure of speech | 1 | 2 |
| Psychiatric symptom | | 1 |
| Restlessness | 8 | 22 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 2 |
| | | 4 | 6 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 4 | | |
| 66 | 172 | 2 | 6 |
| | 1 | | |
| 4 | 13 | | 1 |
| | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| 3 | 9 | | 1 |
| 1 | 2 | | |
| 1 | 1 | | 1 |
| 6 | 22 | 1 | 2 |
| 1 | 1 | | |
| | | | 1 |
| | | 4 | 4 |
| 27 | 61 | 1 | 2 |
| 9 | 16 | | |
| 4 | 9 | | 2 |
| 1 | 1 | | |
| 3 | 7 | | 1 |
| | 2 | | |
| | | 1 | 1 |
| | 2 | | |
| | | | 1 |
| 1 | 1 | | 1 |
| | 1 | | |
| 7 | 18 | 1 | 4 |

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System Organ Class

Psychiatric disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sitophobia | | 1 | | 1 | | |
| Sleep disorder | 10 | 37 | 10 | 35 | | 2 |
| Sleep disorder due to a general medical condition | 1 | 4 | 1 | 4 | | |
| Sleep disorder due to general medical condition, insomnia type | 1 | 3 | 1 | 3 | | |
| Sleep talking | | 1 | | 1 | | |
| Sleep terror | 1 | 1 | 1 | 1 | | |
| Somatic symptom disorder | | 1 | | 1 | | |
| Staring | 2 | 3 | 1 | 1 | 1 | 2 |
| Stress | 8 | 15 | 8 | 15 | | |
| Substance abuse | | 1 | | | | 1 |
| Suicidal ideation | 1 | 1 | | | 1 | 1 |
| Suicide attempt | 1 | 1 | | | 1 | 1 |
| Tachyphrenia | 1 | 5 | 1 | 5 | | |
| Tearfulness | | 1 | | 1 | | |
| Tension | 2 | 4 | 2 | 4 | | |
| Terminal insomnia | 1 | 4 | 1 | 4 | | |
| Thinking abnormal | 8 | 14 | 8 | 14 | | |
| Tic | | 1 | | 1 | | |
| | 351 | 841 | 282 | 716 | 69 | 125 |

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System Organ Class

Renal and urinary disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | | 3 | | | | 3 |
| Bladder discomfort | | 1 | | 1 | | |
| Bladder disorder | 1 | 1 | 1 | 1 | | |
| Bladder pain | 1 | 1 | 1 | 1 | | |
| Chromaturia | 3 | 9 | 3 | 9 | | |
| Costovertebral angle tenderness | | 1 | | 1 | | |
| Dysuria | 6 | 10 | 5 | 9 | 1 | 1 |
| Haematuria | 2 | 3 | 2 | 2 | | 1 |
| Haemorrhage urinary tract | 1 | 1 | | | 1 | 1 |
| Incontinence | | 2 | | 1 | | 1 |
| Micturition disorder | 1 | 1 | | | 1 | 1 |
| Micturition urgency | 2 | 3 | 1 | 2 | 1 | 1 |
| Nephrolithiasis | 2 | 3 | | | 2 | 3 |
| Nephropathy | 1 | 1 | 1 | 1 | | |
| Nocturia | | 1 | | 1 | | |
| Pollakiuria | 8 | 17 | 8 | 17 | | |
| Polyuria | | 4 | | 4 | | |
| Renal atrophy | 1 | 1 | | | 1 | 1 |
| Renal disorder | 5 | 7 | 2 | 4 | 3 | 3 |
| Renal failure | 2 | 3 | | | 2 | 3 |
| Renal haemorrhage | 1 | 1 | | | 1 | 1 |
| Renal impairment | 1 | 2 | | | 1 | 2 |
| Renal pain | 8 | 17 | 7 | 16 | 1 | 1 |
| Urethral disorder | 1 | 1 | 1 | 1 | | |
| Urethral haemorrhage | 1 | 1 | | | 1 | 1 |
| Urge incontinence | | 1 | | 1 | | |
| Urinary incontinence | 2 | 5 | 2 | 5 | | |
| Urinary retention | 3 | 4 | 1 | 1 | 2 | 3 |
| Urinary tract disorder | 1 | 1 | 1 | 1 | | |
| Urine abnormality | 1 | 1 | 1 | 1 | | |
| Urine odour abnormal | 2 | 2 | 1 | 1 | 1 | 1 |
| | 57 | 109 | 38 | 81 | 19 | 28 |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal withdrawal bleeding | 1 | 1 | 1 | 1 | | |
| Adnexa uteri pain | | 1 | | 1 | | |
| Breast discharge | 4 | 4 | 4 | 4 | | |
| Breast discomfort | 1 | 3 | 1 | 3 | | |
| Breast mass | 1 | 2 | 1 | 2 | | |
| Breast milk discolouration | | 1 | | 1 | | |
| Breast pain | 9 | 18 | 9 | 18 | | |
| Breast swelling | 1 | 4 | 1 | 4 | | |
| Breast tenderness | 2 | 5 | 2 | 4 | | 1 |
| Dysmenorrhoea | 1 | 5 | 1 | 5 | | |
| Erectile dysfunction | 4 | 4 | | | 4 | 4 |
| Genital lesion | 1 | 1 | 1 | 1 | | |
| Genital ulceration | 1 | 1 | 1 | 1 | | |
| Infertility | 1 | 1 | 1 | 1 | | |
| Menopausal symptoms | 1 | 1 | 1 | 1 | | |
| Menorrhagia | 5 | 8 | 5 | 8 | | |
| Menstrual disorder | 4 | 12 | 4 | 12 | | |
| Menstruation delayed | 2 | 2 | 1 | 1 | 1 | 1 |
| Menstruation irregular | 1 | 11 | 1 | 11 | | |
| Metrorrhagia | 2 | 6 | 2 | 6 | | |
| Nipple pain | 1 | 4 | 1 | 4 | | |
| Nipple swelling | | 2 | | 2 | | |
| Pelvic pain | 1 | 3 | 1 | 3 | | |
| Penile haemorrhage | | 1 | | | | 1 |
| Polymenorrhoea | 1 | 1 | 1 | 1 | | |
| Premenstrual syndrome | 2 | 2 | 2 | 2 | | |
| Pruritus genital | | 1 | | | | 1 |
| Scrotal disorder | 1 | 1 | 1 | 1 | | |
| Scrotal erythema | 1 | 1 | 1 | 1 | | |
| Scrotal inflammation | 1 | 1 | 1 | 1 | | |
| Scrotal pain | 1 | 1 | 1 | 1 | | |
| Suppressed lactation | | 1 | | 1 | | |

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System Organ Class

Reproductive system and breast disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Testicular pain | 2 | 2 | 2 | 2 | | |
| Testicular swelling | | 1 | | 1 | | |
| Uterine haemorrhage | | 1 | | | | 1 |
| Uterine inflammation | 1 | 1 | 1 | 1 | | |
| Vaginal discharge | 1 | 1 | 1 | 1 | | |
| Vaginal haemorrhage | 1 | 8 | 1 | 4 | | 4 |
| Vaginal lesion | 1 | 1 | 1 | 1 | | |
| Vulval disorder | 1 | 1 | 1 | 1 | | |
| Vulvovaginal pruritus | | 1 | | | | 1 |
| Vulvovaginal rash | | 1 | | | | 1 |
| Vulvovaginal swelling | | 1 | | | | 1 |
| Withdrawal bleed | 1 | 1 | 1 | 1 | | |
| | 59 | 130 | 54 | 114 | 5 | 16 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Acute respiratory distress syndrome | | 1 | | | | 1 |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Aphonia | 2 | 4 | 1 | 2 | 1 | 2 |
| Aspiration | 1 | 1 | | | 1 | 1 |
| Asthma | 12 | 25 | 10 | 21 | 2 | 4 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Bronchiectasis | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 6 | | 4 | 1 | 2 |
| Choking | 1 | 4 | | | 1 | 4 |
| Choking sensation | 1 | 3 | | | 1 | 3 |
| Chronic obstructive pulmonary disease | 3 | 4 | | 1 | 3 | 3 |
| Cough | 116 | 369 | 103 | 321 | 13 | 48 |
| Diaphragmatic paralysis | 1 | 1 | | | 1 | 1 |
| Dry throat | 5 | 30 | 5 | 25 | | 5 |
| Dysphonia | 15 | 45 | 11 | 29 | 4 | 16 |
| Dyspnoea | 175 | 477 | 112 | 309 | 63 | 168 |
| Dyspnoea exertional | 6 | 16 | 6 | 14 | | 2 |
| Epistaxis | 16 | 40 | 11 | 34 | 5 | 6 |
| Grunting | | 2 | | 1 | | 1 |
| Haemoptysis | 3 | 11 | 2 | 8 | 1 | 3 |
| Hiccups | 2 | 5 | 2 | 5 | | |
| Hyperventilation | 5 | 14 | 4 | 9 | 1 | 5 |
| Hypopnoea | 3 | 6 | 2 | 4 | 1 | 2 |
| Hypoxia | | 2 | | | | 2 |
| Increased bronchial secretion | | 1 | | 1 | | |
| Increased upper airway secretion | 1 | 5 | | 3 | 1 | 2 |
| Increased viscosity of bronchial secretion | 1 | 1 | | | 1 | 1 |
| Increased viscosity of upper respiratory secretion | 1 | 1 | | | 1 | 1 |
| Intranasal paraesthesia | 1 | 3 | 1 | 3 | | |
| Irregular breathing | 1 | 1 | 1 | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Laryngeal oedema | 1 | 3 |
| Laryngeal pain | | 1 |
| Laryngospasm | | 3 |
| Lower respiratory tract congestion | | 1 |
| Lung disorder | 3 | 5 |
| Lung infiltration | 1 | 3 |
| Nasal congestion | 42 | 173 |
| Nasal crusting | 1 | 1 |
| Nasal discomfort | 5 | 12 |
| Nasal disorder | 1 | 2 |
| Nasal dryness | 1 | 4 |
| Nasal oedema | 5 | 12 |
| Nasal pruritus | 2 | 2 |
| Obstructive airways disorder | | 4 |
| Organising pneumonia | | 1 |
| Oropharyngeal blistering | | 1 |
| Oropharyngeal discomfort | 6 | 22 |
| Oropharyngeal pain | 78 | 283 |
| Oropharyngeal spasm | 2 | 3 |
| Oropharyngeal swelling | | 1 |
| Orthopnoea | | 1 |
| Painful respiration | 5 | 8 |
| Paranasal sinus discomfort | 4 | 16 |
| Paranasal sinus hypersecretion | 3 | 5 |
| Pharyngeal disorder | 1 | 4 |
| Pharyngeal enanthema | 1 | 1 |
| Pharyngeal erythema | 1 | 6 |
| Pharyngeal hypoaesthesia | 3 | 12 |
| Pharyngeal inflammation | 1 | 4 |
| Pharyngeal mass | 3 | 3 |
| Pharyngeal oedema | 2 | 4 |
| Pharyngeal paraesthesia | 3 | 21 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 3 |
| | 1 | | |
| | | | 3 |
| | 1 | | |
| 1 | 3 | 2 | 2 |
| | 1 | 1 | 2 |
| 40 | 161 | 2 | 12 |
| 1 | 1 | | |
| 5 | 10 | | 2 |
| 1 | 2 | | |
| 1 | 3 | | 1 |
| 2 | 7 | 3 | 5 |
| 2 | 2 | | |
| | 1 | | 3 |
| | | | 1 |
| | 1 | | |
| 5 | 15 | 1 | 7 |
| 74 | 265 | 4 | 18 |
| | | 2 | 3 |
| | | | 1 |
| | | | 1 |
| 3 | 6 | 2 | 2 |
| 4 | 16 | | |
| 3 | 5 | | |
| 1 | 4 | | |
| 1 | 1 | | |
| 1 | 5 | | 1 |
| 3 | 8 | | 4 |
| 1 | 4 | | |
| 2 | 2 | 1 | 1 |
| | | 2 | 4 |
| 3 | 15 | | 6 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Pharyngeal swelling | 31 | 96 |
| Pleural effusion | | 2 |
| Pleurisy | 2 | 3 |
| Pleuritic pain | 1 | 3 |
| Pneumonia aspiration | 2 | 2 |
| Pneumonitis | | 1 |
| Productive cough | 7 | 19 |
| Pulmonary congestion | 2 | 6 |
| Pulmonary embolism | | 3 |
| Pulmonary oedema | 2 | 3 |
| Pulmonary pain | 5 | 8 |
| Pulmonary thrombosis | 3 | 3 |
| Respiration abnormal | 2 | 3 |
| Respiratory arrest | 2 | 4 |
| Respiratory disorder | 6 | 9 |
| Respiratory distress | 4 | 15 |
| Respiratory failure | 1 | 4 |
| Respiratory symptom | 1 | 2 |
| Respiratory tract congestion | 5 | 15 |
| Respiratory tract oedema | | 1 |
| Rhinalgia | 2 | 8 |
| Rhinitis allergic | | 1 |
| Rhinorrhoea | 54 | 164 |
| Sinus congestion | 3 | 18 |
| Sinus disorder | 11 | 22 |
| Sinus pain | 2 | 10 |
| Sneezing | 15 | 44 |
| Snoring | 1 | 3 |
| Sputum discoloured | | 3 |
| Status asthmaticus | | 1 |
| Stridor | 1 | 5 |
| Suffocation feeling | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 20 | 56 | 11 | 40 |
| | | | 2 |
| 1 | 1 | 1 | 2 |
| 1 | 3 | | |
| | | 2 | 2 |
| | 1 | | |
| 7 | 17 | | 2 |
| | | 2 | 6 |
| | | | 3 |
| | | 2 | 3 |
| 5 | 7 | | 1 |
| | | 3 | 3 |
| 1 | 2 | 1 | 1 |
| | | 2 | 4 |
| 3 | 5 | 3 | 4 |
| 1 | 2 | 3 | 13 |
| | 1 | 1 | 3 |
| 1 | 1 | | 1 |
| 5 | 15 | | |
| | | | 1 |
| 2 | 8 | | |
| | 1 | | |
| 53 | 156 | 1 | 8 |
| 3 | 17 | | 1 |
| 10 | 21 | 1 | 1 |
| 2 | 10 | | |
| 15 | 44 | | |
| 1 | 2 | | 1 |
| | 2 | | 1 |
| | | | 1 |
| | | 1 | 5 |
| | 1 | | |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachypnoea | 1 | 6 | 1 | 3 | | 3 |
| Throat clearing | 3 | 5 | 2 | 3 | 1 | 2 |
| Throat irritation | 35 | 123 | 29 | 99 | 6 | 24 |
| Throat tightness | 31 | 118 | 15 | 58 | 16 | 60 |
| Tonsillar disorder | 1 | 1 | | | 1 | 1 |
| Tonsillar erythema | | 1 | | 1 | | |
| Tonsillar hypertrophy | 3 | 6 | 3 | 6 | | |
| Tonsillolith | | 1 | | 1 | | |
| Tracheomalacia | | 1 | | | | 1 |
| Upper-airway cough syndrome | 4 | 15 | 4 | 15 | | |
| Upper airway obstruction | | 2 | | | | 2 |
| Upper respiratory tract congestion | 7 | 29 | 7 | 28 | | 1 |
| Use of accessory respiratory muscles | 1 | 1 | 1 | 1 | | |
| Vocal cord disorder | 3 | 3 | | | 3 | 3 |
| Wheezing | 12 | 41 | 9 | 26 | 3 | 15 |
| | 818 | 2,539 | 627 | 1949 | 191 | 590 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acne | 4 | 9 | 4 | 9 | | |
| Alopecia | 1 | 4 | 1 | 4 | | |
| Angioedema | 6 | 18 | | | 6 | 18 |
| Blister | 10 | 29 | 6 | 25 | 4 | 4 |
| Blood blister | 1 | 1 | | | 1 | 1 |
| Butterfly rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Circumoral swelling | | 1 | | 1 | | |
| Cold sweat | 16 | 51 | 15 | 46 | 1 | 5 |
| Dermatitis | 3 | 8 | 3 | 8 | | |
| Dermatitis acneiform | 1 | 1 | 1 | 1 | | |
| Dermatitis allergic | | 4 | | 3 | | 1 |
| Dermatitis contact | | 4 | | 4 | | |
| Dermatitis diaper | 1 | 1 | | | 1 | 1 |
| Dermatitis exfoliative | | 1 | | | | 1 |
| Diabetic wound | 1 | 1 | | | 1 | 1 |
| Drug eruption | | 2 | | 2 | | |
| Dry skin | 8 | 11 | 8 | 11 | | |
| Ecchymosis | | 1 | | 1 | | |
| Eczema | 2 | 4 | 2 | 4 | | |
| Erythema | 94 | 253 | 81 | 217 | 13 | 36 |
| Hidradenitis | | 2 | | 2 | | |
| Hyperhidrosis | 101 | 289 | 94 | 266 | 7 | 23 |
| Livedo reticularis | 1 | 4 | | 1 | 1 | 3 |
| Macule | 1 | 2 | 1 | 2 | | |
| Madarosis | 1 | 1 | 1 | 1 | | |
| Mechanical urticaria | | 1 | | 1 | | |
| Miliaria | 3 | 3 | 3 | 3 | | |
| Night sweats | 27 | 72 | 27 | 67 | | 5 |
| Pain of skin | 9 | 23 | 8 | 21 | 1 | 2 |
| Palmar erythema | | 4 | | 3 | | 1 |
| Palpable purpura | 1 | 1 | 1 | 1 | | |
| Papule | | 2 | | 2 | | |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pemphigoid | 1 | 1 | | | 1 | 1 |
| Petechiae | 7 | 17 | 5 | 13 | 2 | 4 |
| Photosensitivity reaction | 3 | 11 | 3 | 11 | | |
| Pigmentation disorder | 1 | 1 | | | 1 | 1 |
| Piloerection | | 5 | | 4 | | 1 |
| Pityriasis | 1 | 1 | 1 | 1 | | |
| Plantar erythema | | 1 | | 1 | | |
| Pruritus | 156 | 481 | 136 | 429 | 20 | 52 |
| Psoriasis | 2 | 3 | 2 | 3 | | |
| Purpura | 2 | 3 | 1 | 2 | 1 | 1 |
| Rash | 168 | 471 | 138 | 399 | 30 | 72 |
| Rash erythematous | 32 | 82 | 29 | 69 | 3 | 13 |
| Rash macular | 16 | 54 | 13 | 47 | 3 | 7 |
| Rash maculo-papular | 3 | 13 | 3 | 13 | | |
| Rash morbilliform | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash papular | 10 | 30 | 9 | 29 | 1 | 1 |
| Rash pruritic | 23 | 77 | 21 | 72 | 2 | 5 |
| Rash vesicular | 6 | 14 | 5 | 12 | 1 | 2 |
| Rosacea | 1 | 2 | 1 | 2 | | |
| Scab | 1 | 2 | 1 | 2 | | |
| Sensitive skin | 4 | 11 | 4 | 11 | | |
| Skin burning sensation | 10 | 24 | 9 | 23 | 1 | 1 |
| Skin depigmentation | 1 | 1 | 1 | 1 | | |
| Skin discolouration | 9 | 26 | 8 | 22 | 1 | 4 |
| Skin discomfort | 1 | 1 | 1 | 1 | | |
| Skin disorder | 9 | 23 | 7 | 20 | 2 | 3 |
| Skin exfoliation | 6 | 10 | 6 | 9 | | 1 |
| Skin fissures | 1 | 1 | | | 1 | 1 |
| Skin haemorrhage | 1 | 1 | 1 | 1 | | |
| Skin indentation | | 1 | | 1 | | |
| Skin irritation | 3 | 11 | 3 | 11 | | |
| Skin laxity | 1 | 1 | 1 | 1 | | |

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System Organ Class

Skin and subcutaneous tissue disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Skin lesion | 8 | 10 | 8 | 10 | | |
| Skin mass | 1 | 2 | 1 | 2 | | |
| Skin odour abnormal | | 1 | | 1 | | |
| Skin oedema | 1 | 1 | 1 | 1 | | |
| Skin reaction | 4 | 8 | 3 | 6 | 1 | 2 |
| Skin swelling | 3 | 7 | 3 | 7 | | |
| Skin tightness | | 3 | | 2 | | 1 |
| Skin ulcer | 1 | 1 | 1 | 1 | | |
| Skin warm | | 2 | | 2 | | |
| Stevens-Johnson syndrome | | 1 | | | | 1 |
| Urticaria | 78 | 333 | 61 | 266 | 17 | 67 |
| Vasculitic rash | 1 | 1 | 1 | 1 | | |
| Yellow skin | 2 | 2 | 1 | 1 | 1 | 1 |
| | 874 | 2,564 | 747 | 2218 | 127 | 346 |

System Organ Class

Social circumstances

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bedridden | 1 | 8 | 1 | 7 | | 1 |
| Contraindication to vaccination | 1 | 2 | 1 | 2 | | |
| Exercise lack of | | 1 | | 1 | | |
| Impaired driving ability | 5 | 9 | 5 | 9 | | |
| Impaired work ability | 2 | 11 | 2 | 11 | | |
| Loss of personal independence in daily activities | 15 | 40 | 10 | 32 | 5 | 8 |
| Sitting disability | 1 | 1 | 1 | 1 | | |
| Urinary assistance device user | 1 | 1 | 1 | 1 | | |
| Walking disability | 1 | 1 | | | 1 | 1 |
| | 27 | 74 | 21 | 64 | 6 | 10 |

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System Organ Class

Surgical and medical procedures

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 immunisation | | 1 | | 1 | | |
| Endodontic procedure | 1 | 1 | 1 | 1 | | |
| Spinal fusion surgery | | 1 | | | | 1 |
| Wound closure | 1 | 1 | 1 | 1 | | |
| | 2 | 4 | 2 | 3 | | 1 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aneurysm | 1 | 1 | | | 1 | 1 |
| Aneurysm ruptured | 1 | 1 | | | 1 | 1 |
| Angiopathy | 2 | 2 | 2 | 2 | | |
| Blood pressure fluctuation | 5 | 8 | 5 | 7 | | 1 |
| Circulatory collapse | | 3 | | | | 3 |
| Cyanosis | 2 | 9 | 1 | 6 | 1 | 3 |
| Deep vein thrombosis | 4 | 10 | | | 4 | 10 |
| Diastolic hypotension | | 1 | | | | 1 |
| Flushing | 45 | 213 | 38 | 165 | 7 | 48 |
| Giant cell arteritis | | 1 | | 1 | | |
| Haemorrhage | 13 | 19 | | 1 | 13 | 18 |
| Hot flush | 23 | 81 | 19 | 71 | 4 | 10 |
| Hyperaemia | | 1 | | 1 | | |
| Hypertension | 64 | 140 | 39 | 87 | 25 | 53 |
| Hypertensive crisis | 1 | 3 | | | 1 | 3 |
| Hypertensive emergency | | 3 | | | | 3 |
| Hypotension | 17 | 35 | 10 | 21 | 7 | 14 |
| Internal haemorrhage | 1 | 1 | | | 1 | 1 |
| Labile hypertension | | 1 | | 1 | | |
| Lymphoedema | 2 | 11 | 2 | 11 | | |
| Malignant hypertension | 1 | 1 | | | 1 | 1 |
| May-Thurner syndrome | 1 | 1 | | | 1 | 1 |
| Microembolism | | 1 | | | | 1 |
| Orthostatic hypotension | 2 | 3 | 1 | 1 | 1 | 2 |
| Pallor | 18 | 37 | 11 | 26 | 7 | 11 |
| Peripheral coldness | 14 | 43 | 13 | 41 | 1 | 2 |
| Peripheral vascular disorder | 1 | 2 | 1 | 2 | | |
| Phlebitis | | 1 | | 1 | | |
| Poor peripheral circulation | | 2 | | 1 | | 1 |
| Raynaud's phenomenon | 1 | 3 | 1 | 3 | | |
| Shock | 2 | 2 | | | 2 | 2 |
| Shock symptom | 2 | 4 | | | 2 | 4 |

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System Organ Class

Vascular disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Superficial vein prominence | | 1 | | 1 | | |
| Systolic hypertension | 1 | 1 | | | 1 | 1 |
| Thrombosis | 14 | 18 | | | 14 | 18 |
| Varicose vein | | 1 | | 1 | | |
| Vascular pain | | 1 | | 1 | | |
| Vasodilatation | | 1 | | 1 | | |
| Vein discolouration | 2 | 3 | 2 | 3 | | |
| Vein disorder | 1 | 1 | 1 | 1 | | |
| | 241 | 671 | 146 | 457 | 95 | 214 |

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* I=Interval, C=Cumulative
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Country Where Event Occurred
UNITED STATES MINOR OUTLYING ISLA

System Organ Class

General disorders and administration site conditions

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vaccination site pain | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Injury, poisoning and procedural complications

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Cough | 1 | 1 | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 |
| Sinus congestion | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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APPENDIX 2.5.2: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Age Group by Preferred Term per Country

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval) / 42,086 (Cumulative)

Total Number of Adverse Events (PT): 91,739 (Interval) / 158,648 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

AFGHANISTAN

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chills | | 1 | | 1 | | |
| Erythema | | 1 | | 1 | | |
| Facial paralysis | | 1 | | | | 1 |
| Feeling of body temperature change | | 1 | | 1 | | |
| Muscle tightness | | 1 | | 1 | | |
| Paraesthesia | | 1 | | 1 | | |
| Pruritus | | 1 | | 1 | | |
| Rash | | 1 | | 1 | | |
| Swelling face | | 1 | | 1 | | |
| | | 9 | | 8 | | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Country Where Event Occurred

ANDORRA

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product administered to patient of inappropriate age | | 1 | | 1 |
| | | 1 | | 1 |

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* I=Interval, C=Cumulative
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 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANGOLA

Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 1 | 1 | 4 | 4 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRIA

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dyspnoea exertional | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 1 | 1 | 4 | 4 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Asthenia | 3 | 3 | 2 | 2 | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 1 | 1 | 1 | 1 | | |
| Chills | 2 | 2 | 1 | 1 | 1 | 1 |
| Circulatory collapse | 3 | 3 | | | 3 | 3 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 2 | 2 | 2 | 2 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Diarrhoea haemorrhagic | 1 | 1 | | | 1 | 1 |
| Diplopia | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 2 | 2 | | | 2 | 2 |
| Dizziness | 6 | 6 | 3 | 3 | 3 | 3 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Fatigue | 6 | 6 | 4 | 4 | 2 | 2 |
| Feeling cold | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Feeling jittery | 1 | 1 | 1 | 1 | | |
| Flushing | 2 | 2 | | | 2 | 2 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 12 | 12 | 10 | 10 | 2 | 2 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 2 | 2 | 1 | 1 | 1 | 1 |
| Impaired work ability | 1 | 1 | | | 1 | 1 |

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

Age Range

18 - 30 years

| Preferred Term | Interval Total # | Cumulative Total # | Spontaneous | | | |
|-----------------------------|------------------|--------------------|-------------|---|---------|---|
| | Spontaneous AE | Spontaneous AE | Nonserious | | Serious | |
| | | | I | C | I | C |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Nausea | 2 | 2 | 2 | 2 | | |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 2 | 2 | 2 | 2 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 3 | 3 | 3 | 3 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 2 | 2 | | | 2 | 2 |
| Parosmia | 1 | 1 | 1 | 1 | | |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Poor peripheral circulation | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 6 | 6 | 5 | 5 | 1 | 1 |
| Rash | 3 | 3 | | | 3 | 3 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 6 | 6 | 5 | 5 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vertigo | 3 | 3 | 2 | 2 | 1 | 1 |
| Vomiting | 2 | 2 | 2 | 2 | | |
| | 119 | 119 | 62 | 62 | 57 | 57 |

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

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Alopecia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 3 | 4 | | | 3 | 4 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 11 | 11 | 4 | 4 | 7 | 7 |
| Asthenia | 4 | 4 | 4 | 4 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 3 | 3 | 1 | 1 | 2 | 2 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 4 | 4 | 4 | 4 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Burning sensation | 1 | 2 | | 1 | 1 | 1 |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Cardiovascular disorder | 3 | 3 | 2 | 2 | 1 | 1 |
| Chapped lips | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 17 | 17 | 7 | 7 | 10 | 10 |
| Circulatory collapse | 5 | 5 | | | 5 | 5 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 5 | 6 | 3 | 4 | 2 | 2 |
| Disorganised speech | 1 | 1 | 1 | 1 | | |
| Dizziness | 16 | 16 | 11 | 11 | 5 | 5 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dry mouth | 2 | 2 | 2 | 2 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Dry throat | 1 | 1 |
| Dysaesthesia | 1 | 1 |
| Dysgraphia | 1 | 1 |
| Dysphagia | 1 | 1 |
| Dyspnoea | 5 | 5 |
| Dyspnoea exertional | 1 | 1 |
| Ear infection | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Erythema | 2 | 2 |
| Eye pain | 1 | 1 |
| Eye swelling | 1 | 1 |
| Facial paralysis | 2 | 2 |
| Facial paresis | 1 | 1 |
| Fatigue | 18 | 20 |
| Feeling abnormal | 2 | 2 |
| Feeling cold | 1 | 1 |
| Feeling drunk | 1 | 2 |
| Feeling hot | 2 | 2 |
| Fibrin D dimer increased | 1 | 1 |
| Flushing | 3 | 3 |
| Formication | 1 | 1 |
| Gastrointestinal disorder | 1 | 1 |
| Hangover | | 1 |
| Headache | 30 | 31 |
| Hemiparaesthesia | 1 | 1 |
| Hepatic pain | 1 | 1 |
| Hot flush | 2 | 2 |
| Hypersensitivity | 5 | 5 |
| Hypersomnia | 1 | 1 |
| Hypertension | 3 | 3 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 7 | 7 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 15 | 17 | 3 | 3 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 19 | 20 | 11 | 11 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 5 | 5 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 6 | 6 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypoaesthesia oral | 2 | 2 |
| Hypotension | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Insomnia | 3 | 3 |
| Lacrimation increased | 1 | 1 |
| Laryngeal pain | 1 | 1 |
| Lip dry | 1 | 1 |
| Lip erythema | 1 | 1 |
| Lip pruritus | 1 | 1 |
| Lip swelling | 4 | 4 |
| Lividity | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenopathy | 7 | 7 |
| Lymph node pain | 2 | 2 |
| Malaise | 4 | 5 |
| Memory impairment | 1 | 1 |
| Migraine | 1 | 3 |
| Monoplegia | 1 | 1 |
| Movement disorder | 1 | 1 |
| Muscle spasms | 2 | 2 |
| Muscular weakness | 3 | 3 |
| Myalgia | 7 | 8 |
| Myocarditis | 1 | 1 |
| Narcolepsy | 1 | 1 |
| Nausea | 15 | 16 |
| Neuralgia | 2 | 2 |
| Neuralgic amyotrophy | 1 | 1 |
| Neuritis | 1 | 1 |
| Nuchal rigidity | 1 | 1 |
| Obstructive airways disorder | 1 | 1 |
| Occipital neuralgia | 1 | 1 |
| Ocular hyperaemia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 2 | 2 |
| 3 | 3 | 4 | 4 |
| 2 | 2 | | |
| 3 | 4 | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 2 | 3 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 6 | 7 | 9 | 9 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Off label use | 2 | 2 |
| Oral discomfort | 2 | 2 |
| Oral pruritus | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 3 | 3 |
| Pain in extremity | 12 | 12 |
| Pain of skin | 1 | 1 |
| Palatal swelling | 1 | 1 |
| Pallor | 1 | 1 |
| Palmar erythema | 1 | 1 |
| Palpitations | 4 | 4 |
| Panic attack | 1 | 1 |
| Paraesthesia | 13 | 13 |
| Paraesthesia oral | 2 | 2 |
| Paresis | 1 | 1 |
| Peripheral coldness | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal swelling | 1 | 1 |
| Poor quality product administered | | 1 |
| Presyncope | 7 | 7 |
| Product preparation error | | 1 |
| Product use issue | 2 | 2 |
| Pruritus | 12 | 13 |
| Pupils unequal | 1 | 1 |
| Pyrexia | 15 | 15 |
| Rash | 5 | 5 |
| Rash morbilliform | 1 | 1 |
| Rash pruritic | 2 | 2 |
| Rash pustular | 1 | 1 |
| Reduced facial expression | 1 | 1 |
| Respiratory disorder | 1 | 1 |
| Restlessness | 3 | 3 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| 9 | 9 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| 5 | 5 | 8 | 8 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | 6 | 6 |
| | 1 | | |
| 2 | 2 | | |
| 2 | 3 | 10 | 10 |
| | | 1 | 1 |
| 6 | 6 | 9 | 9 |
| 3 | 3 | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Rhinitis allergic | 1 | 1 |
| Sensation of foreign body | 1 | 1 |
| Shock | 1 | 1 |
| Skin burning sensation | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Skin tightness | 1 | 1 |
| Sleep attacks | 1 | 1 |
| Sleep disorder due to general medical condition, hypersomnia type | 1 | 1 |
| Somatic symptom disorder | 1 | 1 |
| Somnolence | 5 | 5 |
| Speech disorder | 1 | 1 |
| Swelling | 2 | 2 |
| Swelling face | 2 | 2 |
| Swollen tongue | 4 | 4 |
| Syncope | 3 | 3 |
| Syringe issue | 1 | 1 |
| Tachycardia | 2 | 2 |
| Taste disorder | 1 | 1 |
| Throat irritation | 3 | 3 |
| Throat tightness | 1 | 1 |
| Thrombocytopenia | 1 | 1 |
| Tongue discomfort | 1 | 1 |
| Tremor | 1 | 1 |
| Trigeminal neuralgia | 1 | 1 |
| Underdose | 1 | 1 |
| Urticaria | 3 | 3 |
| Urticaria pressure | 1 | 1 |
| Vaccination site discolouration | 2 | 2 |
| Vaccination site erythema | 2 | 2 |
| Vaccination site haemorrhage | 1 | 1 |
| Vaccination site induration | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 5 | 5 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| 2 | 2 | 2 | 2 |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site lymphadenopathy | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site movement impairment | 3 | 3 | 3 | 3 | | |
| Vaccination site pain | 20 | 23 | 18 | 21 | 2 | 2 |
| Vaccination site pruritus | 2 | 3 | | 1 | 2 | 2 |
| Vaccination site pustule | 1 | 1 | 1 | 1 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 5 | 5 | 3 | 3 | 2 | 2 |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 4 | 4 | 2 | 2 | 2 | 2 |
| Viral rash | 1 | 1 | | | 1 | 1 |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 467 | 487 | 222 | 241 | 245 | 246 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 4 | 4 | 2 | 2 | 2 | 2 |
| Asthenia | 3 | 3 | 3 | 3 | | |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blepharospasm | 1 | 1 | | | 1 | 1 |
| Blood lactate dehydrogenase increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Bundle branch block right | 1 | 1 | | | 1 | 1 |
| Bursitis | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 2 | 3 | 2 | 3 | | |
| Chills | 10 | 10 | 7 | 7 | 3 | 3 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Concomitant disease aggravated | 1 | 1 | | | 1 | 1 |
| Conjunctivitis | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 4 | 5 | 3 | 4 | 1 | 1 |
| Diplopia | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disease progression | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | 1 | 1 | | |
| Dizziness | 6 | 6 | 4 | 4 | 2 | 2 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dysphagia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 2 | 2 | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Ear discomfort | 1 | 1 |
| Erythema | 3 | 3 |
| Eye irritation | 1 | 1 |
| Eye pruritus | 1 | 1 |
| Face oedema | 2 | 2 |
| Facial paralysis | 1 | 1 |
| Facial paresis | 2 | 2 |
| Fatigue | 14 | 15 |
| Feeling of body temperature change | 1 | 1 |
| Flushing | 3 | 3 |
| Headache | 15 | 15 |
| Herpes zoster | 1 | 1 |
| Histamine intolerance | 1 | 1 |
| Hypersensitivity | 3 | 3 |
| Hypoaesthesia | 2 | 2 |
| Hypogeusia | 1 | 1 |
| Hyposmia | 1 | 1 |
| Impaired work ability | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Inflammation | 1 | 1 |
| Influenza like illness | 1 | 1 |
| Injection site urticaria | 1 | 1 |
| Intraocular pressure increased | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 3 | 3 |
| Lymph node pain | 1 | 1 |
| Lymph node palpable | 1 | 1 |
| Malaise | 2 | 2 |
| Migraine | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Movement disorder | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 12 | 13 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 13 | 13 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Muscular weakness | 1 | 1 |
| Myalgia | 3 | 3 |
| Nausea | 8 | 9 |
| Neuropathy peripheral | 1 | 1 |
| Night sweats | 1 | 1 |
| Ocular hyperaemia | 1 | 1 |
| Oedema mucosal | 1 | 1 |
| Oral mucosal erythema | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain in extremity | 3 | 3 |
| Pallor | 1 | 1 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 8 | 8 |
| Paraesthesia oral | 2 | 2 |
| Pharyngeal swelling | 1 | 1 |
| Photophobia | 1 | 1 |
| Presyncope | 4 | 4 |
| Product administered at inappropriate site | 1 | 1 |
| Pruritus | 4 | 4 |
| Pyrexia | 11 | 11 |
| Rash | 1 | 1 |
| Rash macular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Rash pustular | 2 | 2 |
| Rheumatoid arthritis | 1 | 1 |
| Serum ferritin increased | 1 | 1 |
| Sinus congestion | 1 | 1 |
| Speech disorder | 1 | 1 |
| Swelling | 1 | 1 |
| Swelling face | 2 | 2 |
| Swelling of eyelid | 1 | 1 |
| Tachycardia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 6 | 7 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 5 | 5 | 3 | 3 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 3 | 3 |
| 6 | 6 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Tendon disorder | 1 | 1 | 1 | 1 | | |
| Tension headache | 2 | 2 | 1 | 1 | 1 | 1 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tongue discomfort | 1 | 1 | 1 | 1 | | |
| Transaminases increased | 1 | 1 | 1 | 1 | | |
| Tunnel vision | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 10 | 10 | 8 | 8 | 2 | 2 |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vertigo | 3 | 3 | 1 | 1 | 2 | 2 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 2 | | 1 | 1 | 1 |
| | 227 | 232 | 133 | 138 | 94 | 94 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute coronary syndrome | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Autoimmune haemolytic anaemia | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Cachexia | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Death | 4 | 4 | | | 4 | 4 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| General physical health deterioration | 2 | 2 | | | 2 | 2 |
| Groin pain | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 2 | 1 | 1 | 1 | 1 |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Influenza | | 1 | | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 2 | 1 | 1 | 1 | 1 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Pyrexia | 5 | 5 | 2 | 2 | 3 | 3 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Systemic inflammatory response syndrome | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 47 | 50 | 17 | 18 | 30 | 32 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 3 | 1 | 1 | | 2 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure immeasurable | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Breath sounds | 1 | 1 | 1 | 1 | | |
| Cardiac failure | 2 | 3 | | | 2 | 3 |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Choking | 1 | 1 | | | 1 | 1 |
| Cholestasis | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| COVID-19 | 2 | 3 | | | 2 | 3 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Death | 4 | 6 | | | 4 | 6 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dizziness postural | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 2 | 3 | | | 2 | 3 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Escherichia sepsis | 1 | 1 | | | 1 | 1 |
| Eye movement disorder | 1 | 1 | | | 1 | 1 |
| Fatigue | 3 | 4 | 2 | 2 | 1 | 2 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 2 | 2 | | | 2 | 2 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypertensive crisis | 2 | 2 | | | 2 | 2 |
| Hypertensive emergency | 1 | 1 | | | 1 | 1 |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Hypotonia | 2 | 2 | 1 | 1 | 1 | 1 |
| Incorrect route of product administration | 1 | 2 | 1 | 2 | | |
| Interleukin level increased | 1 | 1 | | | 1 | 1 |
| Left ventricular failure | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lung infiltration | 1 | 1 | | | 1 | 1 |
| Marasmus | 1 | 1 | | | 1 | 1 |
| Meningitis bacterial | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | | 1 | | | | 1 |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Nausea | 1 | 3 | | 2 | 1 | 1 |
| Oxygen saturation | 1 | 1 | | | 1 | 1 |
| Oxygen saturation immeasurable | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Pemphigus | 1 | 1 | | | 1 | 1 |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pruritus | 2 | 2 | | | 2 | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pulmonary embolism | 1 | 2 | | | 1 | 2 |
| Pulmonary oedema | | 1 | | | | 1 |
| Pyrexia | 5 | 5 | 3 | 3 | 2 | 2 |
| Rales | 1 | 2 | 1 | 1 | | 1 |
| Rash | 2 | 2 | | | 2 | 2 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Respiratory depression | | 1 | | | | 1 |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| Retching | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Seizure | 2 | 2 | | | 2 | 2 |
| Septic shock | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 3 | | | 2 | 3 |
| Syncope | 3 | 3 | | | 3 | 3 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| Urinary retention | | 1 | | | | 1 |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| Vaginal discharge | | 1 | | 1 | | |
| Vomiting | 2 | 4 | 1 | 3 | 1 | 1 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 113 | 135 | 25 | 32 | 88 | 103 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Antiphospholipid syndrome | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Blood creatine phosphokinase MB increased | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Complication associated with device | 1 | 1 | 1 | 1 | | |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| COVID-19 | 13 | 13 | 1 | 1 | 12 | 12 |
| Drug ineffective | 14 | 14 | | | 14 | 14 |
| Dyspnoea | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 4 | 4 | 4 | 4 | | |
| Headache | 4 | 5 | 4 | 5 | | |
| Influenza like illness | 3 | 3 | 3 | 3 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Pneumonia | 2 | 2 | | | 2 | 2 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pruritus | | 1 | | 1 | | |
| Pyrexia | 3 | 3 | 3 | 3 | | |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Urticaria | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 3 | 1 | 3 | | |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 64 | 69 | 28 | 33 | 36 | 36 |

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Country Where Event Occurred

BAHRAIN

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Chills | 2 | 2 | 2 | 2 |
| Hot flush | 1 | 1 | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 |
| Pruritus | | 1 | | 1 |
| Pyrexia | 2 | 2 | 2 | 2 |
| | 10 | 11 | 10 | 11 |

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Country Where Event Occurred
BELGIUM

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Blood pressure decreased | 1 | 1 | 1 | 1 |
| Syncope | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 3 | 3 | | | 3 | 3 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Chills | 3 | 3 | | | 3 | 3 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Endolymphatic hydrops | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Fatigue | 6 | 6 | 2 | 2 | 4 | 4 |
| Headache | 4 | 4 | | | 4 | 4 |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 5 | 5 | 1 | 1 | 4 | 4 |
| Nausea | 5 | 5 | | | 5 | 5 |
| Nervous system disorder | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 5 | 5 | 1 | 1 | 4 | 4 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tonsillitis | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site pain | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site warmth | | 1 | | 1 | | |
| Vertigo | 2 | 2 | | | 2 | 2 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 64 | 66 | 13 | 15 | 51 | 51 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 2 | 2 | 1 | 1 | 1 | 1 |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Angioedema | 3 | 3 | | | 3 | 3 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 3 | | | 3 | 3 |
| Asthenia | | 1 | | 1 | | |
| Back pain | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Chills | 10 | 10 | 2 | 2 | 8 | 8 |
| Coagulopathy | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 1 | 1 | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Dizziness | 4 | 4 | 1 | 1 | 3 | 3 |
| Dizziness postural | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Erythema | 2 | 2 | 2 | 2 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fatigue | 17 | 18 | 4 | 5 | 13 | 13 |
| Feeling cold | 1 | 1 | | | 1 | 1 |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Flushing | 1 | 1 | 1 | 1 | | |
| Headache | 21 | 22 | 3 | 4 | 18 | 18 |
| Heart rate irregular | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Hypertension | 2 | 2 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Influenza | 1 | 1 |
| Influenza like illness | 1 | 1 |
| Insomnia | 1 | 1 |
| Lip swelling | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Lymphoedema | 1 | 1 |
| Malaise | 9 | 9 |
| Musculoskeletal stiffness | 1 | 3 |
| Myalgia | 16 | 16 |
| Nasal congestion | 1 | 1 |
| Nausea | 8 | 8 |
| Neck pain | 2 | 2 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 1 | 1 |
| Neurogenic shock | 1 | 1 |
| Off label use | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 5 | 6 |
| Palpitations | 2 | 3 |
| Peripheral swelling | 1 | 1 |
| Poor quality sleep | | 1 |
| Presyncope | 1 | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 2 | 2 |
| Pyrexia | 11 | 11 |
| Respiratory disorder | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 6 | 6 |
| | 2 | 1 | 1 |
| 1 | 1 | 15 | 15 |
| 1 | 1 | | |
| 1 | 1 | 7 | 7 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 10 | 10 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Sensory disturbance | 1 | 2 | 1 | 2 | | |
| Skin disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Sleep deficit | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 1 | 1 | | | 1 | 1 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Swollen tongue | | 1 | | 1 | | |
| Syncope | 3 | 3 | | | 3 | 3 |
| Tachycardia | 3 | 3 | 1 | 1 | 2 | 2 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Thoracic outlet syndrome | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis | 1 | 1 | | | 1 | 1 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 5 | 2 | 4 | 1 | 1 |
| Vaccination site reaction | 5 | 5 | | | 5 | 5 |
| Vaccination site swelling | 2 | 3 | 2 | 3 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| | 204 | 217 | 49 | 62 | 155 | 155 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anxiety | 2 | 2 | | | 2 | 2 |
| Arthralgia | 5 | 5 | | | 5 | 5 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Asthma exercise induced | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Balance disorder | 2 | 2 | | | 2 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chillblains | 1 | 1 | | | 1 | 1 |
| Chills | 14 | 14 | | | 14 | 14 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Diabetic complication | 1 | 1 | | | 1 | 1 |
| Dizziness | 3 | 4 | | | 3 | 4 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 3 | 3 | | | 3 | 3 |
| Dystonia | 1 | 1 | | | 1 | 1 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Erythema | 2 | 2 | | | 2 | 2 |
| Fall | | 1 | | | | 1 |
| Fatigue | 14 | 14 | | | 14 | 14 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Headache | 15 | 15 |
| Heart rate increased | 1 | 1 |
| Hot flush | 2 | 2 |
| Hyperhidrosis | 2 | 2 |
| Hypertension | 3 | 3 |
| Incorrect route of product administration | 1 | 1 |
| Infection | 1 | 1 |
| Influenza like illness | 2 | 2 |
| Insomnia | 1 | 1 |
| Laryngitis | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Malaise | 12 | 12 |
| Memory impairment | | 1 |
| Mobility decreased | 1 | 1 |
| Muscle tightness | 1 | 1 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 10 | 10 |
| Nausea | 10 | 10 |
| Neck pain | 1 | 1 |
| Nervous system disorder | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 2 | 2 |
| Pallor | 1 | 1 |
| Paraesthesia | 2 | 2 |
| Paraesthesia oral | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal swelling | 1 | 1 |
| Pruritus | 1 | 1 |
| Pyrexia | 11 | 11 |
| Rash | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 14 | 14 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 12 | 12 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 10 | 10 |
| | | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 10 | 10 |
| | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 3 | 3 | | | 3 | 3 |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sleep disorder due to a general medical condition | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 2 | | | 2 | 2 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 4 | 4 | | | 4 | 4 |
| Vaccination site reaction | 6 | 6 | | | 6 | 6 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vertigo | 3 | 3 | 1 | 1 | 2 | 2 |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 2 | 2 | | | 2 | 2 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 198 | 201 | 8 | 9 | 190 | 192 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Arthralgia | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 2 | 2 | 2 | 2 | | |
| Cardiac arrest | | 1 | | | | 1 |
| Cardio-respiratory arrest | 2 | 2 | | | 2 | 2 |
| Cardiovascular disorder | | 2 | | | | 2 |
| Chills | 3 | 3 | | | 3 | 3 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysphagia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 2 | | 1 | 1 | 1 |
| Gait disturbance | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Headache | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Lip swelling | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 3 | | 1 | 2 | 2 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 5 | 5 | 1 | 1 | 4 | 4 |
| Nausea | 3 | 4 | 1 | 2 | 2 | 2 |
| Neutrophilia | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pneumonitis | 1 | 1 | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pulmonary embolism | | 1 | | | | 1 |
| Pyrexia | 5 | 5 | | | 5 | 5 |
| Salivary hypersecretion | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Sensation of foreign body | 2 | 2 | 2 | 2 | | |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 2 | 2 | 1 | 1 | 1 | 1 |
| | 65 | 72 | 13 | 16 | 52 | 56 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | | | 1 |
| Acute kidney injury | 1 | 2 | | | 1 | 2 |
| Acute respiratory failure | 1 | 2 | | | 1 | 2 |
| Agitation | 2 | 4 | | | 2 | 4 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Amnesia | | 1 | | | | 1 |
| Angle closure glaucoma | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Blood lactic acid increased | 1 | 2 | | | 1 | 2 |
| Bradycardia | | 1 | | | | 1 |
| Cardiac disorder | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 5 | 7 | | | 5 | 7 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Cheyne-Stokes respiration | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Coma | 1 | 1 | | | 1 | 1 |
| Confusional state | | 2 | | | | 2 |
| COVID-19 | 4 | 4 | | | 4 | 4 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Death | | 1 | | | | 1 |
| Depressed level of consciousness | 3 | 4 | | | 3 | 4 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Disorientation | | 1 | | | | 1 |
| Drug ineffective | 3 | 3 | | | 3 | 3 |
| Dry skin | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 3 | | | 2 | 3 |
| Dysstasia | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Eye movement disorder | | 1 | | | | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Fall | 4 | 4 | 1 | 1 | 3 | 3 |
| Fatigue | 2 | 3 | 1 | 2 | 1 | 1 |
| Fibrin D dimer increased | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 6 | 7 | | | 6 | 7 |
| Glaucoma | 1 | 1 | | | 1 | 1 |
| Haemorrhage intracranial | | 1 | | | | 1 |
| Headache | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Herpes ophthalmic | 2 | 2 | | | 2 | 2 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | | 1 | | | | 1 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hyponatraemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 4 | | | 3 | 4 |
| Hypovolaemic shock | | 1 | | | | 1 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Intestinal dilatation | | 1 | | | | 1 |
| Intestinal ischaemia | | 2 | | | | 2 |
| Lacrimation increased | 1 | 1 | 1 | 1 | | |
| Leukocytosis | | 1 | | | | 1 |
| Livedo reticularis | 1 | 1 | | | 1 | 1 |
| Liver function test abnormal | 2 | 3 | | | 2 | 3 |
| Lung infiltration | | 1 | | | | 1 |
| Malaise | 6 | 11 | | 1 | 6 | 10 |
| Metabolic acidosis | | 1 | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # | Cumulative Total # |
|-----------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Myocardial infarction | 1 | 1 |
| Nausea | 3 | 3 |
| Neck pain | 1 | 1 |
| Nervous system disorder | 1 | 3 |
| Neurogenic shock | 1 | 1 |
| Neutropenia | | 1 |
| Ocular hyperaemia | 1 | 1 |
| Oral herpes | 2 | 2 |
| Oxygen saturation decreased | 4 | 5 |
| Paresis | 1 | 1 |
| Patient elopement | | 1 |
| Peripheral coldness | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pleural effusion | 1 | 1 |
| Pneumonia | 1 | 1 |
| Pneumonitis | | 1 |
| Presyncope | | 2 |
| Productive cough | 1 | 1 |
| Pulmonary embolism | 1 | 1 |
| Pulmonary oedema | 2 | 2 |
| Pyrexia | 3 | 4 |
| Rales | 1 | 1 |
| Renal disorder | | 1 |
| Renal failure | 1 | 1 |
| Respiration abnormal | 1 | 1 |
| Respiratory disorder | 1 | 3 |
| Respiratory failure | 1 | 1 |
| Respiratory tract infection | 2 | 2 |
| Restlessness | 1 | 1 |
| Sedation | 1 | 1 |
| Sepsis | | 1 |
| Septic shock | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 3 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 4 | 5 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 3 | 4 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sneezing | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Staring | | 1 | | | | 1 |
| Sudden death | 6 | 7 | | | 6 | 7 |
| Syncope | 3 | 3 | | | 3 | 3 |
| Tachycardia | | 1 | | | | 1 |
| Tachypnoea | | 1 | | | | 1 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Troponin increased | 2 | 2 | | | 2 | 2 |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site reaction | 2 | 2 | | | 2 | 2 |
| Vomiting | 1 | 2 | | | 1 | 2 |
| | 135 | 191 | 8 | 12 | 127 | 179 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arthralgia | 5 | 5 | 1 | 1 | 4 | 4 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 5 | 5 | | | 5 | 5 |
| COVID-19 | 27 | 32 | | | 27 | 32 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 26 | 31 | | | 26 | 31 |
| Dysphagia | | 1 | | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Exposure via skin contact | | 1 | | 1 | | |
| Fatigue | 7 | 8 | 1 | 2 | 6 | 6 |
| Headache | 7 | 7 | 1 | 1 | 6 | 6 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Illness | | 1 | | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 2 | | 1 | 1 | 1 |
| Lymph node pain | 1 | 1 | | | 1 | 1 |
| Malaise | 3 | 3 | 1 | 1 | 2 | 2 |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Myalgia | 5 | 5 | 1 | 1 | 4 | 4 |
| Nausea | 3 | 3 | 1 | 1 | 2 | 2 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Occupational exposure to product | | 1 | | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 2 | 2 | | | 2 | 2 |
| Pruritus | 1 | 1 | | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pyrexia | 2 | 2 | | | 2 | 2 |
| Sense of oppression | 1 | 1 | 1 | 1 | | |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Skin disorder | 2 | 2 | | | 2 | 2 |
| Swollen tongue | 1 | 1 | 1 | 1 | | |
| Syncope | 2 | 2 | | | 2 | 2 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tongue discomfort | 1 | 1 | 1 | 1 | | |
| Upper airway obstruction | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 2 | 2 | | | 2 | 2 |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |
| | 125 | 141 | 15 | 21 | 110 | 120 |

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Country Where Event Occurred

BERMUDA

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

BULGARIA

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| COVID-19 | | 1 | | | | 1 | |
| Dizziness | 1 | 2 | 1 | 2 | | | |
| Drug ineffective | | 1 | | | | 1 | |
| Erythema | | 1 | | 1 | | | |
| Heart rate increased | 1 | 1 | 1 | 1 | | | |
| Hot flush | 1 | 1 | 1 | 1 | | | |
| Lymphocyte count decreased | | 1 | | 1 | | | |
| Malaise | 1 | 1 | 1 | 1 | | | |
| Nausea | 1 | 2 | 1 | 2 | | | |
| Palpitations | | 1 | | 1 | | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | | |
| Pyrexia | 1 | 1 | 1 | 1 | | | |
| Renal pain | 1 | 1 | 1 | 1 | | | |
| Seizure | 1 | 1 | | | 1 | 1 | |
| Spinal pain | 1 | 1 | 1 | 1 | | | |
| Swelling | | 1 | | 1 | | | |
| Vaccination site erythema | | 1 | | 1 | | | |
| Vaccination site pain | | 2 | | 2 | | | |
| Vaccination site swelling | | 1 | | 1 | | | |
| | 10 | 22 | 9 | 19 | 1 | 3 | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Anti-thyroid antibody positive | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 5 | 3 | 5 | | |
| Asthenia | 5 | 7 | 3 | 5 | 2 | 2 |
| Blood pressure inadequately controlled | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Body temperature increased | 4 | 6 | 3 | 5 | 1 | 1 |
| Chills | 7 | 9 | 5 | 7 | 2 | 2 |
| Diarrhoea | | 1 | | 1 | | |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Epigastric discomfort | 1 | 1 | 1 | 1 | | |
| Fatigue | 3 | 4 | 3 | 4 | | |
| Headache | 8 | 11 | 6 | 9 | 2 | 2 |
| Hyperhidrosis | 2 | 3 | 1 | 2 | 1 | 1 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Jugular vein distension | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 2 | 4 | 2 | 4 | | |
| Lymph node pain | | 1 | | 1 | | |
| Meningism | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 5 | 7 | 5 | 7 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Neck pain | | 1 | | 1 | | |
| Pain | | 1 | | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pyrexia | 3 | 5 | 2 | 4 | 1 | 1 |
| Rash | 1 | 1 | 1 | 1 | | |
| Sweating fever | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling | | 1 | | 1 | | |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site pain | 10 | 14 | 9 | 13 | 1 | 1 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 6 | 7 | 5 | 6 | 1 | 1 |
| Vasospasm | 1 | 1 | | | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 2 | 2 | 1 | 1 | 1 | 1 |
| Vomiting | | 1 | | 1 | | |
| | 92 | 123 | 63 | 94 | 29 | 29 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 3 | 3 | 3 | 3 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 2 | 2 | 2 | 2 | | |
| Body temperature increased | 3 | 3 | 3 | 3 | | |
| Chills | 2 | 2 | 2 | 2 | | |
| Conjunctivitis allergic | 1 | 1 | 1 | 1 | | |
| Dental discomfort | 1 | 1 | 1 | 1 | | |
| Erythema | 2 | 2 | 2 | 2 | | |
| Extrasystoles | 1 | 1 | 1 | 1 | | |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 4 | 4 | 4 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 2 | 3 | 1 | 2 | 1 | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Myalgia | 5 | 6 | 5 | 6 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Palpitations | 1 | 1 | 1 | 1 | | |
| Peripheral sensory neuropathy | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pyrexia | 4 | 4 | 4 | 4 | | |
| Rash | | 1 | | 1 | | |
| Rash erythematous | | 1 | | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Rheumatoid factor positive | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 3 | 4 | 3 | 4 | | |
| Vaccination site extravasation | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 5 | 5 | 5 | 5 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 3 | 3 | 3 | 3 | | |
| | 59 | 65 | 57 | 63 | 2 | 2 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Application site pain | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 2 | 1 | 2 | | |
| Asthenia | 2 | 3 | 2 | 3 | | |
| Back pain | 1 | 2 | 1 | 2 | | |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Body temperature increased | 1 | 2 | | 1 | 1 | 1 |
| Chills | 1 | 2 | 1 | 1 | | 1 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 1 | | | | 1 |
| Decreased appetite | 2 | 2 | 1 | 1 | 1 | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dizziness | 3 | 5 | 3 | 4 | | 1 |
| Dizziness postural | | 1 | | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Dyspnoea | | 1 | | | | 1 |
| Erectile dysfunction | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Headache | | 2 | | 1 | | 1 |
| Head discomfort | | 1 | | | | 1 |
| Hyperhidrosis | 1 | 2 | 1 | 1 | | 1 |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 3 | 1 | 3 | | |
| Nausea | 1 | 3 | 1 | 2 | | 1 |
| Pallor | | 1 | | 1 | | |
| Paraesthesia | | 1 | | 1 | | |
| Paraesthesia oral | | 1 | | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral coldness | | 1 | | 1 | | |
| Pyrexia | 1 | 1 | | 1 | 1 | 1 |
| Reduced facial expression | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 4 | 2 | 4 | | |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 2 | 1 | 1 | | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 34 | 62 | 26 | 44 | 8 | 18 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 1 | | 1 | | |
| Anosmia | | 1 | | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 2 | | | | 2 |
| Drug ineffective | | 2 | | | | 2 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Gastrointestinal disorder | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| | 6 | 12 | 6 | 8 | | 4 |

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Country Where Event Occurred

CANADA

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Exposure via breast milk | 1 | 5 | 1 | 5 |
| | 1 | 5 | 1 | 5 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Anxiety | | 1 | | 1 | | |
| Arthralgia | | 3 | | 3 | | |
| Asthenia | | 3 | | 3 | | |
| Beta haemolytic streptococcal infection | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Chest discomfort | | 1 | | | | 1 |
| Chest pain | 1 | 2 | 1 | 1 | | 1 |
| Chills | | 1 | | 1 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| Decreased appetite | | 2 | | 2 | | |
| Diarrhoea | | 2 | | 2 | | |
| Distractibility | | 1 | | 1 | | |
| Disturbance in attention | | 1 | | 1 | | |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 2 | 1 | 2 | | |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Erythema | | 1 | | 1 | | |
| Exposure during pregnancy | | 2 | | 2 | | |
| Eyelid function disorder | 1 | 1 | | | 1 | 1 |
| Eye pain | | 1 | | 1 | | |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 6 | 1 | 6 | | |
| Feeling abnormal | | 2 | | 2 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Headache | 1 | 8 |
| Herpes zoster | | 1 |
| Hot flush | | 1 |
| Hypoacusis | 2 | 2 |
| Hypoaesthesia | 2 | 2 |
| Hypoaesthesia eye | 1 | 1 |
| Impaired driving ability | 1 | 1 |
| Impaired work ability | 1 | 2 |
| Inappropriate schedule of product administration | | 1 |
| Insomnia | | 1 |
| Lip swelling | | 1 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lung disorder | | 1 |
| Lymphadenopathy | 2 | 3 |
| Malaise | 1 | 2 |
| Maternal exposure during pregnancy | | 2 |
| Migraine | | 1 |
| Muscle spasms | | 1 |
| Muscle twitching | | 1 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | | 4 |
| Nausea | | 7 |
| Neck pain | 1 | 2 |
| Odynophagia | | 1 |
| Off label use | | 4 |
| Oropharyngeal pain | 1 | 3 |
| Overdose | | 1 |
| Pain | 1 | 2 |
| Pain in extremity | 2 | 7 |
| Pain in jaw | 1 | 1 |
| Palpitations | 1 | 2 |
| Paraesthesia | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 8 | | |
| | 1 | | |
| | 1 | | |
| 2 | 2 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 2 | 3 | | |
| 1 | 2 | | |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 4 | | |
| | 7 | | |
| 1 | 2 | | |
| | 1 | | |
| | 4 | | |
| 1 | 3 | | |
| | 1 | | |
| 1 | 2 | | |
| 2 | 7 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Polydipsia | 1 | 1 | 1 | 1 | | |
| Polyuria | 1 | 1 | 1 | 1 | | |
| Product use issue | | 3 | | 3 | | |
| Pruritus | | 1 | | 1 | | |
| Psychotic disorder due to a general medical condition | 1 | 1 | 1 | 1 | | |
| Pulmonary pain | | 1 | | | | 1 |
| Pyrexia | 2 | 6 | 2 | 6 | | |
| Rash | 1 | 2 | 1 | 2 | | |
| Rash pustular | | 1 | | 1 | | |
| Swelling | | 1 | | 1 | | |
| Swollen tongue | 1 | 2 | 1 | 2 | | |
| Tachycardia | | 1 | | 1 | | |
| Taste disorder | | 1 | | 1 | | |
| Temporomandibular joint syndrome | 1 | 1 | 1 | 1 | | |
| Type IV hypersensitivity reaction | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 5 | 1 | 5 | | |
| Vaccination site rash | | 1 | | 1 | | |
| Vaccination site swelling | 1 | 2 | 1 | 2 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | | 2 | | 2 | | |
| | 52 | 155 | 47 | 146 | 5 | 9 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Abdominal pain lower | | 1 | | 1 | | | |
| Abdominal pain upper | | 1 | | 1 | | | |
| Abortion spontaneous | 1 | 1 | | | 1 | | 1 |
| Affect lability | | 1 | | 1 | | | |
| Anaphylactic reaction | | 3 | | | | | 3 |
| Angioedema | | 1 | | | | | 1 |
| Anxiety | 1 | 2 | 1 | 2 | | | |
| Aphthous ulcer | | 1 | | 1 | | | |
| Arthralgia | 4 | 9 | 4 | 7 | | | 2 |
| Asthenia | 1 | 2 | | 1 | 1 | | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | | |
| Blood glucose decreased | 1 | 1 | | | 1 | | 1 |
| Body temperature increased | | 1 | | 1 | | | |
| Bursitis | 1 | 1 | 1 | 1 | | | |
| Chest discomfort | 2 | 2 | 2 | 2 | | | |
| Chest pain | 2 | 2 | 2 | 2 | | | |
| Chills | 4 | 12 | 4 | 12 | | | |
| Cold sweat | 1 | 1 | 1 | 1 | | | |
| Condition aggravated | | 1 | | | | | 1 |
| Cough | 1 | 1 | 1 | 1 | | | |
| COVID-19 | | 2 | | 1 | | | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | | |
| Depression | | 1 | | 1 | | | |
| Diarrhoea | 1 | 6 | 1 | 6 | | | |
| Disease recurrence | 1 | 1 | | | 1 | | 1 |
| Dizziness | 4 | 7 | 4 | 7 | | | |
| Drug ineffective | | 1 | | | | | 1 |
| Dysphagia | | 2 | | 2 | | | |
| Dyspnoea | 4 | 5 | 4 | 5 | | | |
| Ear discomfort | | 1 | | 1 | | | |
| Eczema | | 1 | | 1 | | | |
| Erythema | | 1 | | | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Erythema multiforme | 1 | 1 |
| Exposure during pregnancy | 2 | 2 |
| Eye swelling | 1 | 2 |
| Face oedema | | 1 |
| Facial pain | 2 | 2 |
| Facial paralysis | 2 | 3 |
| Fatigue | 8 | 19 |
| Fear | | 1 |
| Feeling abnormal | 1 | 2 |
| Feeling cold | | 2 |
| Feeling drunk | 1 | 1 |
| Feeling hot | 1 | 2 |
| Feeling of body temperature change | 1 | 1 |
| Fibromyalgia | | 1 |
| Fluid retention | 1 | 2 |
| Flushing | | 1 |
| Gastric disorder | 1 | 1 |
| Gastrooesophageal reflux disease | | 1 |
| Grip strength decreased | 1 | 1 |
| Headache | 6 | 20 |
| Head discomfort | | 1 |
| Heart rate increased | | 1 |
| Herpes zoster | 1 | 1 |
| Hyperaesthesia | 1 | 1 |
| Hyperhidrosis | | 1 |
| Hypersensitivity | 1 | 3 |
| Hypersomnia | 1 | 1 |
| Hypertension | 1 | 3 |
| Hypertensive crisis | 1 | 1 |
| Hypoaesthesia | 2 | 4 |
| Hypotension | | 1 |
| Illness | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 2 | | |
| | | | 1 |
| 2 | 2 | | |
| | | 2 | 3 |
| 7 | 17 | 1 | 2 |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | 1 |
| 1 | 1 | | |
| | 1 | 1 | 2 |
| | | 1 | 1 |
| 2 | 2 | | 2 |
| | | | 1 |
| | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # | Cumulative Total # | Spontaneous | | | |
|--|------------------|--------------------|-------------|----|---------|---|
| | Spontaneous AE | Spontaneous AE | Nonserious | | Serious | |
| | | | I | C | I | C |
| Inappropriate schedule of product administration | 5 | 6 | 5 | 6 | | |
| Incomplete course of vaccination | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 3 | 1 | 3 | | |
| Joint range of motion decreased | 1 | 1 | 1 | 1 | | |
| Joint swelling | | 1 | | 1 | | |
| Lethargy | | 1 | | 1 | | |
| Leukoplakia | | 1 | | 1 | | |
| Lymphadenopathy | 4 | 8 | 3 | 7 | 1 | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 2 | 1 | 2 | | |
| Maternal exposure during pregnancy | 1 | 6 | 1 | 6 | | |
| Meningitis aseptic | 1 | 1 | | | 1 | 1 |
| Menstruation delayed | 1 | 1 | 1 | 1 | | |
| Menstruation irregular | | 1 | | 1 | | |
| Migraine | 3 | 3 | 2 | 2 | 1 | 1 |
| Muscular weakness | | 1 | | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 5 | 13 | 5 | 11 | | 2 |
| Nasal congestion | | 1 | | 1 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Nausea | 3 | 5 | 3 | 5 | | |
| Neck pain | 1 | 2 | 1 | 2 | | |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Off label use | 5 | 12 | 5 | 12 | | |
| Oral herpes | | 1 | | 1 | | |
| Oropharyngeal pain | 1 | 2 | 1 | 2 | | |
| Overdose | 1 | 2 | 1 | 2 | | |
| Pain | 3 | 9 | 3 | 9 | | |
| Pain in extremity | 3 | 11 | 2 | 10 | 1 | 1 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 2 | 8 | 2 | 6 | | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Paraesthesia oral | 1 | 4 |
| Petechiae | | 1 |
| Pharyngeal swelling | | 2 |
| Pneumonia | 1 | 1 |
| Presyncope | | 2 |
| Product administered at inappropriate site | 1 | 2 |
| Product preparation issue | 1 | 1 |
| Product supply issue | 1 | 1 |
| Product use issue | 5 | 11 |
| Pruritus | 1 | 3 |
| Pulmonary embolism | 2 | 2 |
| Pulmonary infarction | 1 | 1 |
| Pyrexia | 4 | 15 |
| Rash | 1 | 2 |
| Rash erythematous | 1 | 1 |
| Rash macular | | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Rheumatoid arthritis | | 1 |
| Sinus pain | | 1 |
| Skin burning sensation | | 1 |
| Skin lesion | | 1 |
| Sneezing | | 1 |
| Stress | | 1 |
| Swelling | | 1 |
| Swelling face | 2 | 2 |
| Swollen tongue | | 2 |
| Syncope | | 1 |
| Systemic lupus erythematosus | 1 | 1 |
| Tachycardia | 2 | 5 |
| Tachypnoea | | 1 |
| Tendonitis | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 3 | | 1 |
| | 1 | | |
| | 1 | | 1 |
| | | 1 | 1 |
| | 1 | | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 5 | 11 | | |
| 1 | 2 | | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 4 | 15 | | |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | | 1 |
| | | | 1 |
| | 2 | 2 | 3 |
| | 1 | | |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thirst | | 1 | | 1 | | |
| Throat irritation | | 2 | | 2 | | |
| Throat tightness | | 1 | | 1 | | |
| Tongue disorder | | 1 | | | | 1 |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| Urticaria | 2 | 7 | 2 | 7 | | |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 5 | 11 | 5 | 10 | | 1 |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | | 1 | | 1 | | |
| Vulval disorder | | 1 | | | | 1 |
| Wheezing | 2 | 2 | 2 | 2 | | |
| | 163 | 377 | 135 | 312 | 28 | 65 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Acne | 1 | 1 | 1 | 1 | | |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | | 2 | | | | 2 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 5 | 2 | 5 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Chills | 4 | 5 | 4 | 5 | | |
| Cold sweat | | 1 | | 1 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| Dehydration | 1 | 1 | 1 | 1 | | |
| Diarrhoea | | 1 | | 1 | | |
| Diplopia | 1 | 1 | | | 1 | 1 |
| Disease recurrence | | 1 | | 1 | | |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Dysgeusia | 2 | 3 | 2 | 3 | | |
| Dyskinesia | 1 | 1 | 1 | 1 | | |
| Dysphagia | | 1 | | 1 | | |
| Dyspnoea | 2 | 3 | | | 2 | 3 |
| Fatigue | 4 | 7 | 4 | 7 | | |
| Headache | 6 | 13 | 6 | 13 | | |
| Herpes zoster | | 1 | | 1 | | |
| Hyperaesthesia | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 2 | | | 1 | 2 |
| Hypoaesthesia oral | | 1 | | | | 1 |
| Hypotension | | 1 | | | | 1 |
| Inappropriate schedule of product administration | 1 | 2 | 1 | 2 | | |
| IVth nerve paralysis | 1 | 1 | | | 1 | 1 |
| Joint swelling | | 1 | | | | 1 |
| Lip swelling | | 1 | | | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Lymphadenopathy | | 1 |
| Malaise | 1 | 1 |
| Mouth swelling | | 1 |
| Muscle spasms | 1 | 1 |
| Musculoskeletal pain | | 1 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 4 | 8 |
| Nausea | 6 | 9 |
| Neck pain | 1 | 1 |
| Oesophageal disorder | 1 | 1 |
| Off label use | 1 | 3 |
| Oral candidiasis | 1 | 1 |
| Oral mucosal blistering | | 1 |
| Overdose | | 1 |
| Pain | | 2 |
| Pain in extremity | 2 | 3 |
| Pain of skin | | 1 |
| Paraesthesia | 1 | 1 |
| Paraesthesia oral | 1 | 2 |
| Peripheral swelling | | 1 |
| Pharyngeal swelling | 1 | 1 |
| Presyncope | 1 | 1 |
| Product administered at inappropriate site | | 1 |
| Product use issue | | 2 |
| Pruritus | | 2 |
| Pyrexia | 2 | 5 |
| Rash | 1 | 3 |
| Rash erythematous | 1 | 1 |
| Swelling | 1 | 1 |
| Swelling face | 1 | 1 |
| Tachycardia | | 1 |
| Throat tightness | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 4 | 8 | | |
| 6 | 9 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| 1 | 2 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | |
| | 2 | | |
| 2 | 5 | | |
| 1 | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tongue pruritus | | 1 | | 1 | | |
| Tremor | | 2 | | 1 | | 1 |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 8 | 3 | 8 | | |
| Vaccination site reaction | 1 | 2 | 1 | 2 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vaccination site urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Vision blurred | | 1 | | 1 | | |
| Visual impairment | | 1 | | 1 | | |
| Vomiting | | 2 | | 2 | | |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 72 | 152 | 58 | 126 | 14 | 26 |

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 * AE=Adverse Event
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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Abdominal pain upper | | 1 | | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Back pain | | 1 | | 1 | | |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | 2 | 2 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Eyelid sensory disorder | 1 | 1 | 1 | 1 | | |
| Eye pruritus | | 1 | | 1 | | |
| Fatigue | 3 | 5 | 3 | 5 | | |
| Gastroenteritis | | 1 | | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 3 | 5 | 3 | 5 | | |
| Hypersomnia | | 1 | | 1 | | |
| Hypoaesthesia | 1 | 2 | 1 | 2 | | |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 2 | 1 | 2 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Pharyngeal hypoaesthesia | | 1 | | 1 | | |
| Product preparation issue | 1 | 1 | 1 | 1 | | |
| Pruritus | | 1 | | 1 | | |
| Pyrexia | 2 | 2 | 2 | 2 | | |
| Secretion discharge | 1 | 1 | 1 | 1 | | |
| Swelling | 1 | 1 | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Upper-airway cough syndrome | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| Wheezing | 1 | 1 | 1 | 1 | | |
| | 35 | 51 | 29 | 45 | 6 | 6 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Agitation | | 1 | | 1 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Cellulitis | | 1 | | | | 1 |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| COVID-19 | 1 | 2 | | | 1 | 2 |
| Deafness | | 1 | | | | 1 |
| Decreased appetite | 1 | 2 | | 1 | 1 | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Disseminated varicella zoster virus infection | | 1 | | | | 1 |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Gout | | 1 | | 1 | | |
| Hypokinesia | | 1 | | 1 | | |
| Inappropriate schedule of product administration | 2 | 2 | 2 | 2 | | |
| Insomnia | | 1 | | 1 | | |
| Lethargy | | 1 | | 1 | | |
| Limb discomfort | 1 | 2 | 1 | 2 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Lymphoedema | | 1 | | 1 | | |
| Oedema | | 1 | | 1 | | |
| Pain | | 1 | | 1 | | |
| Rash macular | | 1 | | 1 | | |
| Rash maculo-papular | 1 | 1 | | | 1 | 1 |
| Skin injury | | 1 | | 1 | | |
| Somnolence | | 1 | | 1 | | |
| Varicella | | 1 | | 1 | | |
| Vital functions abnormal | | 1 | | | | 1 |
| Vomiting | | 1 | | 1 | | |
| | 10 | 34 | 3 | 21 | 7 | 13 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Allergy to vaccine | | 1 | | 1 | | | |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 | |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 | |
| Aphasia | 1 | 1 | 1 | 1 | | | |
| Chills | 1 | 2 | 1 | 2 | | | |
| Cognitive disorder | 1 | 1 | 1 | 1 | | | |
| Confusional state | 1 | 1 | 1 | 1 | | | |
| COVID-19 | 2 | 5 | | | 2 | 5 | |
| Diarrhoea | | 1 | | 1 | | | |
| Disease recurrence | 1 | 1 | 1 | 1 | | | |
| Dizziness | 4 | 4 | 4 | 4 | | | |
| Drug ineffective | 2 | 6 | | | 2 | 6 | |
| Erythema | 1 | 1 | 1 | 1 | | | |
| Exposure during pregnancy | 2 | 4 | | 2 | 2 | 2 | |
| Exposure via breast milk | | 2 | | 2 | | | |
| Fatigue | 3 | 6 | 3 | 6 | | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | | |
| Feeling hot | 1 | 1 | 1 | 1 | | | |
| Foetal growth restriction | 2 | 2 | | | 2 | 2 | |
| Headache | 1 | 3 | 1 | 3 | | | |
| Hypersensitivity | 5 | 7 | | | 5 | 7 | |
| Hypertension | 3 | 3 | 3 | 3 | | | |
| Hypotension | 1 | 1 | 1 | 1 | | | |
| Inappropriate schedule of product administration | 2 | 3 | 2 | 3 | | | |
| Incomplete course of vaccination | | 1 | | 1 | | | |
| Incorrect dose administered | 2 | 2 | 2 | 2 | | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | | |
| Injection site pain | | 1 | | 1 | | | |
| Lethargy | | 1 | | 1 | | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | | |
| Malaise | 3 | 5 | 3 | 5 | | | |
| Maternal exposure during pregnancy | 1 | 5 | 1 | 5 | | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Maternal exposure timing unspecified | | 2 | | 2 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Nausea | | 1 | | 1 | | |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 8 | 1 | 8 | | |
| Overdose | | 3 | | 3 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Pain in extremity | 1 | 3 | 1 | 3 | | |
| Periorbital swelling | 1 | 1 | 1 | 1 | | |
| Product preparation issue | | 10 | | 10 | | |
| Product use issue | 1 | 8 | 1 | 8 | | |
| Pyrexia | 5 | 5 | 5 | 5 | | |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Syncope | | 1 | | | | 1 |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | |
| Underdose | 2 | 6 | 2 | 6 | | |
| Vaccination site pain | | 1 | | 1 | | |
| Vaccination site urticaria | 2 | 2 | 2 | 2 | | |
| | 67 | 139 | 50 | 111 | 17 | 28 |

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Country Where Event Occurred

CHILE

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Complement factor C3 decreased | 1 | 1 | 1 | 1 | | |
| C-reactive protein decreased | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Monocyte count decreased | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 2 | 2 | 2 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Rhabdomyolysis | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | | | 1 | 1 |
| Venous thrombosis | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 30 | 30 | 22 | 22 | 8 | 8 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Abdominal pain upper | | 1 | | 1 | | | |
| Anaphylactic reaction | 1 | 2 | | | 1 | | 2 |
| Angioedema | | 1 | | | | | 1 |
| Arrhythmia | 1 | 1 | | | 1 | | 1 |
| Arthralgia | | 2 | | 1 | | | 1 |
| Arthritis | | 1 | | | | | 1 |
| Asthenia | | 1 | | 1 | | | |
| Back pain | | 1 | | 1 | | | |
| Chest pain | 1 | 1 | | | 1 | | 1 |
| Chills | | 3 | | 2 | | | 1 |
| Choking | 1 | 1 | | | 1 | | 1 |
| Diarrhoea | | 3 | | 3 | | | |
| Disease recurrence | | 1 | | 1 | | | |
| Dizziness | 1 | 1 | | | 1 | | 1 |
| Dysbiosis | | 1 | | | | | 1 |
| Dyspnoea | 1 | 2 | | | 1 | | 2 |
| Eye pruritus | | 1 | | | | | 1 |
| Eye swelling | | 1 | | | | | 1 |
| Fatigue | 1 | 2 | 1 | 2 | | | |
| Feeling cold | | 1 | | 1 | | | |
| Headache | 1 | 4 | 1 | 3 | | | 1 |
| Hyperhidrosis | | 1 | | 1 | | | |
| Hypersensitivity | | 1 | | 1 | | | |
| Hyperventilation | 1 | 1 | | | 1 | | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | | 1 |
| Hypotension | 1 | 1 | | | 1 | | 1 |
| Incorrect route of product administration | | 1 | | 1 | | | |
| Joint swelling | | 2 | | 1 | | | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | | 1 |
| Lymphadenopathy | | 2 | | 1 | | | 1 |
| Lymph node pain | | 2 | | 2 | | | |
| Malaise | | 1 | | 1 | | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|----|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Muscle spasms | | 1 | | 1 | | | |
| Myalgia | | 1 | | | | | 1 |
| Nasal congestion | | 1 | | 1 | | | |
| Nausea | | 1 | | 1 | | | |
| Ocular hyperaemia | | 1 | | | | | 1 |
| Off label use | | 1 | | 1 | | | |
| Pain | 1 | 2 | | 1 | 1 | | 1 |
| Pain in extremity | 1 | 2 | 1 | 2 | | | |
| Pallor | 1 | 1 | | | 1 | | 1 |
| Paraesthesia | 1 | 1 | | | 1 | | 1 |
| Photophobia | | 1 | | | | | 1 |
| Pyrexia | | 4 | | 3 | | | 1 |
| Rash | 1 | 1 | | | 1 | | 1 |
| Rash pruritic | 1 | 1 | | | 1 | | 1 |
| Respiratory distress | | 1 | | | | | 1 |
| Sensory loss | | 1 | | 1 | | | |
| Swelling face | | 1 | | | | | 1 |
| Synovial cyst | | 1 | | 1 | | | |
| Tachycardia | 1 | 1 | | | 1 | | 1 |
| Urticaria | 1 | 1 | | | 1 | | 1 |
| Vaccination site pain | | 1 | | | | | 1 |
| | 20 | 72 | 3 | 36 | 17 | | 36 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 1 | | | | 1 |
| Abnormal faeces | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Nausea | | 1 | | | | 1 |
| Pancreatitis | | 1 | | | | 1 |
| Urine analysis abnormal | | 1 | | | | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 3 | 7 | 3 | 3 | | 4 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Burning sensation | | 2 | | 2 | | |
| Crying | | 1 | | | | 1 |
| Dermatitis allergic | | 4 | | 4 | | |
| Diarrhoea | | 2 | | 2 | | |
| Dizziness | | 1 | | 1 | | |
| Dry mouth | | 1 | | | | 1 |
| Erythema | | 1 | | 1 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | | 1 | | 1 | | |
| Guillain-Barre syndrome | 1 | 1 | | | 1 | 1 |
| Headache | | 3 | | 3 | | |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Incomplete course of vaccination | 7 | 7 | 7 | 7 | | |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | | 2 | | 2 | | |
| Malaise | | 2 | | 2 | | |
| Maternal exposure timing unspecified | | 1 | | 1 | | |
| Mental disorder | 1 | 1 | 1 | 1 | | |
| Myalgia | | 2 | | 2 | | |
| Nausea | | 1 | | 1 | | |
| Off label use | | 1 | | 1 | | |
| Pain | | 1 | | 1 | | |
| Paraesthesia | | 1 | | | | 1 |
| Peripheral swelling | | 1 | | 1 | | |
| Polydipsia | | 1 | | 1 | | |
| Product use issue | | 1 | | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Respiratory disorder | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | | 2 | | 2 | | |
| | 14 | 48 | 9 | 40 | 5 | 8 |

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Country Where Event Occurred

COLOMBIA

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Candida infection | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Gingivitis | | 1 | | 1 |
| Hypersensitivity | | 1 | | 1 |
| Leukocytosis | | 1 | | 1 |
| Off label use | | 1 | | 1 |
| Oral candidiasis | | 1 | | 1 |
| Product use issue | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| Stomatitis | | 1 | | 1 |
| | | 10 | | 10 |

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Country Where Event Occurred

COSTA RICA

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Chills | | 1 | | 1 |
| Feeling hot | | 1 | | 1 |
| Headache | 1 | 2 | 1 | 2 |
| Incorrect route of product administration | 1 | 2 | 1 | 2 |
| Limb discomfort | 1 | 2 | 1 | 2 |
| Lymph node pain | | 1 | | 1 |
| Pain in extremity | | 1 | | 1 |
| Vaccination site pain | 2 | 3 | 2 | 3 |
| | 5 | 13 | 5 | 13 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 1 | | 1 | | |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Energy increased | | 1 | | 1 | | |
| Euphoric mood | | 1 | | 1 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Fatigue | 3 | 4 | 2 | 3 | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Headache | 3 | 7 | 2 | 6 | 1 | 1 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Heart rate irregular | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Insomnia | | 1 | | 1 | | |
| Loss of personal independence in daily activities | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 3 | 2 | 3 | | |
| Miosis | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myalgia | 3 | 4 | 2 | 3 | 1 | 1 |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Pruritus | | 1 | | 1 | | |
| Pyrexia | 2 | 3 | 2 | 3 | | |
| Rash | | 1 | | 1 | | |
| Red blood cell sedimentation rate increased | | 1 | | 1 | | |
| Sensation of foreign body | 1 | 1 | 1 | 1 | | |
| Sleep disorder | | 1 | | 1 | | |
| Tachycardia | 1 | 2 | 1 | 2 | | |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Thirst | 1 | 1 | | | 1 | 1 |
| Throat clearing | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 4 | 2 | 4 | | |
| Vasculitis | | 1 | | 1 | | |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 49 | 72 | 26 | 49 | 23 | 23 |

Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Eye pain | 1 | 1 | 1 | 1 |
| Migraine | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

* I=Interval, C=Cumulative

* AE=Adverse Event

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Hepatic enzyme increased | | 1 | | | | 1 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Joint range of motion decreased | | 1 | | | | 1 |
| Malaise | | 1 | | | | 1 |
| Mobility decreased | | 1 | | | | 1 |
| Muscle contracture | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 2 | 1 | 1 | | 1 |
| Pyrexia | | 1 | | | | 1 |
| Splenomegaly | | 1 | | | | 1 |
| | 5 | 12 | 4 | 4 | 1 | 8 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Communication disorder | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Depression | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 4 | 4 | 3 | 3 | 1 | 1 |
| Eye allergy | | 1 | | 1 | | |
| Eye inflammation | | 1 | | 1 | | |
| Fatigue | 3 | 3 | 3 | 3 | | |
| Feeling abnormal | | 1 | | 1 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Headache | 3 | 4 | 3 | 4 | | |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 2 | 3 | 2 | 3 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pleuritic pain | 1 | 1 | 1 | 1 | | |
| Pneumonitis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 2 | 1 | 2 | | |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Suspected COVID-19 | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 3 | 2 | 3 | | |
| | 36 | 44 | 28 | 36 | 8 | 8 |

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Country Where Event Occurred

CROATIA

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 3 | 2 | 3 | | |
| Chest discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 5 | 6 | 4 | 5 | 1 | 1 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysgeusia | | 1 | | | | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Erythema | 2 | 2 | | | 2 | 2 |
| Extensive swelling of vaccinated limb | 1 | 1 | | | 1 | 1 |
| Eye pain | | 1 | | 1 | | |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 3 | 2 | 3 | | |
| Feeling cold | | 1 | | 1 | | |
| Feeling hot | 2 | 2 | 1 | 1 | 1 | 1 |
| Headache | 9 | 10 | 8 | 9 | 1 | 1 |
| Immune system disorder | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Malaise | 3 | 3 | 3 | 3 | | |
| Muscle tightness | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 4 | 5 | 4 | 5 | | |
| Myosclerosis | 1 | 1 | | | 1 | 1 |
| Nausea | 4 | 4 | 4 | 4 | | |
| Neck pain | | 1 | | 1 | | |
| Pain in extremity | 2 | 3 | 2 | 3 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Panic attack | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 3 | 3 | 1 | 1 | 2 | 2 |
| Pharyngeal paraesthesia | | 1 | | | | 1 |
| Pruritus | 2 | 2 | | | 2 | 2 |
| Pyrexia | 6 | 8 | 5 | 7 | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 2 | 2 | | | 2 | 2 |
| Salivary hypersecretion | 1 | 1 | | | 1 | 1 |
| Sleep paralysis | 1 | 1 | 1 | 1 | | |
| Sleep terror | 1 | 1 | 1 | 1 | | |
| Spinal pain | 1 | 1 | 1 | 1 | | |
| Tongue oedema | 1 | 2 | | | 1 | 2 |
| Tremor | | 1 | | | | 1 |
| Type I hypersensitivity | 3 | 3 | | | 3 | 3 |
| Urticaria | 2 | 2 | | | 2 | 2 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site pain | 11 | 16 | 8 | 13 | 3 | 3 |
| Vaccination site swelling | 1 | 2 | 1 | 2 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 103 | 124 | 65 | 82 | 38 | 42 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 2 | 1 | 2 | | |
| Allergy to chemicals | | 1 | | 1 | | |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Arthralgia | 3 | 3 | 3 | 3 | | |
| Asthenia | 7 | 7 | 6 | 6 | 1 | 1 |
| Back pain | 2 | 2 | 2 | 2 | | |
| Body temperature increased | 4 | 5 | 3 | 4 | 1 | 1 |
| Bone pain | 3 | 3 | 3 | 3 | | |
| Burning sensation | | 2 | | 1 | | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 11 | 13 | 8 | 10 | 3 | 3 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Conjunctivitis allergic | 1 | 1 | | | 1 | 1 |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Diaphragmatic spasm | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Discomfort | | 1 | | 1 | | |
| Dizziness | 3 | 3 | 2 | 2 | 1 | 1 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dyskinesia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Ear canal erythema | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Ear pruritus | 1 | 1 | | | 1 | 1 |
| Encephalitis post immunisation | 1 | 1 | | | 1 | 1 |
| Erythema | 6 | 8 | | 1 | 6 | 7 |
| Extensive swelling of vaccinated limb | 7 | 7 | | | 7 | 7 |
| Extrapyramidal disorder | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Eyelid function disorder | 1 | 1 |
| Eyelid oedema | 2 | 2 |
| Eyelid ptosis | | 1 |
| Facial paralysis | 1 | 1 |
| Facial paresis | 2 | 3 |
| Fatigue | 7 | 10 |
| Fear | 1 | 1 |
| Feeding disorder | 1 | 1 |
| Feeling hot | 4 | 5 |
| Gastrointestinal pain | 1 | 1 |
| Gingival bleeding | 1 | 1 |
| Headache | 25 | 30 |
| Head discomfort | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 1 | 1 |
| Hypertension | 1 | 1 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 2 | 2 |
| Hypoaesthesia oral | | 1 |
| Hypogeusia | 1 | 1 |
| Hypotension | 1 | 1 |
| Insomnia | | 1 |
| Lacrimation increased | 1 | 1 |
| Lip disorder | | 1 |
| Lip oedema | 1 | 1 |
| Lip swelling | 1 | 1 |
| Localised oedema | 1 | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 3 | 3 |
| Lymph node pain | 1 | 1 |
| Malaise | 3 | 4 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| 6 | 9 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 3 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 17 | 21 | 8 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 3 | 3 | | |
| 1 | 1 | | |
| 3 | 4 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------|------------------------------------|--------------------------------------|
| Monoparesis | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 13 | 14 |
| Nausea | 8 | 8 |
| Neck pain | 2 | 2 |
| Nystagmus | 1 | 1 |
| Ocular hyperaemia | 1 | 1 |
| Oedema mouth | 1 | 1 |
| Oral mucosal erythema | 1 | 1 |
| Oral pain | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | | 1 |
| Pain in extremity | 4 | 4 |
| Pain of skin | 1 | 1 |
| Palpitations | 3 | 3 |
| Panic attack | 1 | 1 |
| Paraesthesia | 3 | 5 |
| Paraesthesia oral | 2 | 2 |
| Paresis | 1 | 1 |
| Peripheral swelling | 1 | 2 |
| Presyncope | 2 | 2 |
| Pruritus | 3 | 4 |
| Pulmonary pain | 1 | 1 |
| Pyrexia | 15 | 19 |
| Rash | 4 | 5 |
| Rash erythematous | | 1 |
| Rash macular | 1 | 1 |
| Rash maculo-papular | 1 | 1 |
| Retching | 1 | 1 |
| Sensory loss | 1 | 1 |
| Serum sickness | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 12 | 13 | 1 | 1 |
| 6 | 6 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 4 | 4 | | |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | 1 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| | | 3 | 4 |
| 1 | 1 | | |
| 12 | 16 | 3 | 3 |
| | | 4 | 5 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Skin oedema | 1 | 1 | 1 | 1 | | |
| Somnolence | 2 | 2 | 1 | 1 | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 3 | 3 | 2 | 2 | 1 | 1 |
| Tinnitus | 2 | 2 | 1 | 1 | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Tremor | 6 | 6 | 5 | 5 | 1 | 1 |
| Type I hypersensitivity | 7 | 8 | | | 7 | 8 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 13 | 13 | 8 | 8 | 5 | 5 |
| Vaccination site haematoma | 2 | 2 | 2 | 2 | | |
| Vaccination site hypersensitivity | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site joint erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site pain | 28 | 31 | 24 | 26 | 4 | 5 |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 7 | 7 | 5 | 5 | 2 | 2 |
| Vertigo | 2 | 2 | 1 | 1 | 1 | 1 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 2 | 2 | 1 | 1 | 1 | 1 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 304 | 346 | 184 | 212 | 120 | 134 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angioedema | | 1 | | | | 1 |
| Arthralgia | 4 | 4 | 4 | 4 | | |
| Asthenia | 2 | 2 | 2 | 2 | | |
| Asthma | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood creatine phosphokinase increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 4 | 4 | | | 4 | 4 |
| Body temperature increased | 1 | 2 | 1 | 2 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 1 | 2 | 1 | 1 | | 1 |
| Burning sensation | 2 | 2 | | | 2 | 2 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 5 | 5 | 5 | 5 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 3 | | | 2 | 3 |
| Erythema | 4 | 5 | | 1 | 4 | 4 |
| Extensive swelling of vaccinated limb | 6 | 6 | | | 6 | 6 |
| Eye haematoma | 1 | 1 | | | 1 | 1 |
| Eye haemorrhage | 1 | 1 | | | 1 | 1 |
| Eye opacity | 1 | 1 | 1 | 1 | | |
| Fatigue | 3 | 3 | 2 | 2 | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Fibromyalgia | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Headache | 9 | 10 |
| Hyperhidrosis | 1 | 1 |
| Illness | 1 | 1 |
| Incorrect dose administered | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Lymphopenia | 1 | 1 |
| Malaise | 3 | 3 |
| Migraine | 1 | 1 |
| Multi-organ disorder | | 1 |
| Muscle contractions involuntary | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 5 | 5 |
| Nasal congestion | 1 | 1 |
| Nausea | 2 | 2 |
| Night sweats | 1 | 1 |
| Pain in extremity | 4 | 4 |
| Palpitations | 2 | 2 |
| Paraesthesia | 1 | 1 |
| Paraesthesia oral | 2 | 2 |
| Pharyngeal swelling | 1 | 1 |
| Psoriasis | 1 | 1 |
| Pyrexia | 13 | 15 |
| Rales | 1 | 1 |
| Rash | 2 | 3 |
| Respiratory tract oedema | | 1 |
| Rheumatoid factor positive | 1 | 1 |
| Rhinorrhoea | 1 | 1 |
| Sensory disturbance | 1 | 1 |
| Stridor | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Swelling face | | 1 |
| Swollen tongue | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 5 | 6 | 4 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 5 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 8 | 10 | 5 | 5 |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 3 | 3 | 2 | 2 | 1 | 1 |
| Tachypnoea | | 1 | | | | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Type I hypersensitivity | 5 | 5 | | | 5 | 5 |
| Underdose | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 5 | 6 | 4 | 5 | 1 | 1 |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 10 | 11 | 8 | 9 | 2 | 2 |
| Vaccination site swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Viral infection | 1 | 1 | 1 | 1 | | |
| Vitreous detachment | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 2 | | | 1 | 2 |
| | 147 | 166 | 79 | 87 | 68 | 79 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| Dizziness | | 1 | | 1 | | |
| Erythema | 1 | 1 | | | 1 | 1 |
| Headache | | 1 | | 1 | | |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 1 | 1 | | | 1 | 1 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | | 1 | | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| | 15 | 18 | 6 | 9 | 9 | 9 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Cardiac failure | 1 | 1 | 1 | 1 |
| Chest discomfort | 1 | 1 | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 |
| Death | 1 | 1 | 1 | 1 |
| Dyspnoea | 3 | 3 | 3 | 3 |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 |
| Speech disorder | 1 | 1 | 1 | 1 |
| Swelling face | 1 | 1 | 1 | 1 |
| Type I hypersensitivity | 1 | 1 | 1 | 1 |
| | 12 | 12 | 12 | 12 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

CYPRUS

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Head titubation | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 1 | 1 | 1 | | |
| Syncope | 2 | 2 | | | 2 | 2 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| | 12 | 12 | 9 | 9 | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 2 | 2 | 2 | 2 | | |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | 2 | 2 | | |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| Dermatitis atopic | 1 | 1 | 1 | 1 | | |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Dyspnoea | | 1 | | 1 | | |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Eczema | 1 | 1 | 1 | 1 | | |
| Epistaxis | 1 | 1 | | | 1 | 1 |
| Eyelid ptosis | | 1 | | 1 | | |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Facial paresis | 1 | 3 | | | 1 | 3 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 2 | 4 | 2 | 4 | | |
| Hypersensitivity | | 1 | | 1 | | |
| Hypoaesthesia | | 1 | | | | 1 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 3 | 3 | 3 | 3 | | |
| Myalgia | 5 | 5 | 5 | 5 | | |
| Nausea | 3 | 3 | 3 | 3 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 3 | 4 | 3 | 4 | | |
| SARS-CoV-2 ant body test negative | | 1 | | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 4 | 4 | 4 | 4 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 47 | 58 | 39 | 46 | 8 | 12 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | | 1 | | 1 | | |
| Cervix oedema | | 1 | | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Condition aggravated | | 1 | | 1 | | |
| Cough | | 1 | | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 3 | 2 | 3 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 2 | 2 | 2 | | |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Face oedema | 1 | 1 | 1 | 1 | | |
| Facial paralysis | | 1 | | | | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Hypertension | | 1 | | | | 1 |
| Hypoacusis | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia eye | | 1 | | | | 1 |
| Hypoaesthesia oral | | 1 | | | | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Muscle contracture | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Rash | | 1 | | 1 | | |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Sinus congestion | | 1 | | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Tachyarrhythmia | | 1 | | | | 1 | |
| Tachycardia | 1 | 2 | 1 | 1 | | 1 | |
| Upper respiratory tract congestion | | 1 | | 1 | | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | | |
| Vasculitis | 1 | 1 | 1 | 1 | | | |
| Vertigo | 1 | 1 | 1 | 1 | | | |
| | 28 | 44 | 22 | 32 | 6 | 12 | |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Arthralgia | 1 | 1 | 1 | 1 | | | |
| Balance disorder | 1 | 1 | 1 | 1 | | | |
| Blood pressure increased | | 1 | | | | | 1 |
| Chills | 1 | 1 | 1 | 1 | | | |
| Dysphagia | 1 | 1 | 1 | 1 | | | |
| Facial paresis | 1 | 1 | | | 1 | 1 | |
| Gait disturbance | 1 | 1 | 1 | 1 | | | |
| Lymphadenopathy | | 1 | | | | | 1 |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | | |
| Pyrexia | 1 | 1 | 1 | 1 | | | |
| Respiratory tract oedema | 1 | 1 | | | 1 | 1 | |
| | 9 | 11 | 7 | 7 | 2 | 4 | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paresis | 2 | 2 | | | 2 | 2 |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| Guillain-Barre syndrome | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Hyponatraemia | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | | 1 | | | | 1 |
| Nausea | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Sluggishness | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 26 | 27 | 16 | 16 | 10 | 11 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 6 | 6 | 6 | 6 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Back pain | | 1 | | 1 | | |
| Chills | 3 | 3 | 3 | 3 | | |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Contusion | 1 | 1 | 1 | 1 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dizziness | | 1 | | 1 | | |
| Dysgeusia | | 1 | | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Headache | 2 | 2 | 2 | 2 | | |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Malaise | 4 | 4 | 4 | 4 | | |
| Migraine | | 1 | | 1 | | |
| Myalgia | 6 | 6 | 6 | 6 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Pyrexia | 3 | 3 | 3 | 3 | | |
| Swollen tongue | | 1 | | 1 | | |
| Vaccination site pain | 4 | 6 | 4 | 6 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| | 41 | 48 | 40 | 47 | 1 | 1 |

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Country Where Event Occurred

CZECH REPUBLIC

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaesthesia oral | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Arthralgia | 6 | 6 | 5 | 5 | 1 | 1 |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood pressure systolic increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chills | 7 | 8 | 4 | 5 | 3 | 3 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | | 1 | | | | 1 |
| COVID-19 | | 1 | | | | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Dizziness | 2 | 2 | 1 | 1 | 1 | 1 |
| Drug ineffective | | 1 | | | | 1 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Erythema | 2 | 2 | 2 | 2 | | |
| Fatigue | 7 | 9 | 6 | 8 | 1 | 1 |
| Feeling hot | 3 | 3 | 3 | 3 | | |
| Grunting | 1 | 1 | | | 1 | 1 |
| Headache | 6 | 9 | 4 | 7 | 2 | 2 |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | 1 | 1 | | |
| Influenza | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Irritability | 1 | 1 | 1 | 1 | | |
| Joint warmth | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 2 | 2 | 1 | 1 | 1 | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Mucosal disorder | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 8 | 8 |
| Nausea | 4 | 5 |
| Neck pain | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Pain | 1 | 2 |
| Pain in extremity | 1 | 1 |
| Pallor | 3 | 3 |
| Paraesthesia | 1 | 1 |
| Paraesthesia oral | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal oedema | 1 | 1 |
| Photosensitivity reaction | 1 | 1 |
| Presyncope | 1 | 1 |
| Pyrexia | 12 | 14 |
| Rash pruritic | 1 | 1 |
| Rash pustular | 1 | 1 |
| Respiratory depression | 1 | 1 |
| Respiratory disorder | 1 | 1 |
| Rhinorrhoea | | 1 |
| Shock | 1 | 1 |
| Skin disorder | 1 | 1 |
| Somnolence | | 1 |
| Syncope | 1 | 1 |
| Tension headache | 1 | 1 |
| Vaccination site erythema | 4 | 4 |
| Vaccination site induration | 1 | 1 |
| Vaccination site oedema | 2 | 2 |
| Vaccination site pain | 8 | 8 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| 7 | 7 | 1 | 1 |
| 2 | 3 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 9 | 11 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 7 | 7 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vomiting | 2 | 2 | 2 | 2 | | |
| | 128 | 145 | 83 | 96 | 45 | 49 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Acute vestibular syndrome | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | | 2 | | | | 2 |
| Anal incontinence | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 1 | 2 | | | 1 | 2 |
| Angioedema | | 1 | | | | 1 |
| Anosmia | 2 | 2 | 2 | 2 | | |
| Anxiety | 1 | 2 | | 1 | 1 | 1 |
| Application site coldness | 1 | 1 | | | 1 | 1 |
| Arthralgia | 18 | 19 | 15 | 16 | 3 | 3 |
| Asthenia | 12 | 13 | 11 | 12 | 1 | 1 |
| Asthma | | 1 | | | | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Back pain | 2 | 2 | 2 | 2 | | |
| Blindness | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 2 | 1 | 1 | | 1 |
| Blood pressure systolic increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 1 | | | 1 | 1 |
| Burning sensation mucosal | 2 | 2 | 2 | 2 | | |
| Chest discomfort | 2 | 2 | | | 2 | 2 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 24 | 25 | 22 | 22 | 2 | 3 |
| Circulatory collapse | 2 | 2 | | | 2 | 2 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| C-reactive protein increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Dermatitis | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Diarrhoea | 6 | 6 |
| Disease recurrence | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 6 | 8 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 1 | 1 |
| Dry mouth | 1 | 1 |
| Dyspepsia | 1 | 1 |
| Dysphagia | 1 | 2 |
| Dyspnoea | 5 | 8 |
| Ear discomfort | 1 | 1 |
| Erythema | 5 | 7 |
| Eye pain | 2 | 2 |
| Facial paresis | 1 | 1 |
| Fatigue | 30 | 33 |
| Feeling abnormal | 2 | 2 |
| Feeling cold | 1 | 1 |
| Feeling hot | 3 | 3 |
| Flushing | 2 | 2 |
| Frequent bowel movements | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 |
| Generalised oedema | 1 | 1 |
| Headache | 30 | 31 |
| Head discomfort | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 7 | 7 |
| Hypertension | 3 | 4 |
| Hyperventilation | | 1 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 4 | 5 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 5 | 5 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 4 | 5 | 2 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | 4 | 6 |
| | | 1 | 1 |
| 2 | 4 | 3 | 3 |
| 2 | 2 | | |
| | | 1 | 1 |
| 28 | 31 | 2 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 25 | 26 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 5 | 5 |
| 1 | 2 | 2 | 2 |
| | | 1 | |
| 1 | 1 | | |
| 3 | 4 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypokinesia | 1 | 1 |
| Hypotension | 4 | 4 |
| Illusion | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Influenza like illness | 5 | 5 |
| Joint instability | 1 | 1 |
| Joint range of motion decreased | 1 | 1 |
| Joint stiffness | | 1 |
| Limb immobilisation | 1 | 1 |
| Lip swelling | | 1 |
| Localised oedema | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 14 | 15 |
| Lymph node pain | 5 | 5 |
| Lymphoedema | 1 | 1 |
| Malaise | 2 | 3 |
| Mobility decreased | | 1 |
| Muscular weakness | 2 | 2 |
| Musculoskeletal pain | | 1 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 12 | 12 |
| Myosclerosis | 1 | 1 |
| Nausea | 14 | 17 |
| Oedema peripheral | 1 | 1 |
| Off label use | 3 | 3 |
| Oral pruritus | | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Pain | 4 | 4 |
| Pain in extremity | 12 | 14 |
| Pain of skin | 1 | 1 |
| Palpitations | 5 | 5 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 9 | 10 | 5 | 5 |
| 3 | 3 | 2 | 2 |
| 1 | 1 | | |
| 2 | 3 | | |
| | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| | 1 | | |
| 9 | 9 | 3 | 3 |
| | | 1 | 1 |
| 13 | 15 | 1 | 2 |
| | | 1 | 1 |
| 3 | 3 | | |
| | 1 | | |
| | | 1 | 1 |
| 4 | 4 | | |
| 11 | 13 | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Paraesthesia | 9 | 11 |
| Paraesthesia oral | 2 | 2 |
| Peripheral coldness | 3 | 3 |
| Peripheral swelling | 1 | 2 |
| Pharyngeal oedema | | 1 |
| Pharyngeal swelling | 1 | 1 |
| Photophobia | | 1 |
| Photopsia | 1 | 1 |
| Poor quality product administered | 1 | 1 |
| Presyncope | 6 | 6 |
| Product preparation error | 1 | 1 |
| Product use issue | 3 | 3 |
| Pruritus | 9 | 10 |
| Pyrexia | 33 | 33 |
| Rash | 11 | 12 |
| Rash macular | 2 | 2 |
| Respiratory tract oedema | 1 | 1 |
| Retching | 1 | 1 |
| Rhinorrhoea | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 |
| Seizure | 1 | 1 |
| Sensation of foreign body | 1 | 1 |
| Shock | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Skin reaction | 1 | 1 |
| Somnolence | 1 | 2 |
| Swelling | 1 | 2 |
| Swelling face | 5 | 6 |
| Swollen tongue | | 1 |
| Syncope | 1 | 1 |
| Tachycardia | 5 | 6 |
| Tachypnoea | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 5 | 6 | 4 | 5 |
| | | 2 | 2 |
| 3 | 3 | | |
| 1 | 1 | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 5 | 5 |
| 1 | 1 | | |
| 3 | 3 | | |
| 2 | 3 | 7 | 7 |
| 23 | 23 | 10 | 10 |
| 4 | 5 | 7 | 7 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | 1 |
| 1 | 1 | 4 | 5 |
| | | | 1 |
| | | 1 | 1 |
| 4 | 5 | 1 | 1 |
| | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tension headache | 1 | 1 | | | 1 | 1 |
| Throat tightness | | 1 | | | | 1 |
| Tinnitus | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 3 | 3 | 3 | | |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site atrophy | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 15 | 15 | 11 | 11 | 4 | 4 |
| Vaccination site movement impairment | 1 | 2 | 1 | 2 | | |
| Vaccination site oedema | 7 | 7 | 5 | 5 | 2 | 2 |
| Vaccination site pain | 23 | 24 | 18 | 19 | 5 | 5 |
| Vaccination site papule | 1 | 1 | | | 1 | 1 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 3 | 3 | 3 | 3 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 7 | 7 | 5 | 5 | 2 | 2 |
| Vaccination site warmth | 4 | 4 | 4 | 4 | | |
| Vertigo | 7 | 8 | 5 | 6 | 2 | 2 |
| Vision blurred | 2 | 3 | 2 | 3 | | |
| Visual field defect | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 10 | 11 | 7 | 7 | 3 | 4 |
| | 505 | 562 | 348 | 385 | 157 | 177 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Apathy | 1 | 1 | 1 | 1 | | |
| Arthralgia | 3 | 4 | 3 | 4 | | |
| Asthenia | 6 | 7 | 2 | 3 | 4 | 4 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| Chest discomfort | 3 | 3 | 2 | 2 | 1 | 1 |
| Chills | 10 | 11 | 10 | 11 | | |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 3 | 1 | 2 | 1 | 1 |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| COVID-19 pneumonia | 2 | 2 | | | 2 | 2 |
| Decreased appetite | 2 | 2 | 1 | 1 | 1 | 1 |
| Depression | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 5 | 6 | 2 | 2 | 3 | 4 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Ear swelling | 1 | 1 | | | 1 | 1 |
| Erythema | 4 | 4 | 2 | 2 | 2 | 2 |
| Eye inflammation | 1 | 1 | 1 | 1 | | |
| Eye pruritus | | 1 | | 1 | | |
| Facial pain | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Facial paresis | | 1 |
| Fatigue | 7 | 10 |
| Feeling abnormal | 1 | 1 |
| Headache | 11 | 11 |
| Hot flush | 1 | 1 |
| Hyperglycaemia | 1 | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 4 | 5 |
| Hypoaesthesia | 1 | 1 |
| Hypokalaemia | 1 | 1 |
| Hypotension | 2 | 3 |
| Hypoxia | 1 | 1 |
| Incorrect route of product administration | 2 | 2 |
| Influenza like illness | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 |
| Insomnia | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Lip swelling | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenopathy | 4 | 4 |
| Lymph node pain | 2 | 2 |
| Malaise | 2 | 2 |
| Migraine | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal chest pain | | 1 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 6 | 9 |
| Nasal discomfort | 1 | 1 |
| Nausea | 4 | 4 |
| Ocular hyperaemia | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 5 | 8 | 2 | 2 |
| 1 | 1 | | |
| 9 | 9 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 2 | 2 | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 3 | 3 | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 7 | 2 | 2 |
| | | 1 | 1 |
| 4 | 4 | | |
| | | | |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Oedema mouth | 1 | 1 |
| Off label use | 1 | 1 |
| Oral discomfort | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 4 | 4 |
| Palpitations | 2 | 2 |
| Paraesthesia | 6 | 7 |
| Paraesthesia oral | 2 | 2 |
| Peripheral coldness | 2 | 2 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal swelling | | 1 |
| Presyncope | 2 | 2 |
| Product use issue | 1 | 1 |
| Pruritus | 2 | 2 |
| Pyrexia | 16 | 18 |
| Rash | 2 | 2 |
| Rash macular | 1 | 1 |
| Rash pruritic | 2 | 2 |
| Rhinitis | | 1 |
| SARS-CoV-2 test positive | 1 | 2 |
| Sleep disorder | 1 | 1 |
| Spinal pain | 1 | 1 |
| Swelling face | 1 | 1 |
| Swollen tongue | 1 | 2 |
| Syncope | 1 | 1 |
| Tachycardia | 2 | 2 |
| Tachypnoea | 1 | 1 |
| Throat tightness | 1 | 1 |
| Tongue oedema | 1 | 1 |
| Toothache | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| | | 2 | 2 |
| 6 | 6 | | 1 |
| | | 2 | 2 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 2 | 2 | | |
| 12 | 14 | 4 | 4 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 2 | 2 | 1 | 1 | 1 | 1 |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 5 | 5 | 3 | 3 | 2 | 2 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 2 | 2 | 2 | 2 | | |
| Vaccination site pain | 7 | 8 | 7 | 8 | | |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vertigo | 5 | 5 | 3 | 3 | 2 | 2 |
| Vomiting | 3 | 3 | 1 | 1 | 2 | 2 |
| Wheezing | 1 | 1 | 1 | 1 | | |
| | 216 | 245 | 136 | 156 | 80 | 89 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 3 | 3 | 2 | 2 | 1 | 1 |
| Bacterial rhinitis | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chills | 3 | 3 | 3 | 3 | | |
| Communication disorder | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Fatigue | 2 | 2 | 1 | 1 | 1 | 1 |
| Formication | 1 | 1 | 1 | 1 | | |
| Headache | 3 | 3 | 3 | 3 | | |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypersomnia | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Joint effusion | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Nausea | 3 | 3 | 3 | 3 | | |
| Oedema | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Polyarthritis | 1 | 1 | | | 1 | 1 |
| Poor quality product administered | 65 | 65 | 65 | 65 | | |
| Product preparation error | 65 | 65 | 65 | 65 | | |
| Pruritus | 2 | 2 | | | 2 | 2 |
| Pyrexia | 5 | 5 | 4 | 4 | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tongue discomfort | 1 | 1 | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vomiting | 2 | 2 | 2 | 2 | | |
| | 182 | 182 | 159 | 159 | 23 | 23 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Apathy | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 3 | 3 | 3 | 3 | | |
| Condition aggravated | 1 | 1 | 1 | 1 | | |
| Confusional state | 2 | 2 | | | 2 | 2 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 3 | 3 | | | 3 | 3 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 2 | 2 | 1 | 1 | 1 | 1 |
| Delirium | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | 1 | 1 | | |
| Eating disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Fall | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 2 | 2 | | | 2 | 2 |
| Hallucination | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hyperphagia | 1 | 1 | 1 | 1 | | |
| Hypoglycaemia | 1 | 1 | 1 | 1 | | |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypoxia | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Insomnia | 1 | 1 | | | 1 | 1 |
| Jaundice | 1 | 1 | 1 | 1 | | |
| Language disorder | 1 | 1 | | | 1 | 1 |
| Logorrhoea | 1 | 1 | 1 | 1 | | |
| Memory impairment | 1 | 1 | | | 1 | 1 |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Nausea | 1 | 1 | | | 1 | 1 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | 1 | 1 | | |
| Pyrexia | 4 | 4 | 2 | 2 | 2 | 2 |
| Respiratory acidosis | 1 | 1 | 1 | 1 | | |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vomiting | 3 | 3 | 2 | 2 | 1 | 1 |
| | 75 | 75 | 30 | 30 | 45 | 45 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Apathy | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | 2 | 2 | | |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 3 | 4 | 2 | 2 | 1 | 2 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Decreased interest | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Fatigue | 2 | 3 | 2 | 3 | | |
| Hallucination | 1 | 1 | | | 1 | 1 |
| Headache | 2 | 2 | 2 | 2 | | |
| Hypersensitivity | | 1 | | 1 | | |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Mucosal dryness | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | 17 | 17 | 17 | 17 | | |
| Product preparation error | 16 | 16 | 16 | 16 | | |
| Product preparation issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| | 64 | 69 | 57 | 60 | 7 | 9 |

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Country Where Event Occurred

DENMARK

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Erythema | 1 | 1 | 1 | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Angioedema | | 1 | | | | 1 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Arthralgia | 4 | 5 | 3 | 4 | 1 | 1 |
| Axillary pain | | 1 | | 1 | | |
| Chest discomfort | 2 | 2 | 2 | 2 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 5 | 7 | 2 | 4 | 3 | 3 |
| Cough | 3 | 5 | 3 | 4 | | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Derealisation | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 3 | | 1 | 2 | 2 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Dizziness | 10 | 13 | 4 | 5 | 6 | 8 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 4 | | 1 | 1 | 3 |
| Dyspnoea exertional | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Eye pain | 1 | 2 | 1 | 2 | | |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 11 | 13 | 9 | 11 | 2 | 2 |
| Feeling cold | 2 | 2 | 1 | 1 | 1 | 1 |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Flushing | | 1 | | | | 1 |
| Headache | 24 | 31 | 16 | 23 | 8 | 8 |
| Hot flush | | 1 | | 1 | | |
| Hyperacusis | 1 | 1 | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypersensitivity | 2 | 4 |
| Hypersomnia | 1 | 1 |
| Hypertension | 1 | 1 |
| Hyperventilation | 2 | 2 |
| Hypoacusis | 2 | 2 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Influenza | 1 | 1 |
| Influenza like illness | 2 | 3 |
| Lethargy | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 2 | 4 |
| Malaise | 11 | 15 |
| Migraine | | 1 |
| Muscle tightness | 1 | 1 |
| Muscular weakness | 2 | 2 |
| Myalgia | 9 | 16 |
| Nausea | 9 | 11 |
| Obstructive airways disorder | | 1 |
| Odynophagia | 1 | 2 |
| Off label use | 1 | 1 |
| Oral mucosal blistering | 1 | 1 |
| Oropharyngeal pain | 7 | 8 |
| Pain | 1 | 1 |
| Pain in extremity | 4 | 4 |
| Palpitations | 1 | 3 |
| Panic attack | 1 | 1 |
| Paraesthesia | 1 | 1 |
| Paraesthesia oral | 1 | 1 |
| Pharyngeal swelling | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 4 | | |
| 6 | 7 | 5 | 8 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 7 | 14 | 2 | 2 |
| 5 | 6 | 4 | 5 |
| | | | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Photophobia | 1 | 1 |
| Photopsia | 1 | 1 |
| Presyncope | 1 | 2 |
| Product use issue | 1 | 1 |
| Pruritus | 1 | 2 |
| Pyrexia | 14 | 24 |
| Rash | 1 | 2 |
| Rash erythematous | | 1 |
| Rash pruritic | | 1 |
| Renal colic | 1 | 1 |
| Rhinalgia | 1 | 1 |
| Rhinorrhoea | 1 | 1 |
| Sensory disturbance | 2 | 2 |
| Somnolence | 1 | 1 |
| Stomatitis | 1 | 1 |
| Stridor | | 1 |
| Swelling | 1 | 1 |
| Swelling face | | 2 |
| Syncope | 2 | 2 |
| Tachycardia | | 1 |
| Temporomandibular joint syndrome | 1 | 1 |
| Tenderness | 1 | 1 |
| Throat tightness | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tremor | 2 | 2 |
| Urticaria | 2 | 3 |
| Vaccination site abscess | 1 | 1 |
| Vaccination site discolouration | 1 | 1 |
| Vaccination site erythema | 1 | 5 |
| Vaccination site mass | 1 | 1 |
| Vaccination site pain | 11 | 24 |
| Vaccination site pruritus | 1 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 10 | 19 | 4 | 5 |
| 1 | 1 | | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | | | 2 |
| | | 2 | 2 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 4 | | 1 |
| 1 | 1 | | |
| 8 | 21 | 3 | 3 |
| 1 | 3 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Vaccination site rash | | 1 | | | | 1 | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | | |
| Vaccination site swelling | 4 | 9 | 3 | 7 | 1 | 2 | |
| Vaccination site thrombosis | 1 | 1 | | | 1 | 1 | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | | |
| Vaginal discharge | 1 | 1 | 1 | 1 | | | |
| Vaginal haemorrhage | 1 | 1 | 1 | 1 | | | |
| Vision blurred | 1 | 2 | | | 1 | 2 | |
| Vomiting | 2 | 2 | 2 | 2 | | | |
| Vulvovaginal pain | 1 | 1 | 1 | 1 | | | |
| Vulvovaginal pruritus | 1 | 1 | 1 | 1 | | | |
| | 222 | 318 | 142 | 208 | 80 | 110 | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 3 | 5 | 2 | 4 | 1 | 1 |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 2 | 7 | | | 2 | 7 |
| Angioedema | | 1 | | | | 1 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 7 | | 6 | 1 | 1 |
| Asthenia | 1 | 3 | 1 | 2 | | 1 |
| Asthma | 2 | 2 | 1 | 1 | 1 | 1 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 2 | 1 | 2 | | |
| Back pain | | 1 | | 1 | | |
| Blood glucose increased | | 1 | | 1 | | |
| Blood pressure abnormal | | 1 | | | | 1 |
| Blood pressure decreased | | 2 | | | | 2 |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 3 | 4 | 1 | 1 | 2 | 3 |
| Body temperature increased | | 1 | | 1 | | |
| Burning sensation | 2 | 2 | 1 | 1 | 1 | 1 |
| Chest discomfort | 1 | 6 | 1 | 3 | | 3 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 12 | 19 | 11 | 16 | 1 | 3 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Chorioretinitis | 1 | 1 | | | 1 | 1 |
| Cold sweat | | 1 | | 1 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Coordination abnormal | 1 | 1 | | | 1 | 1 |
| Cough | 4 | 8 | 3 | 5 | 1 | 3 |
| C-reactive protein increased | 2 | 2 | | | 2 | 2 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Derealisation | | 1 | | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Dermatitis allergic | 1 | 1 |
| Diarrhoea | 4 | 7 |
| Discomfort | 1 | 3 |
| Disorientation | 1 | 1 |
| Disturbance in attention | | 2 |
| Dizziness | 22 | 36 |
| Dizziness exertional | 1 | 1 |
| Dry eye | | 1 |
| Dry mouth | 1 | 1 |
| Dry skin | 1 | 1 |
| Dry throat | | 1 |
| Dysaesthesia | | 1 |
| Dysgeusia | | 1 |
| Dysphagia | 1 | 2 |
| Dysphonia | 1 | 2 |
| Dyspnoea | 7 | 13 |
| Dyspnoea at rest | | 1 |
| Dyspnoea exertional | 1 | 1 |
| Electrocardiogram ST segment depression | 1 | 1 |
| Erythema | 9 | 13 |
| Eyelid oedema | 1 | 1 |
| Eye pain | 1 | 3 |
| Eye pruritus | | 2 |
| Facial pain | | 1 |
| Fatigue | 30 | 41 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | 3 | 4 |
| Feeling drunk | | 1 |
| Feeling hot | 4 | 8 |
| Flushing | 1 | 3 |
| Gastroesophageal reflux disease | | 1 |
| Groin pain | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 4 | 3 | 3 |
| | | 1 | 3 |
| | | 1 | 1 |
| | 1 | | 1 |
| 14 | 24 | 8 | 12 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | 1 |
| 3 | 6 | 4 | 7 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 5 | 8 | 4 | 5 |
| 1 | 1 | | |
| 1 | 3 | | |
| | 2 | | |
| | 1 | | |
| 24 | 33 | 6 | 8 |
| 1 | 1 | | |
| 3 | 4 | | |
| | 1 | | |
| 4 | 7 | | 1 |
| 1 | 1 | | 2 |
| | 1 | | |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Hand dermatitis | 1 | 1 |
| Headache | 47 | 73 |
| Head discomfort | 1 | 1 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 2 | 3 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 3 | 4 |
| Hypersensitivity | 5 | 8 |
| Hypertension | 6 | 6 |
| Hyperventilation | | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoglycaemia | 1 | 1 |
| Hypokalaemia | 1 | 1 |
| Hypotension | 1 | 1 |
| Influenza | 1 | 1 |
| Influenza like illness | 3 | 4 |
| Injected limb mobility decreased | 1 | 1 |
| Injection site pain | | 1 |
| Insomnia | 3 | 4 |
| Lacrimation increased | 1 | 1 |
| Lethargy | 1 | 1 |
| Leukopenia | 1 | 1 |
| Limb discomfort | 4 | 4 |
| Lip swelling | 2 | 2 |
| Loss of control of legs | 1 | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 9 | 10 |
| Lymph node pain | 2 | 3 |
| Lymphopenia | 1 | 1 |
| Malaise | 19 | 32 |
| Migraine | 2 | 2 |
| Motor dysfunction | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 36 | 58 | 11 | 15 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 3 |
| 1 | 2 | 4 | 6 |
| 2 | 2 | 4 | 4 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | |
| 3 | 4 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 6 | 4 | 4 |
| 2 | 3 | | |
| | | 1 | 1 |
| 14 | 23 | 5 | 9 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Muscle discomfort | | 1 | | 1 | | |
| Muscle fatigue | | 1 | | 1 | | |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscle tightness | | 1 | | 1 | | |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Myalgia | 16 | 26 | 14 | 24 | 2 | 2 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 2 | 3 | 2 | 3 | | |
| Nasal obstruction | | 1 | | 1 | | |
| Nasal pruritus | | 1 | | 1 | | |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Nausea | 23 | 35 | 13 | 22 | 10 | 13 |
| Neck pain | | 1 | | 1 | | |
| Obliterative bronchiolitis | 1 | 1 | | | 1 | 1 |
| Odynophagia | 1 | 1 | | | 1 | 1 |
| Off label use | 3 | 3 | 3 | 3 | | |
| Oral fungal infection | 1 | 1 | 1 | 1 | | |
| Oropharyngeal discomfort | 1 | 2 | 1 | 2 | | |
| Oropharyngeal pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Pain | 3 | 6 | 2 | 4 | 1 | 2 |
| Pain in extremity | 6 | 11 | 6 | 11 | | |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 6 | | 2 | 1 | 4 |
| Palpitations | 3 | 9 | 2 | 5 | 1 | 4 |
| Paraesthesia | 10 | 15 | 7 | 10 | 3 | 5 |
| Paraesthesia oral | 2 | 2 | 2 | 2 | | |
| Periorbital swelling | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 2 | 4 | 1 | 1 | 1 | 3 |
| Photopsia | 1 | 2 | | 1 | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Postmenopausal haemorrhage | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Presyncope | 2 | 9 |
| Productive cough | 1 | 1 |
| Product use issue | 3 | 3 |
| Pruritus | 14 | 20 |
| Pyrexia | 38 | 54 |
| Rash | 5 | 11 |
| Rash erythematous | 4 | 9 |
| Rash pruritic | 3 | 4 |
| Renal pain | 1 | 1 |
| Respiratory failure | | 1 |
| Respiratory tract infection bacterial | 1 | 1 |
| Restlessness | | 3 |
| Rhinitis | 1 | 1 |
| Rhinorrhoea | 1 | 1 |
| Seasonal allergy | 1 | 1 |
| Seizure | 1 | 1 |
| Sensation of foreign body | 1 | 1 |
| Sensory disturbance | 2 | 2 |
| Sensory loss | 1 | 1 |
| Sinus tachycardia | 1 | 2 |
| Sneezing | 3 | 3 |
| Swelling | | 1 |
| Swelling face | 2 | 5 |
| Swelling of eyelid | | 1 |
| Swollen tongue | 1 | 2 |
| Syncope | 2 | 4 |
| Tachycardia | 1 | 3 |
| Tachypnoea | 1 | 1 |
| Taste disorder | 1 | 1 |
| Tenderness | 2 | 2 |
| Throat irritation | 2 | 5 |
| Throat tightness | 1 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 3 | 1 | 6 |
| 1 | 1 | | |
| 3 | 3 | | |
| 9 | 15 | 5 | 5 |
| 28 | 41 | 10 | 13 |
| 3 | 6 | 2 | 5 |
| 3 | 7 | 1 | 2 |
| 3 | 4 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| 3 | 3 | | |
| | 1 | | |
| | 1 | 2 | 4 |
| | 1 | | |
| | | 1 | 2 |
| | | 2 | 4 |
| | | 1 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 4 | 1 | 1 |
| | | 1 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tongue pruritus | 2 | 2 | | | 2 | 2 |
| Tonic convulsion | 1 | 1 | | | 1 | 1 |
| Tremor | 4 | 6 | 2 | 2 | 2 | 4 |
| Upper respiratory tract infection | 1 | 1 | 1 | 1 | | |
| Urinary incontinence | | 1 | | | | 1 |
| Urticaria | 4 | 9 | 3 | 7 | 1 | 2 |
| Vaccination complication | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site discomfort | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 4 | 8 | 3 | 7 | 1 | 1 |
| Vaccination site haematoma | 1 | 2 | 1 | 2 | | |
| Vaccination site haemorrhage | | 1 | | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | | 1 | | 1 | | |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 32 | 59 | 29 | 55 | 3 | 4 |
| Vaccination site paraesthesia | 1 | 2 | 1 | 2 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site rash | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 7 | 12 | 6 | 11 | 1 | 1 |
| Vaccination site warmth | 3 | 5 | 2 | 4 | 1 | 1 |
| Vasodilatation | | 1 | | | | 1 |
| Visual impairment | | 1 | | 1 | | |
| Vomiting | 4 | 8 | 2 | 4 | 2 | 4 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| Wound complication | 1 | 1 | 1 | 1 | | |
| | 524 | 854 | 352 | 590 | 172 | 264 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Angioedema | 1 | 2 | | | 1 | 2 |
| Anxiety | 1 | 2 | | | 1 | 2 |
| Arthralgia | 7 | 10 | 4 | 7 | 3 | 3 |
| Asthenia | 2 | 3 | | | 2 | 3 |
| Auricular swelling | 1 | 1 | 1 | 1 | | |
| Axillary pain | 2 | 2 | 2 | 2 | | |
| Back pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Blood lactate dehydrogenase abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 3 | 2 | 3 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Cardiogenic shock | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 5 | 6 | | | 5 | 6 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 9 | 14 | 5 | 9 | 4 | 5 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 2 | 2 | | | 2 | 2 |
| Cough | | 1 | | | | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Crying | 1 | 1 | | | 1 | 1 |
| Cystitis | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Derealisation | 1 | 1 | 1 | 1 | | |
| Dermatitis allergic | | 1 | | | | 1 |
| Diarrhoea | 2 | 3 | 2 | 3 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # | Cumulative Total # |
|--------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Discomfort | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 17 | 24 |
| Dizziness postural | | 1 |
| Drug ineffective | 1 | 1 |
| Dry mouth | 2 | 2 |
| Dysaesthesia | 1 | 1 |
| Dysphagia | 1 | 2 |
| Dysphonia | | 1 |
| Dyspnoea | 13 | 16 |
| Dyspnoea exertional | 2 | 2 |
| Ear discomfort | 1 | 1 |
| Ear pruritus | 1 | 1 |
| Electrocardiogram QT prolonged | 1 | 1 |
| Erysipelas | 1 | 1 |
| Erythema | 7 | 9 |
| Eye pruritus | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 15 | 20 |
| Feeling cold | 1 | 1 |
| Feeling hot | 3 | 7 |
| Flushing | | 3 |
| Glossodynia | | 1 |
| Headache | 35 | 44 |
| Head discomfort | 2 | 2 |
| Head injury | 1 | 1 |
| Heart rate abnormal | 1 | 1 |
| Heart rate increased | | 1 |
| Hyperacusis | 1 | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 2 | 3 |
| Hypertension | 2 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | | |
| 6 | 8 | 11 | 16 |
| | | | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| | | | 1 |
| 4 | 5 | 9 | 11 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | 3 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 12 | 15 | 3 | 5 |
| 1 | 1 | | |
| | 1 | 3 | 6 |
| | 1 | | |
| 27 | 34 | 8 | 10 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 2 | 3 |
| 1 | 2 | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Hyperventilation | | 1 |
| Hypoaesthesia oral | 2 | 2 |
| Hypophagia | 1 | 1 |
| Hypotension | 1 | 1 |
| Infection | 1 | 1 |
| Influenza | 1 | 1 |
| Influenza like illness | 2 | 3 |
| Joint stiffness | 1 | 1 |
| Joint swelling | 2 | 3 |
| Lacrimation increased | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Loss of consciousness | | 1 |
| Lymphadenopathy | 2 | 2 |
| Malaise | 13 | 22 |
| Mobility decreased | 1 | 1 |
| Muscle fatigue | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 11 | 16 |
| Nasal congestion | 1 | 1 |
| Nasal pruritus | 1 | 1 |
| Nasopharyngitis | | 1 |
| Nausea | 19 | 24 |
| Neck pain | 1 | 1 |
| Neuralgia | 1 | 1 |
| Off label use | 2 | 2 |
| Oral mucosal eruption | 1 | 1 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal pain | 1 | 2 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 5 | 7 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 3 | | |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 2 | 2 |
| 7 | 13 | 6 | 9 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 7 | 11 | 4 | 5 |
| 1 | 1 | | |
| | 1 | | |
| 13 | 15 | 6 | 9 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 5 | 7 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------|------------------------------------|--------------------------------------|
| Painful respiration | 1 | 1 |
| Pain in extremity | 6 | 9 |
| Palpitations | 3 | 5 |
| Paraesthesia | 7 | 9 |
| Paraesthesia oral | 3 | 4 |
| Periarthritis | 2 | 2 |
| Periorbital swelling | 1 | 1 |
| Peripheral swelling | 3 | 4 |
| Pharyngeal oedema | | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | 2 | 4 |
| Pharyngitis | 1 | 1 |
| Photophobia | 1 | 1 |
| Pleural effusion | 1 | 1 |
| Presyncope | 3 | 5 |
| Product use issue | 2 | 2 |
| Pruritus | 6 | 8 |
| Pulmonary embolism | 1 | 1 |
| Pyrexia | 18 | 25 |
| Rash | 3 | 3 |
| Rash erythematous | 2 | 3 |
| Rash morbilliform | 1 | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Rash vesicular | 1 | 1 |
| Restlessness | 1 | 2 |
| Rhinorrhoea | 1 | 1 |
| Salivary hypersecretion | 1 | 1 |
| Sensory disturbance | | 1 |
| Sneezing | 2 | 2 |
| Somnolence | 1 | 1 |
| Sudden cardiac death | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 5 | 8 | 1 | 1 |
| 2 | 4 | 1 | 1 |
| 5 | 5 | 2 | 4 |
| 2 | 2 | 1 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| 2 | 3 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 2 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | 2 | 3 |
| 2 | 2 | | |
| 5 | 6 | 1 | 2 |
| | | 1 | 1 |
| 15 | 21 | 3 | 4 |
| 2 | 2 | 1 | 1 |
| 2 | 2 | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Swelling face | 3 | 3 | 2 | 2 | 1 | 1 |
| Swelling of eyelid | | 1 | | | | 1 |
| Swollen tongue | 2 | 4 | 1 | 1 | 1 | 3 |
| Syncope | 1 | 3 | | | 1 | 3 |
| Tachycardia | | 1 | | 1 | | |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Throat tightness | | 2 | | 1 | | 1 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tremor | | 1 | | | | 1 |
| Tunnel vision | 1 | 1 | | | 1 | 1 |
| Urticaria | 2 | 6 | 2 | 5 | | 1 |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site irritation | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 20 | 24 | 20 | 23 | | 1 |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vomiting | 4 | 5 | 3 | 3 | 1 | 2 |
| | 374 | 504 | 236 | 308 | 138 | 196 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Anaphylactic reaction | | 1 | | | | 1 | |
| Arthralgia | 1 | 1 | 1 | 1 | | | |
| Blood albumin decreased | 1 | 1 | 1 | 1 | | | |
| Blood chloride increased | 1 | 1 | 1 | 1 | | | |
| Blood creatinine increased | 1 | 1 | | | 1 | | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | | |
| Bradycardia | 1 | 1 | | | 1 | | 1 |
| Bronchospasm | | 1 | | | | | 1 |
| Calcium ionised increased | 1 | 1 | 1 | 1 | | | |
| Cardiac arrest | | 1 | | | | | 1 |
| Chest pain | 1 | 1 | | | 1 | | 1 |
| Chills | 1 | 1 | 1 | 1 | | | |
| Chronic obstructive pulmonary disease | | 1 | | | | | 1 |
| Condition aggravated | 1 | 2 | | | 1 | | 2 |
| Coordination abnormal | 1 | 1 | | | 1 | | 1 |
| Cough | | 1 | | | | | 1 |
| COVID-19 | 2 | 2 | | | 2 | | 2 |
| Death | 1 | 1 | | | 1 | | 1 |
| Delirium | 1 | 1 | | | 1 | | 1 |
| Discomfort | | 1 | | | | | 1 |
| Dizziness | 1 | 2 | 1 | 1 | | | 1 |
| Drug ineffective | 1 | 1 | | | 1 | | 1 |
| Dysphonia | 2 | 2 | 2 | 2 | | | |
| Dyspnoea | 2 | 4 | | 1 | 2 | | 3 |
| Face oedema | 1 | 1 | | | 1 | | 1 |
| Fatigue | 5 | 6 | 4 | 5 | 1 | | 1 |
| Feeling cold | 2 | 2 | 1 | 1 | 1 | | 1 |
| Feeling hot | 1 | 1 | | | 1 | | 1 |
| Foaming at mouth | 1 | 2 | | 1 | 1 | | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | | 1 |
| General physical health deterioration | 2 | 3 | | | 2 | | 3 |
| Glomerular filtration rate decreased | 1 | 1 | | | 1 | | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # | Cumulative Total # |
|--|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Haemorrhage intracranial | 1 | 1 |
| Headache | 7 | 8 |
| Heart rate increased | | 1 |
| Herpes zoster | 1 | 1 |
| Hyperhidrosis | | 1 |
| Hypotension | 1 | 2 |
| Illness | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Influenza | 2 | 2 |
| Influenza like illness | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Malaise | 4 | 6 |
| Micturition urgency | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 3 | 3 |
| Nausea | 2 | 4 |
| Neutrophil count increased | 1 | 1 |
| Oedema peripheral | 1 | 2 |
| Off label use | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Oxygen saturation decreased | | 1 |
| Pallor | | 1 |
| Pneumonia | 2 | 2 |
| Pneumonia bacterial | 1 | 1 |
| Presyncope | 1 | 2 |
| Prolonged expiration | | 1 |
| Pruritus | 1 | 1 |
| Pulmonary arterial hypertension | 1 | 1 |
| Pulmonary fibrosis | | 1 |
| Pulmonary oedema | 1 | 1 |
| Pyrexia | 10 | 11 |
| Rash | 1 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 5 | 5 | 2 | 3 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 4 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| 1 | 2 | 1 | 2 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 7 | 7 | 3 | 4 |
| 1 | 2 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Somnolence | 3 | 3 | 2 | 2 | 1 | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachypnoea | | 1 | | | | 1 |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site erythema | 4 | 4 | 3 | 3 | 1 | 1 |
| Vaccination site pain | 5 | 6 | 5 | 6 | | |
| Vaccination site swelling | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vertigo | | 1 | | | | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| Weight increased | | 1 | | 1 | | |
| | 107 | 141 | 60 | 72 | 47 | 69 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Acute leukaemia | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Aggression | | 1 | | | | 1 |
| Altered state of consciousness | 2 | 2 | | | 2 | 2 |
| Anaemia | 2 | 2 | 1 | 1 | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | | 1 | | | | 1 |
| Aspiration | | 1 | | | | 1 |
| Asthenia | 2 | 3 | | 1 | 2 | 2 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Atrial flutter | | 1 | | | | 1 |
| Bacteraemia | | 1 | | | | 1 |
| Blood creatine phosphokinase increased | 1 | 1 | | | 1 | 1 |
| Blood pressure systolic increased | | 1 | | 1 | | |
| Cerebral thrombosis | 1 | 1 | | | 1 | 1 |
| Chest pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Coma | | 1 | | | | 1 |
| Condition aggravated | 2 | 3 | | | 2 | 3 |
| Confusional state | 3 | 4 | 1 | 1 | 2 | 3 |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 10 | 11 | | | 10 | 11 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Death | 4 | 5 | | | 4 | 5 |
| Delusion | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 3 | 4 | | | 3 | 4 |
| Diarrhoea | 3 | 3 | 1 | 1 | 2 | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Dizziness | 7 | 8 |
| Drug ineffective | 6 | 7 |
| Drug interaction | | 1 |
| Dyspnoea | 3 | 6 |
| Dysstasia | 1 | 1 |
| Erythema | 3 | 3 |
| Fatigue | 3 | 4 |
| Feeling abnormal | 1 | 1 |
| Feeling hot | 3 | 3 |
| Fluid intake reduced | | 1 |
| Flushing | 1 | 2 |
| General physical health deterioration | 2 | 4 |
| Hallucination, visual | 1 | 1 |
| Headache | 2 | 3 |
| Heart rate decreased | 1 | 1 |
| Hemiparesis | | 1 |
| Hot flush | 3 | 3 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 1 | 1 |
| Hypertension | | 1 |
| Hypophagia | | 1 |
| Hypotension | 1 | 2 |
| Hypoxia | 1 | 1 |
| Incorrect route of product administration | | 2 |
| Infection | | 1 |
| Loss of consciousness | 1 | 1 |
| Malaise | 8 | 10 |
| Mobility decreased | | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 |
| Nausea | 4 | 5 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 6 | 7 | 1 | 1 |
| | | 6 | 7 |
| | | | 1 |
| | 1 | 3 | 5 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 2 | 3 |
| 1 | 1 | | |
| 3 | 3 | | |
| | 1 | | |
| 1 | 1 | | 1 |
| | | 2 | 4 |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | | |
| | | | 1 |
| 3 | 3 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | 2 | | |
| | | | 1 |
| | | 1 | 1 |
| 3 | 4 | 5 | 6 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 3 | 3 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Oral pruritus | 1 | 1 | 1 | 1 | | |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Pleural effusion | | 1 | | | | 1 |
| Pneumonia | 3 | 4 | | | 3 | 4 |
| Pneumonia aspiration | | 1 | | | | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pulmonary oedema | 1 | 2 | | | 1 | 2 |
| Pyrexia | 11 | 12 | 2 | 2 | 9 | 10 |
| Rales | | 1 | | | | 1 |
| Rash | 1 | 1 | 1 | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Respiratory acidosis | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | | 1 | | | | 1 |
| Respiratory failure | 5 | 6 | | | 5 | 6 |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 2 | 2 | 1 | 1 | 1 | 1 |
| Sepsis | | 1 | | | | 1 |
| Severe acute respiratory syndrome | | 1 | | | | 1 |
| Skin lesion | | 1 | | 1 | | |
| Somnolence | | 1 | | | | 1 |
| Sudden death | | 1 | | | | 1 |
| Swelling face | 1 | 2 | | 1 | 1 | 1 |
| Thinking abnormal | | 1 | | | | 1 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Troponin I increased | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urticaria | 2 | 2 | 2 | 2 | | |
| Vaccination site necrosis | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vomiting | 7 | 10 | 2 | 3 | 5 | 7 |
| | 157 | 212 | 41 | 55 | 116 | 157 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Accidental exposure to product | 1 | 1 | 1 | 1 |
| Exposure via breast milk | 1 | 1 | 1 | 1 |
| Exposure via skin contact | 1 | 1 | 1 | 1 |
| Hypoaesthesia | | 1 | | 1 |
| Incorrect route of product administration | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 |
| Product administration error | | 1 | | 1 |
| Underdose | 1 | 2 | 1 | 2 |
| Vaccination site erythema | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| Vaccination site swelling | 1 | 1 | 1 | 1 |
| Vaccination site warmth | 1 | 1 | 1 | 1 |
| | 11 | 14 | 11 | 14 |

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Country Where Event Occurred
ECUADOR

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Blood pressure increased | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Laryngitis | 1 | 1 | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 | 1 | 1 |
| Tracheitis | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

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Country Where Event Occurred

ESTONIA

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chills | 3 | 3 | 3 | 3 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Flushing | 1 | 1 | 1 | 1 | | |
| Headache | 6 | 6 | 6 | 6 | | |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypopnoea | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Immunisation reaction | 1 | 1 | | | 1 | 1 |
| Intranasal paraesthesia | 1 | 1 | 1 | 1 | | |
| Malaise | 3 | 3 | 1 | 1 | 2 | 2 |
| Maternal exposure during pregnancy | | 2 | | 2 | | |
| Migraine with aura | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 2 | 2 | 2 | | |
| Nausea | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 2 | 3 | 2 | 3 | | |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Pharyngeal paraesthesia | 1 | 1 | 1 | 1 | | |
| Pyrexia | 5 | 5 | 5 | 5 | | |
| Retching | 1 | 1 | | | 1 | 1 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 6 | 7 | 6 | 7 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| | 53 | 57 | 41 | 45 | 12 | 12 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 4 | 4 | 2 | 2 | 2 | 2 |
| Asymptomatic COVID-19 | | 1 | | | | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood creatine phosphokinase increased | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 2 | 2 | 1 | 1 | 1 | 1 |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Drug ineffective | | 1 | | | | 1 |
| Dysgeusia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 2 | 2 | 2 | 2 | | |
| Facial nerve disorder | | 1 | | 1 | | |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Fall | 1 | 1 | 1 | 1 | | |
| Fatigue | 3 | 3 | 2 | 2 | 1 | 1 |
| Feeling hot | | 1 | | 1 | | |
| Fracture | | 1 | | | | 1 |
| Headache | 7 | 8 | 5 | 6 | 2 | 2 |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | | 2 | | 2 | | |
| Immunisation anxiety related reaction | 4 | 4 | 4 | 4 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 2 | 1 | 2 | | |
| Maternal exposure during pregnancy | | 2 | | 2 | | |
| Myalgia | 1 | 2 | 1 | 2 | | |
| Nausea | 3 | 3 | 2 | 2 | 1 | 1 |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Off label use | | 1 | | 1 | | |
| Pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 8 | 10 | 6 | 8 | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Product use issue | | 1 | | 1 | | |
| Pyrexia | 5 | 5 | 4 | 4 | 1 | 1 |
| Somnolence | 4 | 4 | 3 | 3 | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Syringe issue | | 1 | | 1 | | |
| Tachycardia | 1 | 2 | 1 | 2 | | |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| Underdose | | 1 | | 1 | | |
| Vaccination site pain | 7 | 7 | 7 | 7 | | |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| | 74 | 93 | 56 | 72 | 18 | 21 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 2 | 1 | 2 | | |
| Asthenia | 3 | 4 | 2 | 3 | 1 | 1 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | 3 | 3 | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 2 | 2 | | |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Headache | 3 | 4 | 1 | 2 | 2 | 2 |
| Hypersensitivity | 2 | 2 | | | 2 | 2 |
| Hypertension | | 1 | | 1 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Immunisation anxiety related reaction | | 2 | | 2 | | |
| Laryngeal oedema | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | | 1 | | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Nausea | 4 | 4 | 2 | 2 | 2 | 2 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oral herpes | 1 | 1 | 1 | 1 | | |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palpitations | | 1 | | 1 | | |
| Paraesthesia | | 1 | | 1 | | |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Pneumonia | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 2 | 2 | 2 | | |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Restlessness | | 1 | | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| | 51 | 62 | 29 | 40 | 22 | 22 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 1 | 1 | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Immunisation anxiety related reaction | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| Vaccination site oedema | 1 | 1 | 1 | 1 |
| Vaccination site pain | 2 | 2 | 2 | 2 |
| Vaccination site swelling | 1 | 1 | 1 | 1 |
| | 10 | 10 | 10 | 10 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 2 | 1 | 1 | 1 | 1 |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 1 | 1 | 6 | 6 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Dysgeusia | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Muscle spasms | 1 | 1 | 1 | 1 |
| Oral herpes | 1 | 1 | 1 | 1 |
| Vaccination site pain | 5 | 5 | 5 | 5 |
| | 9 | 9 | 9 | 9 |

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Country Where Event Occurred

FINLAND

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Ankylosing spondylitis | 1 | 1 | | | 1 | 1 |
| Appendicitis | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 3 | | | 3 | 3 |
| Asthenia | 4 | 4 | 1 | 1 | 3 | 3 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure diastolic increased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Breast cyst | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 3 | | | 2 | 3 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 2 | | | 1 | 2 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 3 | | | 2 | 3 |
| Erythema | 4 | 4 | 1 | 1 | 3 | 3 |
| Erythema of eyelid | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |
| Eye pain | 2 | 2 | | | 2 | 2 |
| Face oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Facial pain | 1 | 1 | | | 1 | 1 |
| Fatigue | 6 | 6 | | | 6 | 6 |
| Feeling abnormal | 2 | 2 | 1 | 1 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Feeling cold | 1 | 1 |
| Feeling hot | 3 | 3 |
| Flank pain | 1 | 1 |
| Headache | 9 | 10 |
| Heart rate increased | 2 | 3 |
| Hyperaesthesia | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 2 | 2 |
| Hypoaesthesia | 7 | 7 |
| Hypoaesthesia oral | 2 | 2 |
| Hypokalaemia | 1 | 2 |
| Impaired work ability | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Increased upper airway secretion | 1 | 1 |
| Joint range of motion decreased | 1 | 1 |
| Localised oedema | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Loss of control of legs | 1 | 1 |
| Lymphadenopathy | 6 | 6 |
| Lymph node pain | 1 | 1 |
| Lymph nodes scan abnormal | 1 | 1 |
| Malaise | 3 | 4 |
| Malignant lymphoid neoplasm | 1 | 1 |
| Migraine | | 1 |
| Muscle fatigue | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 6 | 6 |
| Myocarditis | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nasal oedema | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 9 | 10 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 7 | 7 |
| | | 2 | 2 |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 4 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # | Cumulative Total # |
|---------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Nausea | 6 | 7 |
| Neck pain | 1 | 1 |
| Neuralgia | 2 | 2 |
| Night sweats | 1 | 1 |
| Nuchal rigidity | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 7 | 7 |
| Pain of skin | 1 | 1 |
| Palpitations | 2 | 2 |
| Paraesthesia | 3 | 4 |
| Paraesthesia oral | 1 | 1 |
| Pharyngeal hypoaesthesia | 1 | 1 |
| Pharyngeal oedema | 3 | 4 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | | 1 |
| Photophobia | 1 | 1 |
| Pyrexia | 7 | 7 |
| Rash macular | 1 | 1 |
| Sensory disturbance | 1 | 1 |
| Somnolence | 1 | 1 |
| Syncope | 2 | 2 |
| Tendon pain | 1 | 1 |
| Throat irritation | 2 | 2 |
| Tongue oedema | 1 | 1 |
| Tremor | | 1 |
| Urticaria | 1 | 1 |
| Vaccination site abscess | 1 | 1 |
| Vaccination site erythema | 6 | 6 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 5 | 6 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 5 | 5 |
| | | 1 | 1 |
| | | 2 | 2 |
| 2 | 2 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 4 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 6 | 6 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 3 | 3 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site haematoma | | 1 | | 1 | | |
| Vaccination site hyperaesthesia | 2 | 2 | | | 2 | 2 |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 4 | 5 | 3 | 4 | 1 | 1 |
| Vaccination site pain | 7 | 8 | 2 | 3 | 5 | 5 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 3 | 4 | 1 | 2 | 2 | 2 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| | 196 | 213 | 36 | 40 | 160 | 173 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 2 | 2 | | | 2 | 2 |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 6 | 6 | | | 6 | 6 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Aphonia | 3 | 3 | 1 | 1 | 2 | 2 |
| Arrhythmia | 3 | 3 | | | 3 | 3 |
| Arthralgia | 8 | 8 | 2 | 2 | 6 | 6 |
| Asthenia | 12 | 13 | 1 | 2 | 11 | 11 |
| Axillary pain | 4 | 5 | 2 | 3 | 2 | 2 |
| Back pain | 2 | 2 | | | 2 | 2 |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 4 | | | 4 | 4 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 3 | 4 | 2 | 2 | 1 | 2 |
| Chest pain | 2 | 2 | | | 2 | 2 |
| Chills | 6 | 6 | 1 | 1 | 5 | 5 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | 4 | 4 | | | 4 | 4 |
| C-reactive protein increased | 1 | 2 | | 1 | 1 | 1 |
| Derealisation | | 1 | | 1 | | |
| Diarrhoea | 4 | 4 | 2 | 2 | 2 | 2 |
| Discomfort | 3 | 3 | 1 | 1 | 2 | 2 |
| Dizziness | 9 | 10 | | | 9 | 10 |
| Dry eye | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dysphonia | 2 | 2 |
| Dyspnoea | 15 | 17 |
| Dysstasia | 1 | 1 |
| Ear canal erythema | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear pain | 1 | 1 |
| Ear pruritus | 1 | 1 |
| Eczema | 1 | 1 |
| Epilepsy | 1 | 1 |
| Erythema | 13 | 15 |
| Extensive swelling of vaccinated limb | 1 | 1 |
| Extrasystoles | 2 | 3 |
| Eye haematoma | 1 | 1 |
| Eyelid irritation | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eye pain | 1 | 1 |
| Face oedema | 2 | 2 |
| Facial pain | 1 | 1 |
| Facial paralysis | 2 | 2 |
| Fatigue | 20 | 20 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | 2 | 2 |
| Feeling hot | 2 | 3 |
| Flatulence | 1 | 1 |
| Flushing | 3 | 3 |
| Gastric disorder | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Haematoma | 2 | 2 |
| Headache | 24 | 25 |
| Head discomfort | 1 | 1 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 7 | 7 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 14 | 16 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | 11 | 12 |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| 8 | 8 | 12 | 12 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | 2 | 2 |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 5 | 5 | 19 | 20 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 7 | 7 |

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Age Range

31 - 50 years

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Hemianaesthesia | 4 | 4 |
| Herpes zoster cutaneous disseminated | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperaesthesia | 2 | 2 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 3 | 4 |
| Hypoaesthesia | 2 | 3 |
| Hypoaesthesia oral | 3 | 4 |
| Hypoaesthesia teeth | 1 | 1 |
| Hypokalaemia | 2 | 3 |
| Incorrect route of product administration | 1 | 1 |
| Increased upper airway secretion | 1 | 1 |
| Insomnia | 1 | 1 |
| Laryngeal pain | 1 | 1 |
| Lip pain | 1 | 1 |
| Lip pruritus | 1 | 1 |
| Localised oedema | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenopathy | 8 | 10 |
| Lymph node pain | 1 | 1 |
| Malaise | 14 | 16 |
| Menstrual disorder | 1 | 1 |
| Middle insomnia | 2 | 2 |
| Migraine | 2 | 2 |
| Mouth swelling | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscle spasticity | 1 | 1 |
| Muscle twitching | 2 | 2 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 3 | 4 |
| | 1 | 2 | 2 |
| 1 | 2 | 2 | 2 |
| 1 | 1 | | |
| | | 2 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 6 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Myalgia | 14 | 14 |
| Mydriasis | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nausea | 13 | 14 |
| Neck pain | 2 | 2 |
| Neuralgia | 1 | 1 |
| Nodule | | 1 |
| Oedema peripheral | 1 | 1 |
| Oral herpes | 1 | 1 |
| Oral pruritus | 2 | 3 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 2 | 2 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 20 | 20 |
| Pain of skin | 2 | 2 |
| Pallor | 3 | 3 |
| Palpitations | 7 | 8 |
| Papule | 1 | 1 |
| Paraesthesia | 10 | 10 |
| Paraesthesia oral | 6 | 7 |
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | 2 | 2 |
| Presyncope | 1 | 2 |
| Pruritus | 5 | 5 |
| Pulmonary pain | 1 | 1 |
| Pyrexia | 20 | 20 |
| Rash | 3 | 5 |
| Rash erythematous | | 1 |
| Rash pruritic | 1 | 1 |
| Respiratory tract irritation | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 14 | 14 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | 12 | 12 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 7 | 13 | 13 |
| 1 | 1 | 1 | 1 |
| | | 3 | 3 |
| 2 | 3 | 5 | 5 |
| 1 | 1 | | |
| 2 | 2 | 8 | 8 |
| 2 | 3 | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | 1 | 1 |
| 3 | 3 | 2 | 2 |
| | | 1 | 1 |
| 3 | 3 | 17 | 17 |
| 1 | 1 | 2 | 4 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rhinitis | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| Rinne tuning fork test abnormal | 1 | 1 | 1 | 1 | | |
| Seizure | | 1 | | | | 1 |
| Sensation of foreign body | 4 | 4 | 1 | 1 | 3 | 3 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Stiff tongue | 1 | 1 | | | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Swelling of eyelid | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 2 | | | 1 | 2 |
| Tachycardia | 3 | 5 | | 1 | 3 | 4 |
| Throat irritation | 5 | 5 | 2 | 2 | 3 | 3 |
| Throat tightness | 2 | 2 | | | 2 | 2 |
| Thrombophlebitis superficial | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 3 | | | 3 | 3 |
| Tympanic membrane hyperaemia | 1 | 1 | 1 | 1 | | |
| Type IV hypersensitivity reaction | | 1 | | 1 | | |
| Urticaria | 10 | 11 | 4 | 4 | 6 | 7 |
| Vaccination site erythema | 8 | 9 | 5 | 6 | 3 | 3 |
| Vaccination site haematoma | 2 | 2 | 2 | 2 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 4 | 4 | | | 4 | 4 |
| Vaccination site oedema | 5 | 6 | 4 | 5 | 1 | 1 |
| Vaccination site pain | 19 | 20 | 8 | 9 | 11 | 11 |
| Vaccination site plaque | | 1 | | 1 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 4 | 4 | 1 | 1 | 3 | 3 |
| Vaccination site warmth | 2 | 3 | 1 | 2 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vertigo | 2 | 2 | | | 2 | 2 |
| Viral infection | 2 | 2 | | | 2 | 2 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Vomiting | 3 | 4 | | | 3 | 4 |
| Weber tuning fork test abnormal | 1 | 1 | 1 | 1 | | |
| Wheezing | 2 | 2 | | | 2 | 2 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 502 | 545 | 126 | 152 | 376 | 393 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 2 | 2 | | | 2 | 2 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 4 | | | 2 | 4 |
| Arthralgia | 4 | 4 | 3 | 3 | 1 | 1 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Asthenia | 3 | 4 | 2 | 3 | 1 | 1 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 2 | 1 | 2 | | |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Chills | 3 | 3 | 3 | 3 | | |
| Cognitive disorder | 1 | 1 | 1 | 1 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | | | 2 | 2 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | | | 2 | 2 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 5 | 5 | 1 | 1 | 4 | 4 |
| Erythema | 1 | 2 | 1 | 1 | | 1 |
| Erythema multiforme | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Eye pain | 2 | 2 | 2 | 2 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fatigue | 7 | 8 | 5 | 6 | 2 | 2 |
| Feeding disorder | 1 | 1 | | | 1 | 1 |
| Feeling abnormal | 2 | 2 | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Feeling cold | | 1 |
| Feeling hot | 2 | 2 |
| Flushing | 2 | 2 |
| Foaming at mouth | 1 | 1 |
| Gait disturbance | | 1 |
| Gingival swelling | 1 | 1 |
| Grip strength decreased | 1 | 1 |
| Hallucination, auditory | 1 | 1 |
| Headache | 10 | 11 |
| Heart rate increased | 1 | 1 |
| Hemianaesthesia | 2 | 2 |
| Hemiparaesthesia | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 2 | 2 |
| Hypoaesthesia | 2 | 2 |
| Hypoaesthesia oral | 1 | 1 |
| Hypotension | | 1 |
| Incorrect route of product administration | 6 | 6 |
| Insomnia | 1 | 1 |
| Irritability postvaccinal | | 1 |
| Lip pain | 1 | 1 |
| Lip swelling | 2 | 2 |
| Lymphadenopathy | 4 | 5 |
| Malaise | 4 | 5 |
| Memory impairment | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 5 | 8 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | 6 | 6 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | | 1 |
| 6 | 6 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 2 | 3 | 3 |
| | 1 | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 3 | 6 | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Nausea | 4 | 4 |
| Nuchal rigidity | | 1 |
| Obstruction | 1 | 1 |
| Off label use | 1 | 1 |
| Oral discomfort | 1 | 1 |
| Oral mucosal blistering | | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 3 | 3 |
| Pain | 2 | 2 |
| Pain in extremity | 5 | 7 |
| Pallor | 1 | 1 |
| Paraesthesia | 3 | 3 |
| Paraesthesia oral | 2 | 2 |
| Product use issue | 1 | 1 |
| Pruritus | 2 | 2 |
| Pyrexia | 2 | 5 |
| Rash erythematous | 1 | 1 |
| Rash macular | 1 | 1 |
| Respiratory rate decreased | 1 | 1 |
| Respiratory tract infection | 1 | 1 |
| Rhinorrhoea | 1 | 1 |
| Self-injurious ideation | 1 | 1 |
| Sensation of foreign body | 1 | 1 |
| Somnolence | | 1 |
| Speech disorder | 1 | 1 |
| Swelling | 2 | 2 |
| Swelling face | 1 | 1 |
| Synovial fluid white blood cells positive | 1 | 1 |
| Tachycardia | 1 | 1 |
| Throat irritation | 1 | 2 |
| Tinnitus | 1 | 1 |
| Toothache | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | 2 | 2 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 2 | 2 |
| 2 | 4 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| 2 | 2 | | |
| | 3 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 1 | 1 | | | 1 | 1 |
| Urticaria | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site erythema | 1 | 2 | 1 | 2 | | |
| Vaccination site haematoma | 1 | 1 | 1 | 1 | | |
| Vaccination site macule | | 1 | | 1 | | |
| Vaccination site movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 5 | 6 | 2 | 3 | 3 | 3 |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| | 174 | 204 | 73 | 98 | 101 | 106 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 2 | | | 2 | 2 |
| Gaze palsy | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 2 | 2 | | | 2 | 2 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Hypotonia | 1 | 1 | | | 1 | 1 |
| Inflammatory marker increased | 1 | 1 | | | 1 | 1 |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Movement disorder | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Nausea | 2 | 2 | 2 | 2 | | |
| Neurological symptom | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pyrexia | 3 | 3 | | | 3 | 3 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Slow speech | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | | | 1 | 1 |
| Vomiting | 2 | 2 | 2 | 2 | | |
| | 43 | 43 | 4 | 4 | 39 | 39 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Apnoea | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | | | 2 | 2 |
| Arthritis reactive | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Confusional state | 2 | 2 | 1 | 1 | 1 | 1 |
| Congestive cardiomyopathy | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 5 | 5 | | | 5 | 5 |
| Death | 3 | 3 | | | 3 | 3 |
| Dementia Alzheimer's type | 1 | 2 | | | 1 | 2 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysphagia | 2 | 2 | | | 2 | 2 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 9 | 9 | 2 | 2 | 7 | 7 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Eyelid ptosis | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 3 | 3 | | | 3 | 3 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 4 | 5 | 2 | 2 | 2 | 3 |
| Gaze palsy | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 5 | 5 | | | 5 | 5 |
| Headache | 1 | 1 | | | 1 | 1 |
| Head discomfort | 1 | 1 | | | 1 | 1 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|----------------------------------|--|--|
| Hypotonia | 1 | 1 |
| Increased upper airway secretion | 2 | 2 |
| Insomnia | 1 | 1 |
| Lip oedema | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Loss of control of legs | 1 | 1 |
| Malaise | 1 | 1 |
| Mobility decreased | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Myalgia | 1 | 1 |
| Nausea | 3 | 3 |
| Opisthotonus | 1 | 1 |
| Oral disorder | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 1 | 1 |
| Pneumonia | 2 | 2 |
| Pneumonia aspiration | 1 | 1 |
| Productive cough | 1 | 1 |
| Pulmonary oedema | 1 | 1 |
| Pyelonephritis | 1 | 1 |
| Pyrexia | 12 | 12 |
| Rash macular | 1 | 1 |
| Rhonchi | 1 | 1 |
| Subcutaneous abscess | 1 | 1 |
| Sudden death | 1 | 1 |
| Swelling | 1 | 1 |
| Swelling face | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Vaccination site erythema | 1 | 1 |
| Vertigo | 1 | 1 |
| Visual impairment | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 11 | 11 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 3 | 3 | 2 | 2 | 1 | 1 |
| Wheezing | 2 | 2 | 1 | 1 | 1 | 1 |
| | 113 | 115 | 15 | 15 | 98 | 100 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | | 1 | | 1 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | | | 2 | 2 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling cold | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Gait disturbance | 1 | 1 | | | 1 | 1 |
| Headache | 2 | 2 | 2 | 2 | | |
| Hemianaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | | 1 | | 1 | | |
| Malaise | 1 | 1 | | | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Poor quality product administered | 12 | 12 | 12 | 12 | | |
| Product preparation error | 12 | 12 | 12 | 12 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 43 | 46 | 32 | 35 | 11 | 11 |

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Country Where Event Occurred
FRANCE

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphonia | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | | 2 | | 2 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | | | 1 | 1 |
| | 13 | 15 | | 2 | 13 | 13 |

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* I=Interval, C=Cumulative
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 8 | 8 | 3 | 3 | 5 | 5 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 3 | 3 | | | 3 | 3 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Coordination abnormal | 1 | 1 | 1 | 1 | | |
| Costovertebral angle tenderness | 1 | 1 | | | 1 | 1 |
| Cough | 3 | 3 | | | 3 | 3 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 2 | 2 | 1 | 1 | 1 | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 4 | 1 | 1 | 3 | 3 |
| Drooling | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 3 | 3 | | | 3 | 3 |
| Dyspnoea exertional | 1 | 1 | | | 1 | 1 |
| Dysuria | 1 | 1 | 1 | 1 | | |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Epstein-Barr virus infection | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Face oedema | 1 | 1 |
| Facial paralysis | 1 | 1 |
| Faeces soft | 1 | 1 |
| Fatigue | 2 | 2 |
| Feeling cold | 1 | 1 |
| Feeling drunk | 1 | 1 |
| Formication | 1 | 1 |
| Gait inability | 1 | 1 |
| Gastrointestinal disorder | 1 | 1 |
| Headache | 9 | 9 |
| Hepatocellular injury | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 1 | 1 |
| Hypertension | 1 | 1 |
| Infection | 2 | 2 |
| Influenza like illness | 1 | 1 |
| Insomnia | 3 | 3 |
| Intercostal neuralgia | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Lip oedema | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Lymphopenia | 1 | 1 |
| Malaise | 5 | 5 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 6 | 6 |
| Myocardial infarction | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 4 | 4 | 2 | 2 |
| | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Nausea | 4 | 4 |
| Neck pain | 2 | 2 |
| Neuralgia | 2 | 2 |
| Neutropenia | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 3 | 3 |
| Pain in extremity | 2 | 2 |
| Palpitations | 1 | 1 |
| Pancytopenia | 1 | 1 |
| Paraesthesia | 5 | 5 |
| Parosmia | 1 | 1 |
| Pericarditis | 1 | 1 |
| Peripheral coldness | 1 | 1 |
| Phonophobia | 1 | 1 |
| Poor quality product administered | 1 | 1 |
| Presyncope | 1 | 1 |
| Product temperature excursion issue | 1 | 1 |
| Pruritus | 1 | 1 |
| Pyrexia | 7 | 7 |
| Rhinorrhoea | 1 | 1 |
| Shock | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 5 | 5 |
| Tachypnoea | 1 | 1 |
| Taste disorder | 1 | 1 |
| Thirst | 1 | 1 |
| Tremor | 2 | 2 |
| Type II hypersensitivity | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 4 | 4 |
| | | 2 | 2 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 4 | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| Vaccination site discolouration | 1 | 1 | | | 1 | 1 |
| Vaccination site haematoma | 1 | 1 | 1 | 1 | | |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 5 | 5 | 3 | 3 | 2 | 2 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vertigo | 3 | 3 | 2 | 2 | 1 | 1 |
| Vomiting | 2 | 2 | 1 | 1 | 1 | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 181 | 181 | 61 | 61 | 120 | 120 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 5 | 5 | 1 | 1 | 4 | 4 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Acute febrile neutrophilic dermatosis | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute vestibular syndrome | 1 | 1 | | | 1 | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Anaphylactoid reaction | 2 | 2 | | | 2 | 2 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Ankylosing spondylitis | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety disorder | 1 | 1 | 1 | 1 | | |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 16 | 16 | 7 | 7 | 9 | 9 |
| Aspartate aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Asthenia | 36 | 36 | 18 | 18 | 18 | 18 |
| Asthma | 3 | 3 | | | 3 | 3 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Aura | 1 | 1 | | | 1 | 1 |
| Autoimmune thyroiditis | 1 | 1 | | | 1 | 1 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Behaviour disorder | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Blood alkaline phosphatase increased | 1 | 1 |
| Blood glucose increased | 1 | 1 |
| Blood pressure decreased | 2 | 2 |
| Blood pressure increased | 2 | 2 |
| Cerebrovascular accident | 1 | 1 |
| Chest discomfort | 4 | 4 |
| Chest pain | 2 | 2 |
| Chillblains | 1 | 1 |
| Chills | 25 | 25 |
| Cold sweat | 1 | 1 |
| Confusional state | 2 | 2 |
| Conjunctival haemorrhage | 1 | 1 |
| Cough | 4 | 4 |
| COVID-19 | 15 | 15 |
| C-reactive protein increased | 1 | 1 |
| Deafness unilateral | 1 | 1 |
| Decreased appetite | 3 | 3 |
| Deep vein thrombosis | 1 | 1 |
| Dermo-hypodermatitis | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 |
| Diarrhoea | 16 | 16 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Discomfort | 4 | 4 |
| Disease recurrence | 2 | 2 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 11 | 11 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 10 | 11 |
| Dysaesthesia | 2 | 2 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 4 | 4 |
| Dysphagia | 3 | 4 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 9 | 9 | 16 | 16 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 4 | 4 | 11 | 11 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 7 | 9 | 9 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 3 | 3 | 8 | 8 |
| | | 1 | 1 |
| | | 10 | 11 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | 3 | 3 |
| | | 3 | 4 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dyspnoea | 8 | 8 |
| Dysstasia | 2 | 2 |
| Ear pain | 2 | 2 |
| Epilepsy | 1 | 1 |
| Epstein-Barr virus test positive | 1 | 1 |
| Eructation | 2 | 2 |
| Erythema | 13 | 13 |
| Extensive swelling of vaccinated limb | 2 | 2 |
| Eyelid oedema | 4 | 4 |
| Facial paralysis | 4 | 4 |
| Fall | 2 | 2 |
| Fatigue | 25 | 26 |
| Fat tissue increased | 1 | 1 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | 1 | 1 |
| Feeling drunk | 1 | 1 |
| Feeling hot | 2 | 2 |
| Flushing | 5 | 5 |
| Frostbite | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Gastrointestinal disorder | 1 | 1 |
| Gastrointestinal motility disorder | 1 | 1 |
| Gastrointestinal pain | 1 | 1 |
| Glomerulonephritis | 1 | 1 |
| Gout | 1 | 1 |
| Hair colour changes | 1 | 1 |
| Headache | 48 | 50 |
| Head injury | 1 | 1 |
| Heart rate increased | 3 | 3 |
| Hemiparaesthesia | 1 | 1 |
| Hemiparesis | 2 | 2 |
| Herpes simplex | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | 5 | 5 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 6 | 6 | 7 | 7 |
| 1 | 1 | 1 | 1 |
| 3 | 3 | 1 | 1 |
| | | 4 | 4 |
| | | 2 | 2 |
| 12 | 13 | 13 | 13 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 20 | 22 | 28 | 28 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Herpes zoster | 3 | 3 |
| Hot flush | 5 | 5 |
| Hyperhidrosis | 9 | 10 |
| Hypersensitivity | 10 | 11 |
| Hypersensitivity vasculitis | 1 | 1 |
| Hypertension | 12 | 12 |
| Hypertensive crisis | | 1 |
| Hyperthermia | 5 | 5 |
| Hyperventilation | 2 | 2 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 4 | 4 |
| Hypoaesthesia oral | 2 | 2 |
| Hypoglycaemia | 2 | 2 |
| Hypokinesia | 1 | 1 |
| Hypoperfusion | 1 | 1 |
| Hypotension | 6 | 6 |
| Hypothermia | 2 | 2 |
| Hypoventilation | 1 | 1 |
| Impaired work ability | 2 | 2 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect route of product administration | 2 | 2 |
| Inflammation | 1 | 1 |
| Influenza | 1 | 1 |
| Influenza like illness | 12 | 12 |
| Injected limb mobility decreased | 4 | 4 |
| Insomnia | 2 | 2 |
| Lacrimation increased | 1 | 1 |
| Lactic acidosis | 1 | 1 |
| Laryngeal discomfort | 1 | 1 |
| Larynx irritation | 1 | 1 |
| Lichen planus | 1 | 1 |
| Limb discomfort | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 3 |
| 2 | 2 | 3 | 3 |
| 3 | 4 | 6 | 6 |
| 1 | 1 | 9 | 10 |
| | | 1 | 1 |
| 1 | 1 | 11 | 11 |
| | | | 1 |
| 2 | 2 | 3 | 3 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | | |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Lip pruritus | 1 | 1 |
| Lip swelling | 2 | 2 |
| Livedo reticularis | 1 | 1 |
| Localised oedema | 1 | 1 |
| Logorrhoea | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenopathy | 14 | 14 |
| Lymph node pain | 1 | 1 |
| Malaise | 21 | 21 |
| Microembolism | 1 | 1 |
| Migraine | 5 | 5 |
| Migraine with aura | 3 | 3 |
| Mobility decreased | 1 | 1 |
| Movement disorder | 1 | 1 |
| Mucosal pain | 1 | 1 |
| Mucous stools | 1 | 1 |
| Muscle contracture | 2 | 2 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | 16 | 16 |
| Myalgia | 28 | 29 |
| Myocardial infarction | 2 | 2 |
| Myoclonus | 1 | 1 |
| Nausea | 30 | 31 |
| Neck pain | 1 | 2 |
| Neuralgia | 4 | 4 |
| Neuropathy peripheral | 1 | 1 |
| Neutrophil count increased | 1 | 1 |
| Noninfective chorioretinitis | 1 | 1 |
| Nystagmus | 1 | 1 |
| Ocular discomfort | | 1 |
| Odynophagia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 8 | 8 | 6 | 6 |
| | | 1 | 1 |
| 7 | 7 | 14 | 14 |
| | | 1 | 1 |
| 2 | 2 | 3 | 3 |
| 3 | 3 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 6 | 6 | 10 | 10 |
| 14 | 15 | 14 | 14 |
| | | 2 | 2 |
| | | 1 | 1 |
| 13 | 14 | 17 | 17 |
| 1 | 2 | | |
| 2 | 2 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Oedema peripheral | 1 | 1 |
| Off label use | 3 | 3 |
| Oral dysaesthesia | 1 | 1 |
| Oral pain | 1 | 1 |
| Oral pruritus | 2 | 2 |
| Oropharyngeal discomfort | | 1 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 2 | 2 |
| Otitis externa | | 1 |
| Overdose | | 1 |
| Pain | 12 | 13 |
| Pain in extremity | 5 | 5 |
| Palatal oedema | 2 | 2 |
| Pallor | 1 | 1 |
| Palpitations | 3 | 3 |
| Pancreatitis acute | 2 | 2 |
| Paraesthesia | 18 | 19 |
| Paraesthesia oral | 5 | 5 |
| Paralysis | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pernio-like erythema | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 2 |
| Phonophobia | 1 | 1 |
| Photophobia | 1 | 1 |
| Photosensitivity reaction | 1 | 1 |
| Piloerection | 1 | 1 |
| Polydipsia | 2 | 2 |
| Poor quality product administered | 8 | 8 |
| Presyncope | 3 | 3 |
| Productive cough | 1 | 1 |
| Product preparation issue | | 3 |
| Product temperature excursion issue | 8 | 8 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 3 | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | 1 | | |
| | 1 | | |
| 7 | 8 | 5 | 5 |
| 2 | 2 | 3 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 2 | 2 |
| 6 | 7 | 12 | 12 |
| 2 | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 8 | 8 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | 3 | | |
| 8 | 8 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Product use issue | 3 | 3 |
| Pruritus | 11 | 11 |
| Psychomotor hyperactivity | 1 | 1 |
| Psychomotor skills impaired | 1 | 1 |
| Pulmonary embolism | 3 | 3 |
| Purpura | 1 | 1 |
| Pyrexia | 30 | 30 |
| Rash | 9 | 9 |
| Rash erythematous | 1 | 1 |
| Rash macular | 1 | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 |
| Respiratory tract oedema | 1 | 1 |
| Rhinitis | 3 | 3 |
| Salivary hypersecretion | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| Sensory loss | 1 | 1 |
| Sinus tachycardia | 2 | 2 |
| Skin mass | 1 | 1 |
| Skin plaque | 2 | 2 |
| Sleep disorder | 1 | 1 |
| Stress | 2 | 2 |
| Subileus | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Suspected COVID-19 | | 1 |
| Swelling face | 1 | 1 |
| Swollen tongue | 1 | 1 |
| Syncope | 4 | 4 |
| Systemic lupus erythematosus | 1 | 1 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 25 | 25 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | | |
| 4 | 4 | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 11 | 11 | 19 | 19 |
| 5 | 5 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 8 | 8 | 17 | 17 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thermohypoaesthesia | 1 | 1 | 1 | 1 | | |
| Throat irritation | 2 | 2 | 1 | 1 | 1 | 1 |
| Thrombocytopenic purpura | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis superficial | 1 | 1 | | | 1 | 1 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tongue movement disturbance | 1 | 1 | | | 1 | 1 |
| Tonic clonic movements | 1 | 1 | | | 1 | 1 |
| Transaminases increased | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 3 | 1 | 1 | 2 | 2 |
| Type I hypersensitivity | 2 | 2 | | | 2 | 2 |
| Underdose | | 2 | | 2 | | |
| Urticaria | 7 | 8 | 2 | 2 | 5 | 6 |
| Vaccination complication | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 3 | 3 | 3 | 3 | | |
| Vaccination site exfoliation | 1 | 1 | | | 1 | 1 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site hypersensitivity | 3 | 3 | 3 | 3 | | |
| Vaccination site induration | 2 | 3 | 2 | 3 | | |
| Vaccination site movement impairment | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site nodule | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 45 | 48 | 29 | 32 | 16 | 16 |
| Vaccination site paraesthesia | 5 | 5 | 4 | 4 | 1 | 1 |
| Vaccination site pruritus | 1 | 1 | | | 1 | 1 |
| Vaccination site recall reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vasculitis | 1 | 1 | | | 1 | 1 |
| Venous thrombosis | 1 | 1 | | | 1 | 1 |
| Vertigo | 4 | 4 | 1 | 1 | 3 | 3 |
| Vertigo positional | 1 | 1 | | | 1 | 1 |
| Vestibular disorder | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| | 2 | | |
| 2 | 2 | 5 | 6 |
| | | 1 | 1 |
| 3 | 3 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| 2 | 3 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 29 | 32 | 16 | 16 |
| 4 | 4 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vestibular neuronitis | 1 | 1 | | | 1 | 1 |
| Vision blurred | 2 | 2 | | | 2 | 2 |
| Vomiting | 15 | 15 | 4 | 4 | 11 | 11 |
| | 930 | 958 | 359 | 380 | 571 | 578 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal distension | 2 | 2 | 1 | 1 | 1 | 1 |
| Abdominal pain | 16 | 17 | 10 | 11 | 6 | 6 |
| Abdominal pain upper | 4 | 4 | 1 | 1 | 3 | 3 |
| Abdominal rigidity | 1 | 1 | | | 1 | 1 |
| Acute coronary syndrome | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Acute vestibular syndrome | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 2 | | 1 | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | 1 | 1 | 1 | 1 | | |
| Anaesthesia oral | 2 | 2 | | | 2 | 2 |
| Anaphylactic reaction | 5 | 6 | | | 5 | 6 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 5 | 5 | | | 5 | 5 |
| Ankylosing spondylitis | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 2 | | 1 | 1 | 1 |
| Aortic dissection | | 2 | | | | 2 |
| Apathy | 2 | 2 | 1 | 1 | 1 | 1 |
| Aphasia | 2 | 2 | | | 2 | 2 |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Aphthous ulcer | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 4 | 4 | | | 4 | 4 |
| Arthralgia | 22 | 22 | 10 | 10 | 12 | 12 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Asthenia | 64 | 65 | 28 | 29 | 36 | 36 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 7 | 7 | | | 7 | 7 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 5 | 5 | 4 | 4 | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Balance disorder | 4 | 4 |
| Blindness unilateral | 1 | 1 |
| Blood glucose increased | 1 | 1 |
| Blood pressure decreased | 1 | 1 |
| Blood pressure increased | 4 | 4 |
| Bradycardia | 2 | 2 |
| Bronchitis | 1 | 1 |
| Bronchospasm | 1 | 1 |
| Burning sensation | 3 | 4 |
| Bursal fluid accumulation | 1 | 1 |
| Bursitis | 2 | 2 |
| Cardiac disorder | 1 | 1 |
| Cardiac failure | 1 | 1 |
| Cardiac fibrillation | 1 | 1 |
| Cardio-respiratory arrest | 1 | 2 |
| Cellulitis | 1 | 1 |
| Cerebral artery stenosis | 1 | 1 |
| Cerebral hyperperfusion syndrome | 1 | 1 |
| Cerebrovascular accident | 1 | 1 |
| Chest discomfort | 10 | 10 |
| Chest pain | 7 | 7 |
| Chillblains | 1 | 1 |
| Chills | 35 | 37 |
| Choking sensation | 1 | 1 |
| Cholestatic liver injury | 1 | 1 |
| Cognitive disorder | 1 | 1 |
| Colitis | 1 | 1 |
| Condition aggravated | 3 | 3 |
| Confusional state | 2 | 2 |
| Conjunctival haemorrhage | 2 | 2 |
| Coronary artery stenosis | 1 | 1 |
| Cough | 10 | 10 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 6 | 6 | 4 | 4 |
| 3 | 3 | 4 | 4 |
| 1 | 1 | | |
| 12 | 14 | 23 | 23 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 5 | 5 | 5 | 5 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| COVID-19 | 40 | 42 |
| COVID-19 pneumonia | 2 | 2 |
| C-reactive protein increased | 4 | 4 |
| Cutaneous vasculitis | 1 | 1 |
| Cyanosis | 1 | 1 |
| Cytomegalovirus infection | 1 | 1 |
| Deafness unilateral | 1 | 1 |
| Death | 1 | 2 |
| Decreased appetite | 6 | 6 |
| Dehydration | 1 | 1 |
| Depressed level of consciousness | 2 | 2 |
| Depression | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 |
| Diarrhoea | 13 | 15 |
| Discomfort | 7 | 7 |
| Disease recurrence | 6 | 6 |
| Disinhibition | 1 | 1 |
| Disorientation | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 15 | 15 |
| Droling | 1 | 1 |
| Drug ineffective | 24 | 26 |
| Dry mouth | 1 | 1 |
| Dry throat | 2 | 2 |
| Dysaesthesia | 3 | 3 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 6 | 6 |
| Dysphagia | 1 | 2 |
| Dysphemia | 3 | 3 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 12 | 12 |
| Dyspnoea at rest | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 10 | 10 | 30 | 32 |
| | | 2 | 2 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 2 | 2 | 4 | 4 |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 6 | 9 | 9 |
| | | 7 | 7 |
| 1 | 1 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 4 | 11 | 11 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 4 | 4 | 2 | 2 |
| | | 1 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| 4 | 4 | 8 | 8 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Dyspnoea exertional | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear disorder | 1 | 1 |
| Ear pain | 1 | 1 |
| Eating disorder | 1 | 1 |
| Eczema | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | 1 |
| Eosinophil count increased | 1 | 1 |
| Epilepsy | 1 | 1 |
| Erectile dysfunction | 1 | 1 |
| Eructation | 1 | 1 |
| Erysipelas | 1 | 1 |
| Erythema | 13 | 14 |
| Extensive swelling of vaccinated limb | 1 | 1 |
| Extrasystoles | 1 | 1 |
| Eye irritation | 1 | 1 |
| Eyelid function disorder | 1 | 1 |
| Eye pain | 2 | 2 |
| Eye swelling | 1 | 1 |
| Face oedema | 4 | 4 |
| Facial pain | 3 | 3 |
| Facial paralysis | 9 | 9 |
| Facial paresis | 1 | 1 |
| Fall | 4 | 4 |
| Fatigue | 37 | 37 |
| Feeling abnormal | 3 | 3 |
| Feeling cold | 4 | 4 |
| Feeling drunk | 2 | 2 |
| Feeling hot | 6 | 6 |
| Flushing | 1 | 1 |
| Formication | 2 | 3 |
| Gait disturbance | 7 | 7 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 8 | 6 | 6 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 3 | 3 |
| | | 9 | 9 |
| | | 1 | 1 |
| | | 4 | 4 |
| 21 | 21 | 16 | 16 |
| 3 | 3 | | |
| 2 | 2 | 2 | 2 |
| 2 | 2 | | |
| 2 | 2 | 4 | 4 |
| 1 | 1 | | |
| 2 | 2 | | 1 |
| 2 | 2 | 5 | 5 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # | Cumulative Total # |
|---------------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Gait inability | 1 | 1 |
| Gamma-glutamyltransferase increased | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 |
| Gastrointestinal pain | 2 | 2 |
| Gastrooesophageal reflux disease | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Gingival discomfort | 1 | 1 |
| Headache | 91 | 95 |
| Head discomfort | 3 | 3 |
| Heart rate increased | 3 | 3 |
| Heart sounds abnormal | 1 | 1 |
| Hemianopia homonymous | 1 | 1 |
| Hemiparesis | 1 | 1 |
| Hepatitis cholestatic | 1 | 1 |
| Hepatitis infectious mononucleosis | 1 | 1 |
| Hepatocellular injury | 1 | 1 |
| Herpes zoster | 3 | 3 |
| Hoffmann's sign | 1 | 1 |
| Horner's syndrome | 1 | 1 |
| Hot flush | 7 | 8 |
| Hyperhidrosis | 9 | 9 |
| Hyperleukocytosis | 1 | 1 |
| Hypersensitivity | 15 | 15 |
| Hypersomnia | 1 | 1 |
| Hypertension | 30 | 32 |
| Hypertensive crisis | 4 | 4 |
| Hypertensive urgency | 1 | 1 |
| Hyperthermia | 4 | 4 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 5 | 5 |
| Hypoaesthesia oral | 2 | 2 |
| Hypokalaemia | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 41 | 45 | 50 | 50 |
| 2 | 2 | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 5 | 3 | 3 |
| 2 | 2 | 7 | 7 |
| | | 1 | 1 |
| 9 | 9 | 6 | 6 |
| 1 | 1 | | |
| 7 | 9 | 23 | 23 |
| | | 4 | 4 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | | |
| 2 | 2 | 3 | 3 |
| | | 2 | 2 |
| | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypokinesia | 1 | 1 |
| Hypotension | 7 | 7 |
| Hypothermia | 1 | 1 |
| Hypotonia | 1 | 1 |
| Illness | 1 | 1 |
| Incorrect dose administered | 1 | 1 |
| Incorrect route of product administration | 5 | 7 |
| Inflammation | 3 | 3 |
| Inflammatory pain | 1 | 1 |
| Influenza | 5 | 5 |
| Influenza like illness | 19 | 19 |
| Initial insomnia | 1 | 1 |
| Injected limb mobility decreased | 5 | 5 |
| Injection site erythema | | 2 |
| Injection site pain | 1 | 2 |
| Injection site rash | 1 | 1 |
| Insomnia | 8 | 10 |
| Irritability | 1 | 1 |
| Joint effusion | 1 | 1 |
| Joint stiffness | 2 | 2 |
| Joint swelling | 1 | 1 |
| Jugular vein thrombosis | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Laryngeal discomfort | 1 | 1 |
| Laryngeal dyspnoea | 1 | 1 |
| Laryngeal oedema | 2 | 2 |
| Left ventricular hypertrophy | 1 | 1 |
| Leukoencephalopathy | 1 | 1 |
| Leukopenia | 1 | 1 |
| Lip oedema | | 1 |
| Lip swelling | 1 | 1 |
| Livedo reticularis | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 4 | 4 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 7 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 5 | 5 |
| 4 | 4 | 15 | 15 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| | 2 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 4 | 6 | 4 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Loss of consciousness | 5 | 6 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 12 | 12 |
| Lymphocyte count decreased | 1 | 1 |
| Lymphopenia | 1 | 1 |
| Macroglossia | 1 | 1 |
| Malaise | 36 | 40 |
| Malnutrition | 1 | 1 |
| Medication error | 1 | 1 |
| Memory impairment | 2 | 2 |
| Mental fatigue | 1 | 1 |
| Metamorphopsia | 1 | 1 |
| Middle insomnia | 1 | 1 |
| Migraine | 7 | 7 |
| Mobility decreased | 2 | 2 |
| Mononucleosis syndrome | 1 | 1 |
| Monoplegia | 1 | 1 |
| Motor dysfunction | 1 | 1 |
| Muscle contracture | 1 | 1 |
| Muscle spasms | 4 | 4 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 |
| Musculoskeletal stiffness | 11 | 11 |
| Myalgia | 42 | 42 |
| Myalgia intercostal | 1 | 1 |
| Mydriasis | 1 | 1 |
| Myelitis | 1 | 1 |
| Myocardial ischaemia | 1 | 1 |
| Myocarditis | 1 | 1 |
| Myokymia | 1 | 1 |
| Myositis | 1 | 1 |
| Nasal congestion | 1 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 5 | 6 |
| 1 | 1 | | |
| 8 | 8 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 13 | 16 | 23 | 24 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 4 | 3 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 10 | 10 |
| 19 | 19 | 23 | 23 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Nasopharyngitis | 1 | 1 |
| Nausea | 44 | 46 |
| Neck pain | 6 | 6 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 4 | 4 |
| Neutropenia | 1 | 1 |
| Neutrophil count decreased | 1 | 1 |
| Neutrophilic dermatosis | 1 | 1 |
| Nightmare | 1 | 1 |
| Obstructive airways disorder | 1 | 1 |
| Ocular discomfort | 2 | 2 |
| Ocular hyperaemia | 1 | 1 |
| Oedema | 1 | 1 |
| Oedema peripheral | 2 | 2 |
| Oesophageal pain | 1 | 1 |
| Off label use | 3 | 3 |
| Ophthalmic herpes zoster | 1 | 1 |
| Oral pain | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 2 | 2 |
| Oropharyngeal swelling | 1 | 1 |
| Overdose | | 4 |
| Oxygen saturation decreased | 4 | 4 |
| Pain | 23 | 23 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 13 | 14 |
| Pallor | 5 | 5 |
| Palpitations | 7 | 8 |
| Pancreatitis acute | 1 | 1 |
| Papule | 1 | 2 |
| Paraesthesia | 24 | 24 |
| Paraesthesia oral | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 16 | 18 | 28 | 28 |
| 1 | 1 | 5 | 5 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 3 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| | 4 | | |
| 1 | 1 | 3 | 3 |
| 14 | 14 | 9 | 9 |
| | | 1 | 1 |
| 5 | 6 | 8 | 8 |
| | | 5 | 5 |
| 3 | 4 | 4 | 4 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 7 | 7 | 17 | 17 |
| | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Parosmia | 2 | 2 | 2 | 2 | | |
| Partial seizures | 1 | 1 | | | 1 | 1 |
| Periarthritis | 1 | 1 | | | 1 | 1 |
| Pericarditis | 4 | 4 | | | 4 | 4 |
| Peripheral swelling | 3 | 3 | 2 | 2 | 1 | 1 |
| Persistent depressive disorder | 1 | 1 | | | 1 | 1 |
| Phaeochromocytoma | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorder | 1 | 1 | | | 1 | 1 |
| Photophobia | 2 | 2 | | | 2 | 2 |
| Pneumonia | 2 | 2 | | | 2 | 2 |
| Pneumonia aspiration | 2 | 2 | | | 2 | 2 |
| Poor quality product administered | 15 | 15 | 15 | 15 | | |
| Presyncope | 7 | 7 | 5 | 5 | 2 | 2 |
| Product administration error | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Product preparation issue | | 6 | | 6 | | |
| Product temperature excursion issue | 15 | 15 | 15 | 15 | | |
| Product use issue | 3 | 3 | 3 | 3 | | |
| Pruritus | 10 | 11 | 6 | 7 | 4 | 4 |
| Pseudodementia | 1 | 1 | | | 1 | 1 |
| Psychomotor skills impaired | 1 | 1 | 1 | 1 | | |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pyrexia | 61 | 64 | 23 | 26 | 38 | 38 |
| Rales | 1 | 1 | | | 1 | 1 |
| Rash | 7 | 8 | 4 | 5 | 3 | 3 |
| Rash erythematous | 3 | 3 | 2 | 2 | 1 | 1 |
| Rash macular | 2 | 2 | | | 2 | 2 |
| Rash maculo-papular | 3 | 3 | 3 | 3 | | |
| Rash papular | 2 | 2 | 2 | 2 | | |
| Rash pruritic | 2 | 2 | 2 | 2 | | |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Retinal artery occlusion | 1 | 1 | | | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Rhinitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Rhinorrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Rhonchi | 1 | 1 | | | 1 | 1 |
| Salivary hypersecretion | 2 | 2 | 1 | 1 | 1 | 1 |
| SARS-CoV-2 ant body test negative | 3 | 3 | 2 | 2 | 1 | 1 |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 2 | 2 | 2 | 2 | | |
| Seizure | 2 | 2 | | | 2 | 2 |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Sinus arrest | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Skin mass | 1 | 1 | 1 | 1 | | |
| Skin plaque | 1 | 1 | 1 | 1 | | |
| Skin warm | 1 | 1 | 1 | 1 | | |
| Sleep apnoea syndrome | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 2 | 2 | | | 2 | 2 |
| Sleep disorder due to general medical condition, insomnia type | 1 | 1 | 1 | 1 | | |
| Somnolence | 3 | 3 | 1 | 1 | 2 | 2 |
| Spinal osteoarthritis | 1 | 1 | 1 | 1 | | |
| Spinal pain | 1 | 1 | | | 1 | 1 |
| Spondylitis | 1 | 1 | | | 1 | 1 |
| Stomatitis | 1 | 1 | | | 1 | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Suicidal ideation | 1 | 1 | | | 1 | 1 |
| Supraventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Supraventricular tachycardia | 2 | 2 | | | 2 | 2 |
| Suspected COVID-19 | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 2 | 1 | 2 | | |
| Syncope | 3 | 3 | | | 3 | 3 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Synovial cyst | 1 | 1 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 23 | 24 |
| Tachypnoea | 3 | 3 |
| Tendonitis | 2 | 2 |
| Tendon pain | 2 | 2 |
| Tension | 1 | 1 |
| Tension headache | 1 | 1 |
| Thirst | 1 | 1 |
| Thrombosis | 2 | 2 |
| Thyroid mass | 1 | 1 |
| Tinnitus | 4 | 4 |
| Tongue oedema | 1 | 1 |
| Tonsillar hypertrophy | 1 | 1 |
| Toothache | 1 | 1 |
| Transient ischaemic attack | 2 | 2 |
| Tremor | 7 | 7 |
| Trismus | 1 | 1 |
| Underdose | | 2 |
| Urticaria | 11 | 11 |
| Vaccination complication | | 1 |
| Vaccination site abscess | 1 | 1 |
| Vaccination site bruising | 1 | 1 |
| Vaccination site coldness | 1 | 1 |
| Vaccination site discomfort | 1 | 1 |
| Vaccination site erythema | 10 | 10 |
| Vaccination site haematoma | 2 | 2 |
| Vaccination site haemorrhage | 1 | 1 |
| Vaccination site hypersensitivity | 11 | 11 |
| Vaccination site induration | 1 | 2 |
| Vaccination site inflammation | 5 | 5 |
| Vaccination site movement impairment | 4 | 4 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 9 | 10 | 14 | 14 |
| | | 3 | 3 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 3 | 3 | 4 | 4 |
| 1 | 1 | | |
| | 2 | | |
| 7 | 7 | 4 | 4 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 9 | 9 | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| 11 | 11 | | |
| 1 | 2 | | |
| 3 | 3 | 2 | 2 |
| 4 | 4 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site nodule | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site pain | 58 | 60 | 37 | 39 | 21 | 21 |
| Vaccination site papule | 1 | 1 | 1 | 1 | | |
| Vaccination site paraesthesia | 2 | 2 | | | 2 | 2 |
| Vaccination site pruritus | 5 | 6 | 4 | 5 | 1 | 1 |
| Vaccination site reaction | 2 | 3 | 2 | 3 | | |
| Vaccination site swelling | 6 | 7 | 4 | 5 | 2 | 2 |
| Vaccination site thrombosis | 1 | 1 | | | 1 | 1 |
| Vaccination site urticaria | | 1 | | 1 | | |
| Vaccination site warmth | 4 | 4 | 4 | 4 | | |
| Vascular purpura | 1 | 1 | | | 1 | 1 |
| Vasodilatation | 1 | 1 | 1 | 1 | | |
| Venous thrombosis | 1 | 1 | | | 1 | 1 |
| Ventricular fibrillation | 1 | 1 | | | 1 | 1 |
| Vertigo | 19 | 19 | 6 | 6 | 13 | 13 |
| Vertigo positional | 1 | 1 | | | 1 | 1 |
| Vestibular neuronitis | 2 | 2 | | | 2 | 2 |
| Vision blurred | 2 | 2 | 2 | 2 | | |
| Visual acuity reduced | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 11 | 11 | 2 | 2 | 9 | 9 |
| Walking disability | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | | | 1 | 1 |
| | 1,551 | 1,625 | 632 | 692 | 919 | 933 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 3 | 3 | 1 | 1 | 2 | 2 |
| Acute abdomen | 1 | 1 | | | 1 | 1 |
| Acute coronary syndrome | 1 | 1 | | | 1 | 1 |
| Acute kidney injury | 2 | 2 | | | 2 | 2 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute respiratory distress syndrome | 1 | 1 | | | 1 | 1 |
| Agitation | 2 | 2 | 1 | 1 | 1 | 1 |
| Amaurosis fugax | 1 | 1 | | | 1 | 1 |
| Anaemia | 2 | 2 | | | 2 | 2 |
| Angioedema | 2 | 3 | | | 2 | 3 |
| Anxiety | 2 | 2 | 1 | 1 | 1 | 1 |
| Apathy | 1 | 1 | 1 | 1 | | |
| Aphasia | 2 | 2 | | | 2 | 2 |
| Aphthous ulcer | | 1 | | 1 | | |
| Arrhythmia | 3 | 3 | | | 3 | 3 |
| Arthralgia | 4 | 4 | 2 | 2 | 2 | 2 |
| Asthenia | 21 | 22 | 5 | 6 | 16 | 16 |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 2 | 2 | | | 2 | 2 |
| Atrioventricular block | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Bacterial infection | 1 | 1 | | | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 3 | 3 | | | 3 | 3 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Blood uric acid increased | | 1 | | 1 | | |
| Bradycardia | 4 | 4 | | | 4 | 4 |
| Bradyphrenia | 1 | 1 | | | 1 | 1 |
| Bronchial obstruction | | 1 | | | | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Bundle branch block right | 1 | 1 |
| Cardiac arrest | 3 | 3 |
| Cardiac failure | 1 | 1 |
| Cardio-respiratory arrest | 1 | 1 |
| Cerebral haematoma | 2 | 2 |
| Cerebrovascular accident | 1 | 1 |
| Chest discomfort | 4 | 4 |
| Chest pain | 3 | 3 |
| Chills | 6 | 7 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Coma | 2 | 2 |
| Confusional state | 1 | 1 |
| Conjunctival haemorrhage | 2 | 2 |
| Conjunctivitis | 1 | 1 |
| Constipation | | 1 |
| Coronary artery disease | 1 | 1 |
| Coronavirus infection | 1 | 1 |
| Cough | 2 | 2 |
| COVID-19 | 16 | 17 |
| COVID-19 pneumonia | 1 | 1 |
| C-reactive protein increased | 3 | 4 |
| Cyanosis | 1 | 1 |
| Death | 6 | 12 |
| Decreased appetite | 2 | 3 |
| Dehydration | 2 | 2 |
| Delirium | 1 | 1 |
| Depressed level of consciousness | 1 | 1 |
| Diabetes mellitus | 2 | 2 |
| Diabetic ketosis | 1 | 1 |
| Diarrhoea | 6 | 6 |
| Diplopia | 3 | 3 |
| Discomfort | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 3 | 3 |
| 3 | 4 | 3 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 16 | 17 |
| | | 1 | 1 |
| 2 | 3 | 1 | 1 |
| | | 1 | 1 |
| | | 6 | 12 |
| 1 | 2 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 3 | 3 | 3 | 3 |
| | | 3 | 3 |
| | | 2 | 2 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dizziness | 5 | 7 |
| Dizziness postural | 1 | 1 |
| Drug ineffective | 12 | 13 |
| Dysarthria | 1 | 1 |
| Dyslipidaemia | 1 | 1 |
| Dyspnoea | 7 | 9 |
| Dyspnoea exertional | 1 | 1 |
| Eczema | 1 | 1 |
| Electroencephalogram abnormal | 1 | 1 |
| Epilepsy | 3 | 3 |
| Erysipelas | 1 | 1 |
| Erythema | 2 | 4 |
| Erythema of eyelid | 1 | 1 |
| Escherichia urinary tract infection | 1 | 1 |
| Eyelid haematoma | 1 | 1 |
| Eyelid ptosis | 1 | 1 |
| Face oedema | 2 | 2 |
| Facial pain | 1 | 1 |
| Facial paralysis | 6 | 6 |
| Facial paresis | 1 | 1 |
| Fall | 4 | 4 |
| Fatigue | 13 | 14 |
| Feeling cold | 2 | 2 |
| Feeling of body temperature change | 1 | 1 |
| Flushing | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Gaze palsy | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Glycosylated haemoglobin increased | | 1 |
| Haematemesis | 1 | 1 |
| Haematochezia | 1 | 1 |
| Haematuria | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 4 | 2 | 3 |
| | | 1 | 1 |
| | | 12 | 13 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 6 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 4 | 4 |
| 9 | 10 | 4 | 4 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Haemothorax | 1 | 1 |
| Hallucination, auditory | 1 | 1 |
| Headache | 12 | 14 |
| Head injury | 2 | 2 |
| Heart rate increased | 2 | 2 |
| Hemianopia homonymous | 1 | 1 |
| Hemiparesis | 2 | 2 |
| Hemiplegia | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Hot flush | 2 | 2 |
| Hyperaesthesia | 1 | 1 |
| Hyperglycaemia | 1 | 1 |
| Hyperglycinaemia | 1 | 1 |
| Hyperhidrosis | 3 | 3 |
| Hyperleukocytosis | 2 | 2 |
| Hypersensitivity | 4 | 4 |
| Hypertension | 14 | 14 |
| Hypertensive crisis | 2 | 2 |
| Hyperthyroidism | 1 | 1 |
| Hypervitaminosis B12 | 1 | 1 |
| Hypocalcaemia | 1 | 1 |
| Hypotension | 6 | 6 |
| Hypothermia | 2 | 2 |
| Hypoxia | 2 | 2 |
| Illrd nerve paralysis | 1 | 1 |
| Incorrect route of product administration | | 2 |
| Increased bronchial secretion | | 1 |
| Influenza like illness | 3 | 3 |
| Insomnia | 2 | 2 |
| Intracardiac thrombus | 1 | 1 |
| Ischaemic stroke | 7 | 7 |
| Jaundice | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 5 | 9 | 9 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 13 | 13 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 6 | 6 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 2 | | |
| | | | 1 |
| 2 | 2 | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 7 | 7 |
| | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # | Cumulative Total # |
|--------------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Language disorder | 1 | 1 |
| Laryngeal dyspnoea | 1 | 1 |
| Laryngitis | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Lip oedema | 1 | 1 |
| Lip swelling | 1 | 1 |
| Livedo reticularis | 2 | 2 |
| Liver injury | 1 | 1 |
| Loss of consciousness | 3 | 3 |
| Lymphadenopathy | | 1 |
| Lymphopenia | 2 | 2 |
| Malaise | 11 | 13 |
| Malignant hypertension | 1 | 1 |
| Migraine with aura | 1 | 1 |
| Monoparesis | 1 | 1 |
| Motor dysfunction | 1 | 1 |
| Mouth haemorrhage | 1 | 1 |
| Muscle fatigue | 1 | 1 |
| Muscle rigidity | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 7 | 8 |
| Myocardial infarction | 1 | 1 |
| Myocardial necrosis marker increased | 1 | 1 |
| Myoclonus | 1 | 1 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 6 | 10 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 1 | 1 |
| Neuromuscular pain | 1 | 1 |
| Neutropenia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | 1 | | |
| | | 2 | 2 |
| 3 | 4 | 8 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 2 | 3 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 6 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Obstruction gastric | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Off label use | | 1 |
| Optic ischaemic neuropathy | 1 | 1 |
| Oropharyngeal pain | 2 | 2 |
| Overdose | 1 | 1 |
| Oxygen saturation decreased | 5 | 5 |
| Pain | 7 | 7 |
| Pain in extremity | 6 | 6 |
| Pallor | 1 | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | 2 | 2 |
| Paraesthesia oral | | 1 |
| Paralysis | 1 | 1 |
| Paresis | 1 | 1 |
| Parkinsonism | 1 | 1 |
| Pericardial effusion | 1 | 1 |
| Periorbital oedema | 1 | 1 |
| Peripheral coldness | 1 | 1 |
| Photophobia | 1 | 1 |
| Photopsia | 1 | 1 |
| Pneumonia aspiration | 4 | 4 |
| Pneumonia bacterial | 1 | 1 |
| Pneumonia moraxella | 1 | 1 |
| Poor quality product administered | 26 | 26 |
| Presyncope | 1 | 1 |
| Product preparation issue | | 2 |
| Product temperature excursion issue | 24 | 24 |
| Product use issue | | 1 |
| Pruritus | 2 | 3 |
| Pulmonary embolism | 3 | 3 |
| Pyrexia | 20 | 25 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | 4 | 4 |
| 3 | 3 | 4 | 4 |
| 3 | 3 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 26 | 26 | | |
| | | 1 | 1 |
| | 2 | | |
| 24 | 24 | | |
| | 1 | | |
| | 1 | 2 | 2 |
| | | 3 | 3 |
| 7 | 11 | 13 | 14 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Rash | 2 | 2 |
| Rash maculo-papular | | 1 |
| Rash papular | 1 | 1 |
| Renal failure | 1 | 1 |
| Respiratory a kalosis | 2 | 2 |
| Respiratory arrest | 1 | 1 |
| Respiratory distress | 3 | 3 |
| Restlessness | 1 | 1 |
| Rhabdomyolysis | 1 | 1 |
| Rib fracture | 1 | 1 |
| SARS-CoV-2 ant body test negative | 2 | 2 |
| Seizure | 5 | 5 |
| Sensorimotor disorder | 1 | 1 |
| Sensory loss | 1 | 1 |
| Septic shock | 1 | 1 |
| Serum ferritin increased | 1 | 1 |
| Sinus disorder | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Skin lesion | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Somnolence | 1 | 1 |
| Speech disorder | 2 | 2 |
| Staring | 1 | 1 |
| Status epilepticus | 1 | 1 |
| Sudden death | 4 | 6 |
| Swelling face | 1 | 1 |
| Syncope | 3 | 3 |
| Tachycardia | 11 | 12 |
| Tachypnoea | 1 | 1 |
| Thrombocytopenia | 1 | 1 |
| Tongue haematoma | | 2 |
| Tonic clonic movements | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 6 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 2 | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | | 1 | | 1 | | |
| Type 2 diabetes mellitus | 1 | 1 | | | 1 | 1 |
| Underdose | 1 | 4 | 1 | 4 | | |
| Urticaria | 3 | 3 | | | 3 | 3 |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 3 | 2 | 3 | | |
| Vaccination site hypersensitivity | 2 | 2 | 2 | 2 | | |
| Vaccination site hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | | | 1 | 1 |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 15 | 15 | 10 | 10 | 5 | 5 |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vasculitis | 1 | 1 | 1 | 1 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Ventricular tachycardia | 2 | 2 | | | 2 | 2 |
| Vertigo | 4 | 4 | | | 4 | 4 |
| Vomiting | 5 | 5 | 1 | 1 | 4 | 4 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| Yellow skin | | 1 | | 1 | | |
| | 578 | 642 | 167 | 213 | 411 | 429 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 3 | 1 | 1 | 1 | 2 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Abnormal behaviour | 1 | 1 | | | 1 | 1 |
| Accidental overdose | 1 | 1 | 1 | 1 | | |
| Acute coronary syndrome | 3 | 3 | | | 3 | 3 |
| Acute kidney injury | 5 | 5 | | | 5 | 5 |
| Acute pulmonary oedema | 7 | 7 | | | 7 | 7 |
| Acute respiratory distress syndrome | 4 | 5 | | | 4 | 5 |
| Acute respiratory failure | 3 | 4 | | | 3 | 4 |
| Adult failure to thrive | 1 | 1 | | | 1 | 1 |
| Aerococcus urinae infection | 1 | 1 | | | 1 | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 6 | 6 | 2 | 2 | 4 | 4 |
| Altered state of consciousness | 5 | 5 | | | 5 | 5 |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Anaphylactic shock | 3 | 4 | | | 3 | 4 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anuria | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 3 | | | 1 | 3 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 3 | 5 | | | 3 | 5 |
| Arrhythmia supraventricular | 1 | 2 | | | 1 | 2 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Aspartate aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Asthenia | 29 | 29 | 14 | 14 | 15 | 15 |
| Asymptomatic COVID-19 | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | 4 | 6 | | | 4 | 6 |
| Atrial flutter | 2 | 2 | | | 2 | 2 |
| Atrioventricular block | 1 | 1 | | | 1 | 1 |
| Atrioventricular block complete | 2 | 2 | | | 2 | 2 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Balance disorder | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Behaviour disorder | 1 | 1 | | | 1 | 1 |
| Benign breast neoplasm | 1 | 1 | 1 | 1 | | |
| Bipolar disorder | 1 | 1 | | | 1 | 1 |
| Blood alkaline phosphatase increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Blood pressure systolic decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure systolic increased | | 1 | | | | 1 |
| Blood thyroid stimulating hormone increased | 1 | 1 | 1 | 1 | | |
| Body temperature decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bradycardia | 4 | 4 | | | 4 | 4 |
| Brain natriuretic peptide increased | 1 | 1 | | | 1 | 1 |
| Breast swelling | 1 | 1 | 1 | 1 | | |
| Bronchiolitis | 1 | 1 | | | 1 | 1 |
| Bronchitis | | 1 | | | | 1 |
| Bronchopneumopathy | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 3 | 3 | | | 3 | 3 |
| Bundle branch block | 1 | 1 | | | 1 | 1 |
| Bundle branch block left | 1 | 1 | | | 1 | 1 |
| Bundle branch block right | 1 | 1 | | | 1 | 1 |
| Burning sensation | 2 | 2 | 1 | 1 | 1 | 1 |
| Cardiac arrest | 3 | 4 | | | 3 | 4 |
| Cardiac failure | 17 | 19 | | | 17 | 19 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cardiac failure congestive | 1 | 1 | | | 1 | 1 |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Cardiogenic shock | 3 | 3 | | | 3 | 3 |
| Cardiomegaly | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 4 | 5 | | | 4 | 5 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| 3 | 3 | 3 | 3 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 3 | 3 | 3 | 3 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 4 | 5 | 4 | 5 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Central nervous system lesion | 1 | 1 | | | 1 | 1 |
| Cerebellar syndrome | 1 | 1 | | | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 5 | 7 | | | 5 | 7 |
| Chest discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Chest injury | 1 | 1 | | | 1 | 1 |
| Chest pain | 5 | 6 | 2 | 2 | 3 | 4 |
| Chills | 2 | 2 | | | 2 | 2 |
| Choking | 1 | 1 | | | 1 | 1 |
| Cholecystitis | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 2 | 2 | | | 2 | 2 |
| Circulatory collapse | 2 | 2 | | | 2 | 2 |
| Clonus | 1 | 1 | | | 1 | 1 |
| Cognitive disorder | 1 | 2 | 1 | 1 | | 1 |
| Coma | 2 | 2 | | | 2 | 2 |
| Condition aggravated | 2 | 3 | 1 | 1 | 1 | 2 |
| Confusional state | 4 | 5 | 1 | 1 | 3 | 4 |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Constipation | 1 | 1 | 1 | 1 | | |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| Cough | 4 | 4 | 2 | 2 | 2 | 2 |
| COVID-19 | 12 | 12 | 1 | 1 | 11 | 11 |
| C-reactive protein increased | 4 | 5 | 3 | 3 | 1 | 2 |
| Creatinine renal clearance decreased | 1 | 1 | | | 1 | 1 |
| Crepitations | 1 | 1 | | | 1 | 1 |
| Cyanosis | 3 | 3 | | | 3 | 3 |
| Cystitis klebsiella | 1 | 1 | | | 1 | 1 |
| Death | 33 | 35 | | | 33 | 35 |
| Decreased appetite | 3 | 3 | 2 | 2 | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Dehydration | 3 | 3 | | | 3 | 3 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 7 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 3 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 2 |
| 1 | 1 | 3 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 33 | 35 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # | Cumulative Total # |
|------------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Dementia | 1 | 1 |
| Depressed level of consciousness | 4 | 5 |
| Dermatitis bullous | 1 | 1 |
| Dermo-hypodermitis | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 |
| Diabetic metabolic decompensation | 1 | 1 |
| Diarrhoea | 13 | 15 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Discomfort | 4 | 4 |
| Disease progression | 1 | 1 |
| Disease recurrence | 5 | 5 |
| Disorientation | 3 | 3 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 6 | 6 |
| Drug ineffective | 9 | 9 |
| Dry mouth | 1 | 1 |
| Dysarthria | 2 | 3 |
| Dysphagia | 4 | 4 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 22 | 23 |
| Dyspnoea exertional | 1 | 1 |
| Dysuria | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear pain | 1 | 1 |
| Electrocardiogram T wave inversion | 1 | 1 |
| Encephalitis | 1 | 1 |
| Eosinophilia | 1 | 1 |
| Epilepsy | 3 | 3 |
| Erysipelas | 1 | 1 |
| Erythema | 8 | 8 |
| Extensor plantar response | 1 | 1 |
| Extradural haematoma | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 9 | 11 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 5 | 5 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 2 | 2 | 4 | 4 |
| | | 9 | 9 |
| 1 | 1 | | |
| | | 2 | 3 |
| 1 | 1 | 3 | 3 |
| 1 | 1 | | |
| 2 | 2 | 20 | 21 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 2 | 2 | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eye disorder | 1 | 1 | | | 1 | 1 |
| Eye injury | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |
| Eyelid ptosis | 1 | 1 | | | 1 | 1 |
| Face oedema | 3 | 3 | | | 3 | 3 |
| Facial paralysis | 8 | 8 | | | 8 | 8 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Faecal vomiting | 2 | 2 | | | 2 | 2 |
| Fall | 10 | 11 | 4 | 4 | 6 | 7 |
| Fatigue | 15 | 15 | 7 | 7 | 8 | 8 |
| Fear | | 1 | | | | 1 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Flushing | 2 | 2 | | | 2 | 2 |
| Foaming at mouth | 1 | 1 | | | 1 | 1 |
| Food aversion | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gamma-glutamyltransferase increased | 1 | 1 | 1 | 1 | | |
| Gastric volvulus | 1 | 1 | | | 1 | 1 |
| Gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Generalised oedema | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 10 | 10 | | | 10 | 10 |
| Glomerular filtration rate decreased | 2 | 2 | | | 2 | 2 |
| Haemarthrosis | 1 | 1 | | | 1 | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haematochezia | 1 | 1 | | | 1 | 1 |
| Haematoma | 3 | 3 | | | 3 | 3 |
| Haemodynamic instability | 1 | 1 | 1 | 1 | | |
| Haemoglobin decreased | 2 | 2 | 2 | 2 | | |
| Haemoptysis | | 1 | | | | 1 |
| Haemorrhagic stroke | 3 | 4 | | | 3 | 4 |
| Hallucinations, mixed | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # | Cumulative Total # | Spontaneous | | | |
|--|------------------|--------------------|-------------|---|---------|----|
| | Spontaneous AE | Spontaneous AE | Nonserious | | Serious | |
| | | | I | C | I | C |
| Headache | 10 | 10 | 5 | 5 | 5 | 5 |
| Head injury | 1 | 1 | | | 1 | 1 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Hemiplegia | 5 | 5 | | | 5 | 5 |
| Hepatic function abnormal | 1 | 1 | 1 | 1 | | |
| Hepatocellular injury | 1 | 1 | | | 1 | 1 |
| Herpes ophthalmic | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 5 | 5 | 1 | 1 | 4 | 4 |
| High-pitched crying | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hyperkalaemia | 3 | 3 | | | 3 | 3 |
| Hyperleukocytosis | 2 | 3 | | | 2 | 3 |
| Hypernatraemia | 2 | 2 | 2 | 2 | | |
| Hypersensitivity | 6 | 6 | 3 | 3 | 3 | 3 |
| Hypersomnia | 2 | 2 | | | 2 | 2 |
| Hypertension | 28 | 28 | 2 | 2 | 26 | 26 |
| Hypertensive crisis | 3 | 3 | | | 3 | 3 |
| Hyperthermia | 6 | 6 | 2 | 2 | 4 | 4 |
| Hypertonia | | 1 | | | | 1 |
| Hypoacusis | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 2 | 2 | | | 2 | 2 |
| Hypoperfusion | 1 | 1 | 1 | 1 | | |
| Hypotension | 24 | 25 | 6 | 6 | 18 | 19 |
| Hypothermia | 2 | 2 | | | 2 | 2 |
| Hypoxia | 5 | 5 | | | 5 | 5 |
| Ill-defined disorder | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 4 | 2 | 4 | | |
| Incorrect dose administered | 2 | 2 | 2 | 2 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Increased bronchial secretion | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # | Cumulative Total # |
|--|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Infarction | 1 | 1 |
| Infection | 1 | 1 |
| Inflammation | 4 | 4 |
| Influenza like illness | 1 | 1 |
| Insulin-requiring type 2 diabetes mellitus | 1 | 1 |
| International normalised ratio abnormal | 1 | 2 |
| Interstitial lung disease | 1 | 1 |
| Intracranial haematoma | 1 | 1 |
| Iron deficiency anaemia | 1 | 1 |
| Ischaemic cardiomyopathy | 1 | 1 |
| Ischaemic stroke | 6 | 7 |
| Jaundice | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Language disorder | 1 | 1 |
| Laryngeal discomfort | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Left ventricular failure | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Lip oedema | 2 | 2 |
| Listless | 1 | 1 |
| Lividity | 1 | 1 |
| Localised oedema | 2 | 2 |
| Loss of consciousness | 9 | 10 |
| Lower respiratory tract congestion | 1 | 1 |
| Lower respiratory tract infection | 1 | 1 |
| Lung abscess | 1 | 1 |
| Lung disorder | 5 | 5 |
| Lymphadenopathy | 1 | 1 |
| Lymphopenia | | 1 |
| Malaise | 30 | 34 |
| Mass | 1 | 1 |
| Melaena | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 6 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 9 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | | |
| | 1 | | |
| 6 | 7 | 24 | 27 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Metastases to peritoneum | 1 | 1 | | | 1 | 1 |
| Miosis | 1 | 1 | | | 1 | 1 |
| Mitral valve disease | 1 | 1 | | | 1 | 1 |
| Muscle tightness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal discomfort | 1 | 1 | 1 | 1 | | |
| Myalgia | 5 | 5 | 1 | 1 | 4 | 4 |
| Mydriasis | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 11 | 11 | | | 11 | 11 |
| Myocardial necrosis | 1 | 1 | | | 1 | 1 |
| Myoclonus | 1 | 1 | | | 1 | 1 |
| Nausea | 7 | 9 | 4 | 4 | 3 | 5 |
| Neuralgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Neutrophil count abnormal | 1 | 1 | | | 1 | 1 |
| N-terminal prohormone brain natriuretic peptide increased | 1 | 1 | | | 1 | 1 |
| Oedema | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 4 | 5 | | | 4 | 5 |
| Off label use | 2 | 2 | 2 | 2 | | |
| Ophthalmic herpes zoster | 3 | 3 | | | 3 | 3 |
| Oral discomfort | | 1 | | 1 | | |
| Overdose | 1 | 2 | 1 | 2 | | |
| Oxygen saturation decreased | 31 | 32 | 2 | 2 | 29 | 30 |
| Pain | 5 | 5 | 1 | 1 | 4 | 4 |
| Pain in jaw | 2 | 2 | 2 | 2 | | |
| Pallor | 2 | 2 | | | 2 | 2 |
| Pancytopenia | 1 | 1 | | | 1 | 1 |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Peau d'orange | 1 | 1 | 1 | 1 | | |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Petechiae | 2 | 2 | 2 | 2 | | |
| Petit mal epilepsy | | 1 | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Platelet count decreased | 1 | 1 | 1 | 1 | | |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 6 | 6 | | | 6 | 6 |
| Pneumonia aspiration | 6 | 6 | | | 6 | 6 |
| Pneumonitis | 1 | 1 | | | 1 | 1 |
| Pneumoperitoneum | 1 | 1 | | | 1 | 1 |
| Polyarthrits | 1 | 1 | | | 1 | 1 |
| Poor quality product administered | 49 | 49 | 49 | 49 | | |
| Presyncope | 2 | 2 | 2 | 2 | | |
| Productive cough | 1 | 2 | 1 | 1 | | 1 |
| Product preparation error | 1 | 2 | 1 | 2 | | |
| Product temperature excursion issue | 48 | 48 | 48 | 48 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 2 | 1 | 2 | | |
| Pulmonary arterial hypertension | 1 | 1 | | | 1 | 1 |
| Pulmonary congestion | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 4 | 4 | | | 4 | 4 |
| Pulmonary infarction | 1 | 1 | | | 1 | 1 |
| Pulmonary oedema | 2 | 2 | | | 2 | 2 |
| Purpura | 1 | 1 | | | 1 | 1 |
| Pyrexia | 31 | 31 | 7 | 7 | 24 | 24 |
| Rales | 1 | 2 | | | 1 | 2 |
| Rash | 3 | 3 | 2 | 2 | 1 | 1 |
| Rash erythematous | 2 | 2 | | | 2 | 2 |
| Rash pruritic | 2 | 2 | 1 | 1 | 1 | 1 |
| Renal failure | 3 | 4 | | | 3 | 4 |
| Renal impairment | 2 | 2 | | | 2 | 2 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 2 | 2 | | | 2 | 2 |
| Respiratory distress | 8 | 8 | | | 8 | 8 |
| Respiratory failure | 3 | 3 | | | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 6 | 6 |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 49 | 49 | | |
| 2 | 2 | | |
| 1 | 1 | | 1 |
| 1 | 2 | | |
| 48 | 48 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 7 | 7 | 24 | 24 |
| | | 1 | 2 |
| 2 | 2 | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 3 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 8 | 8 |
| | | 3 | 3 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Restlessness | 2 | 2 | 1 | 1 | 1 | 1 |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 4 | 4 | 1 | 1 | 3 | 3 |
| Seizure | 2 | 2 | | | 2 | 2 |
| Septic shock | 2 | 2 | | | 2 | 2 |
| Sinus bradycardia | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Skin warm | 1 | 1 | 1 | 1 | | |
| Sleep talking | 1 | 1 | 1 | 1 | | |
| Somnolence | 7 | 7 | 3 | 3 | 4 | 4 |
| Status epilepticus | 1 | 1 | | | 1 | 1 |
| Subileus | 1 | 1 | | | 1 | 1 |
| Sudden death | 16 | 20 | | | 16 | 20 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Suspected COVID-19 | 1 | 1 | | | 1 | 1 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 4 | 4 | | | 4 | 4 |
| Tachyarrhythmia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 12 | 13 | | | 12 | 13 |
| Tachypnoea | 4 | 4 | | | 4 | 4 |
| Tension | 2 | 2 | 2 | 2 | | |
| Thirst | 1 | 1 | 1 | 1 | | |
| Thrombocytopenia | 2 | 3 | | | 2 | 3 |
| Thrombophlebitis superficial | 2 | 2 | 1 | 1 | 1 | 1 |
| Tongue biting | 1 | 1 | | | 1 | 1 |
| Tongue coated | 1 | 1 | | | 1 | 1 |
| Tongue discolouration | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Tongue dry | 1 | 1 |
| Tongue oedema | 2 | 2 |
| Tonic clonic movements | 1 | 1 |
| Tooth infection | 1 | 1 |
| Transcription medication error | 1 | 1 |
| Transient ischaemic attack | 4 | 4 |
| Tremor | 3 | 3 |
| Troponin increased | 1 | 1 |
| Tumour perforation | 1 | 1 |
| Underdose | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 |
| Urinary tract candidiasis | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 |
| Urosepsis | 1 | 1 |
| Urticaria | 2 | 3 |
| Vaccination site erythema | 3 | 4 |
| Vaccination site haematoma | 2 | 2 |
| Vaccination site induration | 1 | 1 |
| Vaccination site inflammation | 2 | 2 |
| Vaccination site oedema | 1 | 1 |
| Vaccination site pain | 3 | 3 |
| Vaccination site rash | 1 | 1 |
| Vaccination site swelling | 1 | 1 |
| Vascular purpura | 1 | 1 |
| Venous oxygen saturation decreased | 1 | 1 |
| Vertigo | 1 | 1 |
| Vestibular disorder | 1 | 1 |
| Vision blurred | 2 | 2 |
| Visual impairment | 2 | 2 |
| Vomiting | 24 | 26 |
| White blood cell count increased | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 4 | 4 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 2 |
| 3 | 4 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 11 | 11 | 13 | 15 |
| 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 1,085 | 1,155 | 297 | 306 | 788 | 849 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Accidental overdose | | 1 | | 1 | | |
| Arthralgia | | 2 | | 2 | | |
| Asthenia | 5 | 5 | 4 | 4 | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 3 | 2 | 3 | | |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cough | | 1 | | 1 | | |
| COVID-19 | 45 | 47 | 2 | 2 | 43 | 45 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Drug ineffective | 43 | 46 | | | 43 | 46 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Eyelid irritation | | 1 | | 1 | | |
| Fatigue | 1 | 4 | 1 | 4 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 5 | 3 | 4 | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Herpes zoster | 1 | 2 | 1 | 2 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hypertension | 4 | 4 | 4 | 4 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Intercepted product preparation error | | 1 | | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 2 | 1 | 2 | | |
| Myalgia | 3 | 3 | 2 | 2 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Needle issue | | 1 | | 1 | | |
| Occupational exposure to product | 1 | 2 | 1 | 2 | | |
| Off label use | 2 | 2 | 2 | 2 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | 20 | 22 | 20 | 22 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product packaging quantity issue | 1 | 1 | 1 | 1 | | |
| Product preparation issue | 2 | 8 | 2 | 8 | | |
| Product temperature excursion issue | 19 | 20 | 19 | 20 | | |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pyrexia | 3 | 4 | 3 | 4 | | |
| Rash | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test negative | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | 2 | 2 | | | 2 | 2 |
| Sluggishness | 1 | 1 | 1 | 1 | | |
| Suspected COVID-19 | | 1 | | | | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Underdose | | 7 | | 7 | | |
| Vaccination site dysaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site hypersensitivity | 2 | 2 | 2 | 2 | | |
| Vaccination site movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 5 | 7 | 5 | 7 | | |
| Wrong technique in product usage process | 1 | 2 | 1 | 2 | | |
| | 199 | 243 | 99 | 137 | 100 | 106 |

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Country Where Event Occurred

FRENCH POLYNESIA

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dermatitis bullous | 1 | 1 | 1 | 1 |
| Dermatosis | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred
GERMANY

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | 2 | 3 | 2 | 3 | | |
| Flushing | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | | | 1 | 1 |
| Off label use | 2 | 2 | 2 | 2 | | |
| Product administered to patient of inappropriate age | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| | 15 | 16 | 6 | 7 | 9 | 9 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | 1 | 2 | | | | 1 | 1 | 1 |
| Abdominal pain lower | | 2 | | | | 2 | | |
| Abdominal pain upper | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Abnormal faeces | 2 | 3 | | | 2 | 3 | | |
| Abortion spontaneous | 2 | 2 | | | | | 2 | 2 |
| Abscess | | 1 | | | | | | 1 |
| Acne | | 1 | | | | 1 | | |
| Acute myocardial infarction | | 1 | | | | | | 1 |
| Agranulocytosis | 1 | 1 | | | | | 1 | 1 |
| Altered state of consciousness | | | 1 | 1 | | | | |
| Anaphylactic reaction | 10 | 11 | | | | | 10 | 11 |
| Anaphylactic shock | | | 1 | 1 | | | | |
| Angina pectoris | 1 | 1 | | | | | 1 | 1 |
| Anosmia | 1 | 1 | | | 1 | 1 | | |
| Appendicitis | | | 1 | 1 | | | | |
| Arrhythmia | | 1 | | | | | | 1 |
| Arthralgia | 3 | 6 | 9 | 9 | 3 | 6 | | |
| Arthritis reactive | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 4 | 13 | | | 3 | 12 | 1 | 1 |
| Asthma | 1 | 2 | | | 1 | 2 | | |
| Autonomic nervous system imbalance | 1 | 1 | | | | | 1 | 1 |
| Back pain | | 2 | | | | 2 | | |
| Blood pressure decreased | 1 | 2 | | | | 1 | 1 | 1 |
| Blood pressure increased | | 2 | | | | 1 | | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 | | |
| Breast pain | | | 1 | 1 | | | | |
| Bronchitis bacterial | | 1 | | | | | | 1 |
| Burning sensation | 1 | 2 | | | | | 1 | 2 |
| Capillary nail refill test abnormal | 1 | 1 | | | 1 | 1 | | |
| Cardiovascular disorder | 2 | 2 | | | | | 2 | 2 |
| Cerebrovascular accident | 1 | 1 | | | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Chills | 6 | 15 |
| Circulatory collapse | 5 | 5 |
| Condition aggravated | 1 | 1 |
| Conjunctival haemorrhage | 2 | 2 |
| Conjunctivitis | | 1 |
| Cough | 2 | 3 |
| COVID-19 | 2 | 5 |
| Depressed level of consciousness | 1 | 1 |
| Diarrhoea | 2 | 7 |
| Discomfort | | |
| Disease recurrence | | 1 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 10 | 20 |
| Drug ineffective | 2 | 5 |
| Dry mouth | 1 | 1 |
| Dysaesthesia | 1 | 1 |
| Dyspnoea | 3 | 7 |
| Ear pain | | 1 |
| Eating disorder | 1 | 1 |
| Enanthema | 1 | 1 |
| Enteritis | 1 | 1 |
| Epilepsy | 1 | 1 |
| Epistaxis | | 1 |
| Erysipelas | 1 | 1 |
| Erythema | 7 | 8 |
| Extrapyramidal disorder | 1 | 1 |
| Eye pain | 1 | 1 |
| Facial paralysis | 2 | 2 |
| Fatigue | 8 | 29 |
| Feeling cold | 1 | 5 |
| Feeling hot | 4 | 4 |
| Flank pain | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 13 | 13 | 3 | 12 | 3 | 3 |
| | | | | 5 | 5 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | | 1 |
| 1 | 1 | 2 | 3 | | |
| | | | | 2 | 5 |
| | | 1 | 1 | | |
| 5 | 5 | 1 | 6 | 1 | 1 |
| 2 | 2 | | | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| 18 | 18 | 4 | 11 | 6 | 9 |
| | | | | 2 | 5 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 2 | 2 | 1 | 3 | 2 | 4 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| 2 | 2 | 5 | 6 | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| 20 | 20 | 7 | 28 | 1 | 1 |
| | | | 3 | 1 | 2 |
| | | 3 | 3 | 1 | 1 |
| | | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Flatulence | | 1 |
| Flushing | 5 | 6 |
| Gastrointestinal disorder | 1 | 1 |
| Gastrointestinal pain | | |
| Genital herpes | | 1 |
| Haematoma | | 1 |
| Haemoptysis | | 1 |
| Headache | 18 | 39 |
| Heart rate increased | 1 | 1 |
| Hemiparesis | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | | 3 |
| Hypersensitivity | 6 | 8 |
| Hypertension | 3 | 5 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | | 4 |
| Hypoglycaemia | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hypotension | 4 | 6 |
| Hypotonia | 1 | 1 |
| Incorrect route of product administration | 1 | 4 |
| Influenza like illness | 2 | 6 |
| Irregular breathing | 1 | 1 |
| Limb discomfort | | 3 |
| Local reaction | 1 | 3 |
| Loss of consciousness | 2 | 2 |
| Lymphadenopathy | 3 | 4 |
| Lymph node pain | | 2 |
| Malaise | 3 | 5 |
| Maternal exposure during pregnancy | 1 | 2 |
| Mobility decreased | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 3 | 3 | 2 | 3 |
| | | | | 1 | 1 |
| 1 | 1 | | | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| 23 | 23 | 13 | 34 | 5 | 5 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 3 | | |
| 1 | 1 | 1 | 1 | 5 | 7 |
| | | 1 | 2 | 2 | 3 |
| | | | | 1 | 1 |
| 1 | 1 | | 4 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 3 | 5 |
| | | | | 1 | 1 |
| | | 1 | 4 | | |
| | | 2 | 6 | | |
| | | | | 1 | 1 |
| | | | 3 | | |
| | | | 2 | 1 | 1 |
| | | | | 2 | 2 |
| | | 3 | 4 | | |
| | | | 2 | | |
| 21 | 21 | 1 | 3 | 2 | 2 |
| | | 1 | 2 | | |
| | | 1 | 2 | | |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Monocytosis | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Movement disorder | | 1 |
| Muscle strain | | |
| Muscle tightness | | |
| Muscle twitching | | 1 |
| Muscular weakness | 1 | 4 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 3 | 10 |
| Myocarditis | 4 | 4 |
| Nasal congestion | 1 | 1 |
| Nasopharyngitis | 1 | 3 |
| Nausea | 6 | 12 |
| Neck pain | | 2 |
| Neuralgic amyotrophy | | 1 |
| Neurodermatitis | 1 | 1 |
| Neutropenia | 1 | 1 |
| Oedema | | 1 |
| Off label use | 3 | 4 |
| Oligoarthritis | 1 | 1 |
| Oropharyngeal blistering | 1 | 1 |
| Oropharyngeal pain | 1 | 3 |
| Otitis media | | 1 |
| Pain | 1 | 5 |
| Pain in extremity | 8 | 18 |
| Palatal swelling | 1 | 1 |
| Palpitations | 2 | 8 |
| Paraesthesia | 4 | 5 |
| Pericarditis | 1 | 1 |
| Peripheral swelling | | 1 |
| Peripheral vascular disorder | 3 | 4 |
| Pharyngeal swelling | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| 1 | 1 | | | | |
| 1 | 1 | | | | |
| | | | 1 | | |
| | | | 3 | 1 | 1 |
| | | | 1 | | |
| 11 | 11 | 2 | 9 | 1 | 1 |
| | | | | 4 | 4 |
| | | 1 | 1 | | |
| 1 | 1 | 1 | 3 | | |
| 16 | 16 | 4 | 10 | 2 | 2 |
| | | | 2 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 4 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | |
| | | 1 | 5 | | |
| | | 8 | 18 | | |
| | | | | 1 | 1 |
| 1 | 1 | | 4 | 2 | 4 |
| 1 | 1 | 2 | 3 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 2 | 2 | 2 |
| 1 | 1 | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Pneumonia | 1 | 1 |
| Polyarthritits | 1 | 1 |
| Poor quality product administered | 5 | 5 |
| Presyncope | 3 | 4 |
| Product temperature excursion issue | 5 | 5 |
| Product use issue | 3 | 4 |
| Pruritus | 2 | 6 |
| Pulmonary embolism | 1 | 2 |
| Pulse waveform abnormal | 1 | 1 |
| Pustule | | |
| Pyrexia | 6 | 10 |
| Rash | 7 | 9 |
| Rash pruritic | | 1 |
| Respiratory distress | 1 | 2 |
| Restlessness | 1 | 1 |
| Retching | 1 | 1 |
| SARS-CoV-2 ant body test positive | 4 | 4 |
| Seizure | 5 | 5 |
| Sensation of foreign body | 3 | 4 |
| Sensory loss | | 1 |
| Sinusitis | | 1 |
| Sinus tachycardia | 1 | 2 |
| Somatic symptom disorder | 1 | 1 |
| Somnolence | 1 | 1 |
| Stridor | 1 | 1 |
| Sudden hearing loss | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling | | 3 |
| Swelling face | 1 | 2 |
| Swollen tongue | 1 | 1 |
| Syncope | 6 | 8 |
| Tachycardia | 7 | 10 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 4 | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | 4 | 4 | 1 | 1 |
| | | 3 | 4 | | |
| 1 | 1 | 1 | 3 | 1 | 3 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| 1 | 1 | | | | |
| 13 | 13 | 5 | 8 | 1 | 2 |
| 2 | 2 | 3 | 3 | 4 | 6 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 4 | 4 | | |
| | | | | 5 | 5 |
| | | | | 3 | 4 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 2 | | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 8 |
| 1 | 1 | 2 | 5 | 5 | 5 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | | |
|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-----|---------|-----|--|--|
| | | | Serious | | Nonserious | | Serious | | | |
| | | | I | C | I | C | I | C | | |
| Thirst | | | 1 | 1 | | | | | | |
| Throat irritation | 1 | 1 | 1 | 1 | 1 | 1 | | | | |
| Throat tightness | 1 | 1 | | | | | 1 | 1 | | |
| Tongue pruritus | 1 | 1 | | | | | 1 | 1 | | |
| Tremor | 5 | 7 | | | | | 5 | 7 | | |
| Urticaria | 5 | 5 | 1 | 1 | 2 | 2 | 3 | 3 | | |
| Vaccination site discomfort | 1 | 1 | | | 1 | 1 | | | | |
| Vaccination site erythema | 1 | 3 | | | 1 | 3 | | | | |
| Vaccination site haematoma | | 1 | | | | 1 | | | | |
| Vaccination site inflammation | | | 1 | 1 | | | | | | |
| Vaccination site movement impairment | | 1 | | | | 1 | | | | |
| Vaccination site pain | 10 | 40 | 21 | 21 | 9 | 39 | 1 | 1 | | |
| Vaccination site paraesthesia | 1 | 2 | | | 1 | 2 | | | | |
| Vaccination site pruritus | 1 | 2 | | | 1 | 2 | | | | |
| Vaccination site rash | 1 | 1 | | | 1 | 1 | | | | |
| Vaccination site swelling | 1 | 9 | 6 | 6 | | 8 | 1 | 1 | | |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 | | | | |
| Vaccination site warmth | 1 | 2 | | | 1 | 2 | | | | |
| Vertigo | 3 | 5 | | | 3 | 5 | | | | |
| Visual impairment | 1 | 1 | | | | | 1 | 1 | | |
| Vomiting | 2 | 3 | 5 | 5 | | 1 | 2 | 2 | | |
| Wheezing | 1 | 1 | | | | | 1 | 1 | | |
| | 324 | 606 | 210 | 210 | 160 | 395 | 164 | 211 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | | 3 | 1 | 1 | | 3 | | |
| Abdominal pain upper | 3 | 5 | | | 2 | 4 | 1 | 1 |
| Abnormal faeces | | 4 | | | | 4 | | |
| Abortion missed | 1 | 1 | | | | | 1 | 1 |
| Accidental overdose | | 8 | | | | 6 | | 2 |
| Ageusia | | 1 | | | | 1 | | |
| Agitation | | 1 | | | | 1 | | |
| Allergy to vaccine | 1 | 1 | | | | | 1 | 1 |
| Amnesia | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Anaphylactic reaction | 25 | 32 | | | | | 25 | 32 |
| Anaphylactic shock | 5 | 5 | | | | | 5 | 5 |
| Anaphylactoid reaction | | 1 | | | | | | 1 |
| Angina pectoris | 4 | 4 | | | | | 4 | 4 |
| Angioedema | 7 | 9 | | | | | 7 | 9 |
| Anxiety | 2 | 2 | | | | | 2 | 2 |
| Aphasia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Application site vesicles | 1 | 1 | | | | | 1 | 1 |
| Arrhythmia | 7 | 8 | | | | | 7 | 8 |
| Arthralgia | 6 | 13 | 8 | 8 | 5 | 12 | 1 | 1 |
| Aspiration | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 4 | 18 | | | 3 | 14 | 1 | 4 |
| Asthma | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Ataxia | 1 | 1 | | | | | 1 | 1 |
| Atypical pneumonia | | 1 | | | | | | 1 |
| Back pain | 1 | 2 | | | 1 | 2 | | |
| Bladder discomfort | | 1 | | | | 1 | | |
| Bladder pain | | 1 | | | | 1 | | |
| Blepharitis | 1 | 1 | | | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 | | |
| Blood pressure decreased | 3 | 3 | 1 | 1 | | | 3 | 3 |
| Blood pressure fluctuation | | 1 | | | | 1 | | |
| Blood pressure increased | 1 | 2 | 2 | 2 | | 1 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Body temperature increased | 3 | 9 |
| Bone pain | 2 | 3 |
| Bursitis | | |
| Cardiovascular disorder | 3 | 5 |
| Cardiovascular insufficiency | 1 | 2 |
| Cerebellar ataxia | 1 | 1 |
| Cerebellar syndrome | 2 | 2 |
| Cerebral infarction | 1 | 1 |
| Chest discomfort | 1 | 3 |
| Chest pain | 3 | 3 |
| Chest X-ray abnormal | 1 | 1 |
| Chills | 10 | 27 |
| Circulatory collapse | | 1 |
| Cold sweat | 1 | 2 |
| Cough | 10 | 15 |
| COVID-19 | 8 | 12 |
| Cyanosis | 1 | 1 |
| Deafness | 1 | 1 |
| Deafness transitory | 1 | 1 |
| Death | 2 | 2 |
| Decreased appetite | 1 | 1 |
| Deep vein thrombosis | 1 | 1 |
| Depressed level of consciousness | 1 | 1 |
| Dermatitis allergic | 1 | 3 |
| Dermatitis atopic | 1 | 1 |
| Diabetes mellitus | | 1 |
| Diaphragmalgia | 1 | 1 |
| Diarrhoea | 9 | 18 |
| Diplopia | | 1 |
| Discomfort | | |
| Disorientation | 2 | 2 |
| Disturbance in attention | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 9 | | |
| | | 2 | 3 | | |
| 1 | 1 | | | | |
| | | | 1 | 3 | 4 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 3 | | |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| 8 | 8 | 9 | 24 | 1 | 3 |
| 1 | 1 | | | | 1 |
| | | | | 1 | 2 |
| | | 6 | 11 | 4 | 4 |
| | | 3 | 3 | 5 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| 5 | 5 | 6 | 15 | 3 | 3 |
| | | | | | 1 |
| 1 | 1 | | | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Dizziness | 23 | 42 |
| Dizziness postural | 1 | 1 |
| Drug ineffective | 7 | 14 |
| Dry eye | | 1 |
| Dry mouth | 1 | 2 |
| Dysaesthesia | 1 | 2 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 1 | 2 |
| Dyspepsia | | 1 |
| Dysphagia | 2 | 4 |
| Dysphonia | 4 | 6 |
| Dyspnoea | 21 | 29 |
| Dyspnoea exertional | 3 | 3 |
| Ear discomfort | 1 | 1 |
| Eczema | 1 | 1 |
| Epilepsy | 4 | 5 |
| Episcleritis | | 1 |
| Epistaxis | | 2 |
| Erythema | 6 | 11 |
| Exercise tolerance decreased | | |
| Eye irritation | | 2 |
| Eyelid oedema | 1 | 1 |
| Eye pain | 2 | 2 |
| Eye pruritus | 3 | 4 |
| Eye swelling | | 1 |
| Face oedema | | 1 |
| Facial paralysis | 1 | 1 |
| Facial paresis | 1 | 1 |
| Fatigue | 21 | 65 |
| Feeling cold | 1 | 2 |
| Feeling hot | 4 | 5 |
| Feeling jittery | | |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 17 | 17 | 12 | 26 | 11 | 16 |
| | | | | 1 | 1 |
| | | | | 7 | 14 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 3 |
| | | 4 | 6 | | |
| | | 8 | 13 | 13 | 16 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 4 | 5 |
| | | | 1 | | |
| 1 | 1 | | 2 | | |
| | | 3 | 7 | 3 | 4 |
| 1 | 1 | | | | |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 22 | 23 | 20 | 62 | 1 | 3 |
| | | | 1 | 1 | 1 |
| | | 2 | 3 | 2 | 2 |
| 1 | 1 | | | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Flatulence | 1 | 1 |
| Flushing | 5 | 10 |
| Gait disturbance | 1 | 1 |
| Generalised tonic-clonic seizure | 2 | 2 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematemesis | 1 | 1 |
| Haematoma | 2 | 2 |
| Haematuria | | 1 |
| Headache | 34 | 75 |
| Heart rate increased | 2 | 4 |
| Hepatic pain | 1 | 1 |
| Herpes zoster | 3 | 4 |
| Hordeolum | | 1 |
| Hot flush | | 1 |
| Hunger | | 1 |
| Hyperaesthesia | 1 | 1 |
| Hyperhidrosis | 2 | 3 |
| Hypersensitivity | 9 | 13 |
| Hypersensitivity vasculitis | 1 | 1 |
| Hypersomnia | | 1 |
| Hypertension | 8 | 13 |
| Hypertensive crisis | 2 | 2 |
| Hyperventilation | 6 | 6 |
| Hypoaesthesia | 3 | 3 |
| Hypoaesthesia oral | 2 | 2 |
| Hypotension | 3 | 8 |
| Hypotonia | 2 | 3 |
| Hypoxia | 1 | 1 |
| Idiopathic intracranial hypertension | 1 | 1 |
| Impaired work ability | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect route of product administration | 1 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 1 | 1 | | |
| | | 2 | 4 | 3 | 6 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | 1 | | |
| 20 | 21 | 28 | 64 | 6 | 11 |
| | | | 1 | 2 | 3 |
| | | 1 | 1 | | |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| 1 | 1 | 2 | 3 | | |
| 3 | 3 | | 2 | 9 | 11 |
| | | | | 1 | 1 |
| | | | | | 1 |
| 3 | 3 | 2 | 3 | 6 | 10 |
| | | | | 2 | 2 |
| | | 2 | 2 | 4 | 4 |
| 1 | 1 | 3 | 3 | | |
| | | 2 | 2 | | |
| | | | 2 | 3 | 6 |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 3 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Influenza like illness | 5 | 16 |
| Joint range of motion decreased | 1 | 1 |
| Lacrimation increased | 5 | 5 |
| Laryngeal oedema | | 2 |
| Laryngospasm | 1 | 1 |
| Limb discomfort | | 1 |
| Lip swelling | 2 | 2 |
| Livedo reticularis | | 1 |
| Local reaction | 1 | 1 |
| Loss of consciousness | 1 | 2 |
| Lower respiratory tract congestion | 1 | 1 |
| Lung disorder | 1 | 1 |
| Lymphadenopathy | 4 | 9 |
| Lymph node pain | 1 | 2 |
| Malaise | 5 | 10 |
| Maternal exposure during pregnancy | 3 | 4 |
| Microembolism | 1 | 1 |
| Mobility decreased | 1 | 2 |
| Monoplegia | 1 | 1 |
| Movement disorder | | 1 |
| Multiple sclerosis | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscle spasticity | 1 | 1 |
| Muscle tightness | | 1 |
| Muscular weakness | 2 | 4 |
| Myalgia | 13 | 31 |
| Myosclerosis | 1 | 1 |
| Nasal congestion | | 1 |
| Nasopharyngitis | 1 | 4 |
| Nausea | 12 | 25 |
| Neck pain | | 5 |
| Nervous system disorder | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 16 | | |
| | | 1 | 1 | | |
| | | 3 | 3 | 2 | 2 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 4 | 9 | | |
| | | 1 | 2 | | |
| 24 | 25 | 5 | 9 | | 1 |
| | | 2 | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 4 | | |
| 14 | 15 | 9 | 27 | 4 | 4 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 4 | | |
| 18 | 18 | 7 | 19 | 5 | 6 |
| | | | 5 | | |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Neuralgia | | 1 |
| Neurodermatitis | 1 | 1 |
| Night sweats | 1 | 1 |
| Nodule | 1 | 1 |
| Nystagmus | 1 | 1 |
| Obstructive airways disorder | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | 3 | 4 |
| Odynophagia | | |
| Off label use | 1 | 2 |
| Optic neuritis | 1 | 1 |
| Optic neuropathy | 1 | 1 |
| Oral herpes | 2 | 2 |
| Oral mucosa erosion | | 1 |
| Oropharyngeal pain | 3 | 3 |
| Orthopnoea | | 1 |
| Orthostatic intolerance | | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 4 | 9 |
| Pain in extremity | 18 | 45 |
| Palpitations | 7 | 17 |
| Paraesthesia | 12 | 16 |
| Paraesthesia oral | 2 | 4 |
| Performance status decreased | | 1 |
| Peripheral coldness | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Peripheral vascular disorder | 4 | 7 |
| Personality change | 2 | 2 |
| Petechiae | 1 | 1 |
| Pharyngeal hypoesthesia | 1 | 2 |
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal swelling | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | | | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| 1 | 1 | 2 | 2 | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 4 | 7 | | 2 |
| | | 16 | 41 | 2 | 4 |
| 2 | 2 | 5 | 14 | 2 | 3 |
| 2 | 2 | 5 | 8 | 7 | 8 |
| | | 1 | 2 | 1 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| 1 | 1 | 2 | 3 | 2 | 4 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | 2 |

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* I=Interval, C=Cumulative
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Photopsia | 1 | 1 |
| Photosensitivity reaction | | 1 |
| Pollakiuria | | 1 |
| Poor quality product administered | 11 | 11 |
| Poor quality sleep | | 1 |
| Presyncope | 1 | 1 |
| Product temperature excursion issue | 11 | 11 |
| Product use issue | 1 | 2 |
| Protein urine present | | 1 |
| Pruritus | 9 | 12 |
| Pruritus allergic | 1 | 2 |
| Psychological factor affecting medical condition | | 1 |
| Pyrexia | 14 | 37 |
| Rash | 6 | 13 |
| Rash maculo-papular | | 1 |
| Rash pruritic | | 1 |
| Rash vesicular | 1 | 1 |
| Renal pain | | 1 |
| Respiratory distress | 18 | 22 |
| Respiratory symptom | | 1 |
| Resting tremor | 1 | 1 |
| Restlessness | 1 | 1 |
| Retching | | 1 |
| Retinopathy | 1 | 1 |
| Retrograde amnesia | 1 | 1 |
| Revers ble cerebral vasoconstriction syndrome | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 |
| Rhinalgia | | 1 |
| Rhinorrhoea | 3 | 4 |
| SARS-CoV-2 ant body test positive | 8 | 8 |
| SARS-CoV-2 test positive | 2 | 5 |
| Scratch | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 11 | 11 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 11 | 11 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 4 | 7 | 5 | 5 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| 7 | 8 | 10 | 33 | 4 | 4 |
| 1 | 1 | | 5 | 6 | 8 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 18 | 22 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 3 | 4 | | |
| | | 8 | 8 | | |
| | | | | 2 | 5 |
| | | | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Seizure | 2 | 2 |
| Sensation of foreign body | 3 | 4 |
| Sensory disturbance | 1 | 4 |
| Sinusitis | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Sleep disorder | 1 | 2 |
| Sneezing | 2 | 3 |
| Somnolence | 2 | 3 |
| Speech disorder | 1 | 1 |
| Spinal pain | 1 | 1 |
| Stress | | 2 |
| Stridor | 2 | 2 |
| Sudden death | 1 | 1 |
| Sudden hearing loss | 1 | 1 |
| Sudden visual loss | 1 | 1 |
| Supraventricular extrasystoles | 1 | 1 |
| Swelling | 4 | 7 |
| Swelling face | 1 | 1 |
| Swollen tongue | 3 | 3 |
| Syncope | 5 | 5 |
| Tachyarrhythmia | | 1 |
| Tachycardia | 15 | 25 |
| Tachypnoea | 1 | 1 |
| Taste disorder | | 1 |
| Tension headache | | 1 |
| Tetany | 1 | 1 |
| Thirst | | 1 |
| Throat irritation | 1 | 3 |
| Throat tightness | 4 | 6 |
| Thrombocytopenia | 1 | 1 |
| Tremor | 2 | 6 |
| Trichoglossia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 1 | 2 | 3 |
| | | | 3 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 2 | 3 | | |
| | | 2 | 3 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 6 | 1 | 1 |
| 1 | 1 | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| 1 | 1 | | | 5 | 5 |
| | | | | | 1 |
| 5 | 5 | 4 | 8 | 11 | 17 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | 2 | 3 | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 4 | 1 | 2 |
| | | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Urticaria | 3 | 5 | | | 1 | 2 | 2 | 3 |
| Vaccination site dermatitis | | 1 | | | | 1 | | |
| Vaccination site discomfort | | 2 | | | | 2 | | |
| Vaccination site dysaesthesia | 1 | 1 | | | 1 | 1 | | |
| Vaccination site erythema | 2 | 8 | | | 2 | 8 | | |
| Vaccination site hyperaesthesia | | 1 | | | | 1 | | |
| Vaccination site induration | 1 | 4 | | | 1 | 4 | | |
| Vaccination site joint movement impairment | 1 | 2 | | | 1 | 2 | | |
| Vaccination site joint pain | 2 | 2 | | | 2 | 2 | | |
| Vaccination site movement impairment | 1 | 3 | | | 1 | 3 | | |
| Vaccination site pain | 23 | 70 | 24 | 24 | 23 | 70 | | |
| Vaccination site pruritus | 2 | 5 | | | 2 | 5 | | |
| Vaccination site reaction | | 2 | | | | 2 | | |
| Vaccination site swelling | 4 | 10 | 4 | 4 | 3 | 9 | 1 | 1 |
| Vaccination site warmth | 3 | 8 | 1 | 1 | 3 | 8 | | |
| Venous thrombosis limb | 1 | 1 | | | | | 1 | 1 |
| Vertigo | 1 | 2 | | | | 1 | 1 | 1 |
| Vision blurred | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Visual impairment | 3 | 5 | | | 1 | 2 | 2 | 3 |
| Vomiting | 8 | 10 | 3 | 3 | 5 | 7 | 3 | 3 |
| Weight bearing difficulty | | 1 | | | | | | 1 |
| Wheezing | 2 | 2 | | | 1 | 1 | 1 | 1 |
| White blood cell count increased | 1 | 1 | | | | | 1 | 1 |
| | 717 | 1,313 | 209 | 214 | 381 | 864 | 336 | 449 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | 2 | 3 | | | 2 | 3 | | |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 | | |
| Abdominal pain upper | 2 | 2 | | | 2 | 2 | | |
| Accidental overdose | | 5 | | | | 4 | | 1 |
| Acute myocardial infarction | | 2 | | | | | | 2 |
| Acute respiratory distress syndrome | 1 | 1 | | | | | 1 | 1 |
| Acute respiratory failure | | 1 | | | | | | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 | | |
| Agitation | 1 | 1 | | | | | 1 | 1 |
| Allergy to vaccine | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Anaphylactic reaction | 8 | 10 | | | | | 8 | 10 |
| Anaphylactic shock | 1 | 2 | | | | | 1 | 2 |
| Angina pectoris | 1 | 2 | | | | | 1 | 2 |
| Angioedema | 1 | 1 | | | | | 1 | 1 |
| Anosmia | 1 | 1 | | | 1 | 1 | | |
| Anxiety | 1 | 2 | | | 1 | 2 | | |
| Apathy | 1 | 1 | | | 1 | 1 | | |
| Arrhythmia | 2 | 3 | 1 | 1 | | | 2 | 3 |
| Arthralgia | 5 | 10 | 5 | 5 | 4 | 9 | 1 | 1 |
| Arthropathy | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 7 | 14 | | | 7 | 14 | | |
| Asthma | 1 | 2 | | | 1 | 1 | | 1 |
| Ataxia | 1 | 1 | | | | | 1 | 1 |
| Back pain | 2 | 2 | | | 2 | 2 | | |
| Blood cholesterol increased | 1 | 1 | | | 1 | 1 | | |
| Blood pressure increased | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Body temperature increased | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Bone pain | 4 | 4 | | | 3 | 3 | 1 | 1 |
| Bradycardia | 1 | 1 | | | | | 1 | 1 |
| Bronchial disorder | | 1 | | | | 1 | | |
| Bronchitis | 1 | 1 | | | 1 | 1 | | |
| Burning sensation | 1 | 1 | | | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Cardiac failure | 1 | 1 |
| Cardiovascular disorder | | 2 |
| Chest discomfort | | 1 |
| Chest pain | 1 | 1 |
| Chills | 5 | 8 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Circulatory collapse | | 1 |
| Cold sweat | 3 | 3 |
| Communication disorder | 1 | 1 |
| Condition aggravated | | 1 |
| Coronavirus test positive | 1 | 1 |
| Cough | 5 | 6 |
| COVID-19 | 10 | 16 |
| Cyanosis | | 1 |
| Deafness unilateral | 1 | 1 |
| Death | 2 | 3 |
| Decreased appetite | 1 | 2 |
| Deep vein thrombosis | 1 | 1 |
| Depressed level of consciousness | | 1 |
| Depression | 1 | 1 |
| Diarrhoea | 9 | 11 |
| Diet refusal | 1 | 1 |
| Disease recurrence | | 1 |
| Disturbance in attention | 3 | 3 |
| Dizziness | 17 | 30 |
| Drug ineffective | 7 | 14 |
| Drug interaction | | 1 |
| Dry mouth | 2 | 2 |
| Dysaesthesia | 1 | 1 |
| Dysgeusia | 1 | 1 |
| Dysphagia | 4 | 6 |
| Dyspnoea | 4 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| 4 | 4 | 4 | 7 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | 2 | 3 |
| 1 | 1 | 2 | 2 | 8 | 14 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 7 | 9 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 2 | 1 | 1 |
| 6 | 6 | 9 | 21 | 8 | 9 |
| | | | | 7 | 14 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | 1 | 3 |
| | | 1 | 3 | 3 | 4 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dyspnoea at rest | 1 | 1 |
| Dyspnoea exertional | 2 | 3 |
| Dysstasia | | 1 |
| Epilepsy | 2 | 2 |
| Erythema | 3 | 5 |
| Eye haemorrhage | | 1 |
| Eye irritation | | 1 |
| Eye pruritus | 1 | 1 |
| Eye swelling | 1 | 1 |
| Facial paralysis | 1 | 2 |
| Facial paresis | 1 | 1 |
| Fall | 2 | 2 |
| Fatigue | 14 | 28 |
| Feeling abnormal | 1 | 1 |
| Feeling hot | 4 | 5 |
| Flushing | 2 | 2 |
| Gait disturbance | | 1 |
| General physical health deterioration | 2 | 4 |
| Gingival swelling | 1 | 1 |
| Glomerular filtration rate decreased | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematochezia | 1 | 1 |
| Haematoma | 2 | 2 |
| Hallucination, auditory | 1 | 1 |
| Headache | 21 | 40 |
| Herpes zoster | | 1 |
| Huntington's disease | | 3 |
| Hyperhidrosis | 3 | 6 |
| Hypersensitivity | 8 | 9 |
| Hypersomnia | 1 | 1 |
| Hypertension | 5 | 8 |
| Hypertensive crisis | 3 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 3 | 5 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| 10 | 10 | 12 | 26 | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 2 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 3 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| 12 | 12 | 17 | 36 | 4 | 4 |
| | | | 1 | | |
| | | | | | 3 |
| | | 3 | 6 | | |
| | | 4 | 4 | 4 | 5 |
| | | | | 1 | 1 |
| | | 2 | 4 | 3 | 4 |
| | | | | 3 | 3 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypertensive emergency | 1 | 1 |
| Hypertonia | 1 | 1 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 2 | 4 |
| Hypoaesthesia oral | | 1 |
| Hypophagia | 1 | 1 |
| Hypotension | 2 | 3 |
| Hypotonia | 1 | 1 |
| Illness | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Incorrect route of product administration | 1 | 2 |
| Induration | | 1 |
| Infection | 2 | 2 |
| Infective exacerbation of chronic obstructive airways disease | 1 | 2 |
| Influenza like illness | 3 | 6 |
| Injection site pain | 1 | 3 |
| Insomnia | | 1 |
| IVth nerve paresis | 1 | 1 |
| Jaundice | | 1 |
| Joint range of motion decreased | 1 | 1 |
| Joint swelling | 1 | 1 |
| Language disorder | | 1 |
| Laryngeal oedema | 1 | 1 |
| Left ventricular failure | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Leukopenia | | 1 |
| Limb discomfort | 1 | 3 |
| Lip oedema | | 1 |
| Lip swelling | | 2 |
| Local reaction | | 1 |
| Loss of consciousness | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | 1 | | |
| 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | 3 | 6 | | |
| | | 1 | 2 | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | | | | 2 |
| | | | 1 | | |
| | | | | 1 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Low density lipoprotein increased | 1 | 1 |
| Lung infiltration | 1 | 1 |
| Lymphadenopathy | 2 | 2 |
| Lymph node pain | 2 | 2 |
| Lymphopenia | 1 | 1 |
| Malaise | 6 | 9 |
| Memory impairment | 1 | 1 |
| Mental disorder | 1 | 1 |
| Mesenteric vein thrombosis | | 1 |
| Middle insomnia | | 1 |
| Migraine | 1 | 2 |
| Mouth swelling | 1 | 1 |
| Movement disorder | | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 |
| Myalgia | 7 | 15 |
| Myelitis | 1 | 1 |
| Nasal congestion | | 1 |
| Nasopharyngitis | 3 | 4 |
| Nausea | 12 | 16 |
| Neck pain | | 1 |
| Nervousness | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Off label use | 1 | 2 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 1 | 2 |
| Oxygen saturation decreased | | 1 |
| Pain | | 5 |
| Pain in extremity | 6 | 10 |
| Pallor | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | 2 | 2 | | |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| 4 | 4 | 3 | 5 | 3 | 4 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 8 | 8 | 6 | 14 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 3 | 1 | 1 |
| 1 | 1 | 9 | 13 | 3 | 3 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | | | 1 |
| | | | 4 | | 1 |
| | | 6 | 10 | | |
| | | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Palpitations | 4 | 6 |
| Paraesthesia | 2 | 6 |
| Paraesthesia oral | 1 | 2 |
| Paresis | 1 | 1 |
| Pelvic pain | 1 | 1 |
| Performance status decreased | 1 | 1 |
| Peripheral swelling | 2 | 3 |
| Peripheral vascular disorder | 2 | 2 |
| Personality change | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal swelling | 2 | 3 |
| Pharyngitis | 1 | 1 |
| Photopsia | 1 | 1 |
| Pneumonia | 2 | 2 |
| Pneumonia aspiration | | 2 |
| Poor quality product administered | 5 | 5 |
| Product temperature excursion issue | 5 | 5 |
| Product use issue | 1 | 2 |
| Pruritus | 5 | 7 |
| Psoriasis | | 1 |
| Pulmonary embolism | 2 | 2 |
| Pyrexia | 12 | 19 |
| Quadripareisis | 1 | 1 |
| Rash | 2 | 2 |
| Rash maculo-papular | 1 | 1 |
| Renal failure | 1 | 1 |
| Respiratory distress | 3 | 3 |
| Respiratory failure | 4 | 4 |
| Respiratory tract infection | | 1 |
| Restlessness | 2 | 4 |
| Retching | 1 | 1 |
| Retinal tear | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 1 | 3 | 3 | 3 |
| | | 1 | 5 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | | 2 |
| | | 5 | 5 | | |
| | | 5 | 5 | | |
| | | 1 | 2 | | |
| 1 | 1 | 4 | 6 | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| 4 | 4 | 7 | 12 | 5 | 7 |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 4 | 4 |
| | | | | | 1 |
| | | 1 | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Rhinitis | | 1 |
| Rhinorrhoea | 3 | 5 |
| SARS-CoV-2 ant body test positive | 5 | 5 |
| SARS-CoV-2 test positive | 1 | 1 |
| Seizure | | 4 |
| Sensation of foreign body | 1 | 1 |
| Sense of oppression | | 1 |
| Sialoadenitis | 1 | 1 |
| Skin abrasion | 1 | 1 |
| Skin discolouration | | 1 |
| Skin swelling | 1 | 1 |
| Sleep disorder | 2 | 2 |
| Somnolence | 2 | 3 |
| Speech disorder | | 1 |
| Status epilepticus | | 1 |
| Stomatitis | 1 | 1 |
| Subclavian artery thrombosis | 1 | 1 |
| Sudden death | 1 | 1 |
| Sudden hearing loss | 1 | 1 |
| Supraventricular extrasystoles | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Suspected COVID-19 | | 1 |
| Swelling | | 2 |
| Swelling face | 5 | 7 |
| Swollen tongue | 1 | 2 |
| Syncope | 7 | 8 |
| Tachycardia | 6 | 8 |
| Tachypnoea | 1 | 1 |
| Tension | 1 | 1 |
| Throat irritation | 1 | 1 |
| Throat tightness | | 1 |
| Thrombocytopenia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 3 | 5 | | |
| | | 5 | 5 | | |
| | | | | 1 | 1 |
| | | | | | 4 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | 2 | 3 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 2 | | |
| 2 | 2 | 3 | 3 | 2 | 4 |
| | | | 1 | 1 | 1 |
| | | | | 7 | 8 |
| | | 1 | 2 | 5 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Thrombosis | 1 | 1 |
| Tongue disorder | | 1 |
| Transient ischaemic attack | 1 | 1 |
| Tremor | 3 | 3 |
| Urosepsis | 1 | 1 |
| Urticaria | 1 | 2 |
| Vaccination failure | | |
| Vaccination site erythema | 2 | 4 |
| Vaccination site hyperaesthesia | | 1 |
| Vaccination site joint movement impairment | | 1 |
| Vaccination site pain | 7 | 22 |
| Vaccination site pruritus | 1 | 1 |
| Vaccination site swelling | 1 | 7 |
| Vaccination site warmth | 3 | 3 |
| Varicella zoster virus infection | 1 | 1 |
| Vision blurred | 1 | 2 |
| Visual impairment | 1 | 1 |
| Vitreous disorder | 1 | 1 |
| Vomiting | 6 | 7 |
| Wheezing | 1 | 1 |
| | 455 | 721 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| 1 | 1 | | | | |
| 1 | 1 | | 2 | 2 | 2 |
| | | | 1 | | |
| | | | | | 1 |
| 7 | 7 | 5 | 19 | 2 | 3 |
| | | 1 | 1 | | |
| 2 | 2 | | 6 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 5 | 6 | 1 | 1 |
| | | 1 | 1 | | |
| 74 | 74 | 243 | 431 | 212 | 290 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acidosis | 1 | 1 | | | | | 1 | 1 |
| Acute respiratory distress syndrome | 1 | 1 | | | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Allergy to vaccine | | 1 | | | | | | 1 |
| Anaphylactic reaction | 1 | 2 | | | | | 1 | 2 |
| Angioedema | 1 | 1 | | | | | 1 | 1 |
| Aortic aneurysm | 1 | 1 | | | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | | | 1 | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 | | |
| Asthenia | 3 | 4 | | | 2 | 2 | 1 | 2 |
| Asymptomatic COVID-19 | 1 | 1 | | | | | 1 | 1 |
| Bedridden | | 1 | | | | | | 1 |
| Blister | | 1 | | | | 1 | | |
| Body temperature increased | 1 | 2 | | | 1 | 2 | | |
| Cardiac failure | 1 | 1 | | | | | 1 | 1 |
| Cerebrovascular accident | 1 | 2 | | | | | 1 | 2 |
| Chills | 3 | 5 | | | 1 | 3 | 2 | 2 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | | | 1 | 1 |
| Circulatory collapse | 2 | 2 | | | | | 2 | 2 |
| Cor pulmonale | 1 | 1 | | | | | 1 | 1 |
| COVID-19 | 17 | 21 | | | | 1 | 17 | 20 |
| COVID-19 pneumonia | 2 | 3 | | | | | 2 | 3 |
| Cranial nerve disorder | 1 | 1 | | | 1 | 1 | | |
| Death | 9 | 12 | | | | | 9 | 12 |
| Deep vein thrombosis | 1 | 1 | | | | | 1 | 1 |
| Diarrhoea | | 2 | 1 | 1 | | 1 | | 1 |
| Dizziness | 1 | 3 | | | 1 | 2 | | 1 |
| Drug ineffective | 16 | 19 | | | | | 16 | 19 |
| Dysarthria | 1 | 1 | | | | | 1 | 1 |
| Dysgeusia | | 1 | | | | 1 | | |
| Dyspnoea | 3 | 3 | | | | | 3 | 3 |
| Eczema | 5 | 5 | | | 5 | 5 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Encephalitis | 1 | 1 |
| Erythema multiforme | 1 | 1 |
| Eye pruritus | | 1 |
| Eye swelling | | 1 |
| Facial paralysis | 1 | 1 |
| Fatigue | 1 | 6 |
| Feeling hot | | 1 |
| Gait disturbance | | 1 |
| General physical health deterioration | 1 | 2 |
| Haematemesis | 1 | 1 |
| Headache | 2 | 5 |
| Head discomfort | | 1 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 1 | 1 |
| Herpes zoster | 2 | 3 |
| Hyperhidrosis | | 1 |
| Hyperkalaemia | 1 | 1 |
| Hypersensitivity | 2 | 4 |
| Hypertension | 1 | 2 |
| Hypertensive crisis | 1 | 1 |
| Hypoaesthesia | | 1 |
| Hypoaesthesia oral | | 2 |
| Hypotonia | | 1 |
| Incorrect route of product administration | 1 | 1 |
| Injection site discomfort | | 1 |
| Irregular breathing | | 1 |
| Lacrimation increased | | 1 |
| Loss of consciousness | 3 | 3 |
| Malaise | 2 | 4 |
| Multiple organ dysfunction syndrome | 1 | 2 |
| Myalgia | 2 | 3 |
| Myocardial infarction | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 5 | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 3 | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | 1 | 3 |
| | | | | 1 | 2 |
| 1 | 1 | | 1 | 2 | 2 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Nasopharyngitis | 1 | 1 |
| Nausea | 2 | 2 |
| Neuralgic amyotrophy | 1 | 1 |
| Night sweats | 1 | 1 |
| Occipital neuralgia | 1 | 1 |
| Pain in extremity | | 4 |
| Pallor | 1 | 1 |
| Paresis | | 1 |
| Peripheral vascular disorder | 1 | 1 |
| Personality change | 1 | 1 |
| Poor quality product administered | 1 | 1 |
| Product temperature excursion issue | 1 | 1 |
| Pruritus | 1 | 1 |
| Pulmonary oedema | 1 | 1 |
| Pulmonary sepsis | | 1 |
| Pyrexia | 6 | 9 |
| Rash | 2 | 3 |
| Rash macular | 1 | 1 |
| Respiratory distress | 2 | 4 |
| Respiratory failure | 1 | 1 |
| Rhinorrhoea | | 2 |
| Rhonchi | | 1 |
| Rosacea | | 1 |
| SARS-CoV-2 ant body test positive | 1 | 1 |
| SARS-CoV-2 sepsis | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 |
| Seizure | 1 | 1 |
| Shock | 1 | 1 |
| Sneezing | | 1 |
| Status epilepticus | 1 | 1 |
| Sudden death | | 3 |
| Superinfection bacterial | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 4 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 3 | 4 | 6 |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Swelling face | | 1 |
| Syncope | 2 | 2 |
| Tongue oedema | 1 | 1 |
| Tremor | 1 | 2 |
| Type IV hypersensitivity reaction | 4 | 4 |
| Unresponsive to stimuli | | 1 |
| Urticaria | 1 | 1 |
| Vaccination failure | 2 | 2 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site irritation | | 1 |
| Vaccination site pain | | 6 |
| Ventricular tachycardia | 1 | 1 |
| Vomiting | 1 | 4 |
| | 151 | 239 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 4 | 4 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | 1 | | |
| 1 | 1 | | 6 | | |
| | | | | 1 | 1 |
| | | 1 | 3 | | 1 |
| 3 | 3 | 36 | 79 | 115 | 160 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | 1 | 1 | | | | | 1 | 1 |
| Abdominal pain lower | | 1 | | | | 1 | | |
| Acute abdomen | 1 | 1 | | | | | 1 | 1 |
| Acute coronary syndrome | 3 | 3 | | | | | 3 | 3 |
| Acute kidney injury | 5 | 10 | | | | | 5 | 10 |
| Acute myocardial infarction | 2 | 5 | | | | | 2 | 5 |
| Ageusia | 1 | 2 | | | 1 | 2 | | |
| Aggression | 1 | 1 | | | | | 1 | 1 |
| Agitation | 2 | 2 | | | | | 2 | 2 |
| Alanine aminotransferase increased | 1 | 1 | | | | | 1 | 1 |
| Allergic oedema | | 1 | | | | 1 | | |
| Amaurosis fugax | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic shock | | 2 | | | | | | 2 |
| Angioedema | 1 | 1 | | | | | 1 | 1 |
| Anosmia | | 1 | | | | 1 | | |
| Apathy | 1 | 3 | | | | | 1 | 3 |
| Aphasia | 1 | 1 | | | | | 1 | 1 |
| Arrhythmia | 2 | 3 | | | | | 2 | 3 |
| Arterial occlusive disease | 1 | 1 | | | | | 1 | 1 |
| Arteriosclerosis | 1 | 1 | | | | | 1 | 1 |
| Arthralgia | | 2 | | | | 2 | | |
| Aspartate aminotransferase increased | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 8 | 10 | | | 1 | 2 | 7 | 8 |
| Asthma | 1 | 1 | | | | | 1 | 1 |
| Ataxia | 3 | 3 | | | | | 3 | 3 |
| Atrial fibrillation | 5 | 7 | | | | | 5 | 7 |
| Atrial flutter | 1 | 1 | | | 1 | 1 | | |
| Atrioventricular block complete | 1 | 1 | | | | | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 | | | 1 | 1 | | |
| Automatism | 1 | 1 | | | | | 1 | 1 |
| Basal ganglia infarction | 1 | 1 | | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Blood calcium decreased | | 1 |
| Blood creatine phosphokinase increased | | 1 |
| Blood creatine phosphokinase MB increased | | 1 |
| Blood creatinine increased | | 1 |
| Blood lactate dehydrogenase increased | 2 | 2 |
| Blood potassium decreased | | 1 |
| Blood pressure decreased | 1 | 2 |
| Blood pressure immeasurable | 1 | 1 |
| Blood pressure increased | 2 | 2 |
| Blood urine present | | 1 |
| Body temperature increased | 1 | 4 |
| Bradycardia | 1 | 3 |
| Bronchitis | 1 | 2 |
| Bronchospasm | 1 | 2 |
| Cardiac aneurysm | 1 | 1 |
| Cardiac arrest | 4 | 5 |
| Cardiac failure | 8 | 15 |
| Cardiac failure acute | 1 | 1 |
| Cardiac failure congestive | 1 | 2 |
| Cardiac fibrillation | | 1 |
| Cardiogenic shock | 2 | 3 |
| Cardiopulmonary failure | | 1 |
| Cardio-respiratory arrest | 1 | 1 |
| Cerebral atrophy | 1 | 1 |
| Cerebral haemorrhage | 1 | 2 |
| Cerebral infarction | 2 | 3 |
| Cerebral ischaemia | 1 | 1 |
| Cerebrovascular accident | 9 | 10 |
| Cerebrovascular disorder | 1 | 1 |
| Chest pain | 2 | 2 |
| Cholelithiasis | | 1 |
| Chronic kidney disease | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 3 |
| | | | | 1 | 3 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 5 |
| | | | | 8 | 15 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 9 | 10 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Chronic obstructive pulmonary disease | 2 | 2 |
| Circulatory collapse | 8 | 9 |
| Cold sweat | 1 | 1 |
| Condition aggravated | | 1 |
| Confusional state | 7 | 8 |
| Constipation | | 1 |
| Coronavirus infection | 4 | 4 |
| Coronavirus test positive | 1 | 1 |
| Cough | 2 | 4 |
| COVID-19 | 45 | 62 |
| COVID-19 pneumonia | 4 | 8 |
| C-reactive protein increased | 3 | 3 |
| Crepitations | | 1 |
| Cyanosis | 2 | 2 |
| Death | 25 | 49 |
| Decreased appetite | | 1 |
| Dehydration | 1 | 1 |
| Delirium | 2 | 2 |
| Dementia | | 1 |
| Dementia of the Alzheimer's type, with delirium | | 1 |
| Depressed level of consciousness | 1 | 1 |
| Dermatitis allergic | | 1 |
| Diabetes mellitus | | 1 |
| Diarrhoea | 4 | 5 |
| Diet refusal | 2 | 4 |
| Disease recurrence | 1 | 1 |
| Disorientation | 2 | 3 |
| Disturbance in attention | 3 | 5 |
| Dizziness | 11 | 11 |
| Dizziness postural | | 1 |
| Drug ineffective | 26 | 46 |
| Dry skin | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 8 | 9 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 4 | 4 | 4 |
| | | | 1 | | |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | 2 | 2 | 2 |
| | | 17 | 17 | 28 | 45 |
| | | | | 4 | 8 |
| | | 1 | 1 | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 25 | 49 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 3 | 2 | 2 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | 3 | 4 |
| | | 4 | 4 | 7 | 7 |
| | | | 1 | | |
| | | | | 26 | 46 |
| | | | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dysphagia | 4 | 4 |
| Dyspnoea | 9 | 13 |
| Embolism arterial | 1 | 1 |
| Epilepsy | 9 | 11 |
| Epistaxis | 1 | 1 |
| Erythema | 2 | 3 |
| Eye haemorrhage | 1 | 1 |
| Eye swelling | 1 | 1 |
| Facial paralysis | 3 | 4 |
| Facial paresis | 2 | 2 |
| Fall | 2 | 6 |
| Fatigue | 4 | 7 |
| Febrile infection | | 2 |
| Feeling cold | | 1 |
| Femoral neck fracture | | 1 |
| Femur fracture | 1 | 1 |
| Flatulence | | 1 |
| Food refusal | | 2 |
| Fracture | 1 | 1 |
| Gait disturbance | 4 | 4 |
| General physical condition abnormal | 7 | 8 |
| General physical health deterioration | 15 | 23 |
| Glomerulonephritis minimal lesion | 1 | 1 |
| Gout | 1 | 1 |
| Haematemesis | 1 | 1 |
| Haematocrit decreased | | 1 |
| Haematoma | 2 | 2 |
| Haemoglobin decreased | | 1 |
| Hallucinations, mixed | 1 | 1 |
| Headache | 2 | 5 |
| Head injury | | 1 |
| Heart rate increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 3 | 1 | 1 |
| | | 2 | 3 | 7 | 10 |
| | | | | 1 | 1 |
| | | | | 9 | 11 |
| | | | | 1 | 1 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 3 | 4 |
| | | | | 2 | 2 |
| | | | | 2 | 6 |
| 2 | 2 | 3 | 5 | 1 | 2 |
| | | | | | 2 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 7 | 8 |
| | | 1 | 2 | 14 | 21 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 2 | 2 | 3 |
| | | | | | 1 |
| | | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hemiparesis | 4 | 5 |
| Herpes simplex | 1 | 1 |
| Herpes zoster | 2 | 2 |
| Herpes zoster infection neurological | 1 | 1 |
| Herpes zoster meningitis | 1 | 1 |
| Hypercalcaemia | 1 | 2 |
| Hyperhidrosis | 2 | 2 |
| Hyperpyrexia | | 1 |
| Hypersensitivity | 2 | 6 |
| Hypersomnia | | 1 |
| Hypertension | 3 | 5 |
| Hypertensive crisis | 2 | 2 |
| Hypoaesthesia | | 1 |
| Hyponatraemia | 2 | 2 |
| Hyporesponsive to stimuli | 1 | 1 |
| Hypotension | 3 | 3 |
| Ileus paralytic | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Inappropriate schedule of product administration | 3 | 3 |
| Incorrect route of product administration | 2 | 4 |
| Infarction | 1 | 1 |
| Inflammatory marker increased | 1 | 1 |
| Influenza like illness | 2 | 3 |
| Intestinal ischaemia | 1 | 1 |
| Ischaemic cerebral infarction | 1 | 1 |
| Ischaemic stroke | | 1 |
| Jaw clicking | | 1 |
| Language disorder | 1 | 1 |
| Limb discomfort | | 1 |
| Lipase increased | 1 | 1 |
| Lip oedema | 1 | 1 |
| Liver function test increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 2 | 5 |
| | | | 1 | | |
| | | 1 | 1 | 2 | 4 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | | |
| | | 2 | 4 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Local reaction | 1 | 2 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | | 1 |
| Malaise | | 3 |
| Microcytic anaemia | 1 | 1 |
| Mobility decreased | 1 | 2 |
| Motor dysfunction | | 1 |
| Movement disorder | | 1 |
| Multimorbidity | | 1 |
| Multi-organ disorder | 1 | 1 |
| Multiple organ dysfunction syndrome | 2 | 3 |
| Muscle swelling | | 1 |
| Myalgia | 1 | 2 |
| Myocardial infarction | 2 | 3 |
| Myocarditis | 1 | 1 |
| Myocarditis infectious | 1 | 1 |
| Myoclonus | 1 | 1 |
| Nasal congestion | | 1 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 5 | 11 |
| Necrosis | 1 | 1 |
| Nephrotic syndrome | 1 | 1 |
| Nervous system disorder | 2 | 2 |
| Oedema | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Ophthalmic herpes zoster | 2 | 2 |
| Oxygen saturation decreased | 3 | 6 |
| Pain | 2 | 2 |
| Pain in extremity | 3 | 4 |
| Pancreatitis acute | 1 | 1 |
| Pathogen resistance | | 1 |
| Peripheral circulatory failure | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 6 | 2 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 3 | 6 |
| | | | | 2 | 2 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Peripheral swelling | 1 | 1 |
| Peripheral vascular disorder | 3 | 5 |
| Personality change | 2 | 3 |
| Petechiae | 1 | 1 |
| Pharyngeal inflammation | | 1 |
| Pharyngeal swelling | | 1 |
| Pleurisy | 1 | 1 |
| Pneumonia | 11 | 15 |
| Pneumonia aspiration | | 1 |
| Poor quality sleep | | 1 |
| Product administered at inappropriate site | | 1 |
| Product preparation issue | | 1 |
| Proteinuria | 1 | 1 |
| Pruritus | | 1 |
| Psoriasis | 1 | 1 |
| Psychomotor hyperactivity | 1 | 1 |
| Pulmonary embolism | 1 | 3 |
| Pulmonary oedema | 1 | 1 |
| Pulmonary sepsis | 1 | 1 |
| Pustule | 1 | 1 |
| Pyramidal tract syndrome | 1 | 1 |
| Pyrexia | 9 | 18 |
| Rales | 1 | 1 |
| Rash | 2 | 6 |
| Rash macular | | 1 |
| Rash maculo-papular | 2 | 2 |
| Rash pruritic | | 1 |
| Reaction to excipient | | 1 |
| Red blood cell count decreased | | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 |
| Renal failure | 4 | 6 |
| Respiratory distress | 5 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 3 | 5 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 11 | 15 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | 4 | 9 | 14 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 5 |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 4 | 6 |
| | | | | 5 | 7 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Respiratory failure | 5 | 7 |
| Respiratory tract infection | 2 | 3 |
| Restlessness | 1 | 1 |
| Rhinalgia | | 1 |
| Rhinorrhoea | | 1 |
| Rhonchi | | 1 |
| SARS-CoV-2 ant body test positive | | 1 |
| SARS-CoV-2 test positive | 6 | 8 |
| Seizure | 7 | 8 |
| Sepsis | 1 | 2 |
| Septic shock | 1 | 2 |
| Shock | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Sneezing | 1 | 2 |
| Soft tissue infection | 1 | 1 |
| Somnolence | 3 | 5 |
| Staphylococcal sepsis | | 1 |
| Status epilepticus | 1 | 1 |
| Stridor | | 1 |
| Stupor | 1 | 1 |
| Sudden cardiac death | | 1 |
| Sudden death | 13 | 17 |
| Sudden onset of sleep | 1 | 1 |
| Swollen tongue | 1 | 3 |
| Syncope | 4 | 5 |
| Systemic inflammatory response syndrome | 1 | 1 |
| Tachyarrhythmia | | 2 |
| Tachycardia | | 3 |
| Therapeutic response unexpected | 2 | 2 |
| Throat tightness | 1 | 2 |
| Toxicity to various agents | 1 | 1 |
| Transaminases increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 5 | 7 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | 4 | 4 | 2 | 4 |
| | | | | 7 | 8 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | 3 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 13 | 17 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | | 3 |
| | | 2 | 2 | | |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|---|-----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Transient ischaemic attack | | 1 | | | | | | | 1 |
| Unresponsive to stimuli | 2 | 3 | | | | | 2 | | 3 |
| Upper gastrointestinal haemorrhage | 2 | 2 | | | | | 2 | | 2 |
| Upper respiratory tract infection | 2 | 2 | | | | | 2 | | 2 |
| Urinary tract infection | 1 | 1 | | | | | 1 | | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | | | 1 | | 1 |
| Urticaria | 1 | 3 | | | | 1 | 1 | | 2 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 | | | |
| Vaccination site pain | 3 | 5 | | | 2 | 3 | 1 | | 2 |
| Vaccination site rash | | 1 | | | | 1 | | | |
| Vaccination site reaction | | 1 | | | | 1 | | | |
| Vaccination site swelling | 1 | 2 | | | 1 | 2 | | | |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 | | | |
| Vascular dementia | 1 | 1 | | | | | 1 | | 1 |
| Vascular encephalopathy | 1 | 1 | | | | | 1 | | 1 |
| Ventricular fibrillation | 1 | 3 | | | | | 1 | | 3 |
| Vision blurred | 1 | 1 | | | | | 1 | | 1 |
| Visual acuity reduced | 1 | 1 | | | | | 1 | | 1 |
| Vomiting | 13 | 18 | | | 4 | 5 | 9 | | 13 |
| White blood cell count increased | 1 | 1 | | | | | 1 | | 1 |
| Wound | 1 | 1 | | | 1 | 1 | | | |
| | 549 | 851 | 3 | 3 | 86 | 158 | 463 | | 693 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Abdominal pain lower | 1 | 2 | | 1 | 1 | 1 |
| Abdominal pain upper | | 1 | | 1 | | |
| Ageusia | 1 | 2 | 1 | 2 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | | 1 | | | | 1 |
| Anosmia | | 1 | | 1 | | |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arthralgia | 9 | 10 | 9 | 10 | | |
| Asthenia | 11 | 14 | 11 | 14 | | |
| Asthenopia | | 1 | | 1 | | |
| Axillary pain | 3 | 3 | 3 | 3 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood glucose fluctuation | | 1 | | 1 | | |
| Blood pressure decreased | | 1 | | | | 1 |
| Body temperature increased | 12 | 12 | 12 | 12 | | |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Burning sensation | 1 | 2 | 1 | 2 | | |
| Cardiovascular disorder | 8 | 10 | 8 | 10 | | |
| Cardiovascular insufficiency | 1 | 1 | | | 1 | 1 |
| Cellulitis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | | 1 | | 1 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 38 | 45 | 37 | 44 | 1 | 1 |
| Circulatory collapse | | 1 | | | | 1 |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Condition aggravated | 1 | 1 | 1 | 1 | | |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Contusion | 2 | 2 | 1 | 1 | 1 | 1 |
| Coronavirus infection | 1 | 2 | 1 | 1 | | 1 |
| Coronavirus test positive | 1 | 1 | 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Cough | 1 | 2 |
| COVID-19 | 85 | 130 |
| Cranial nerve disorder | | 1 |
| Death | 8 | 11 |
| Decreased appetite | 1 | 1 |
| Dehydration | 1 | 1 |
| Diarrhoea | 5 | 7 |
| Disease recurrence | 2 | 2 |
| Disturbance in attention | 3 | 5 |
| Dizziness | 13 | 24 |
| Drug ineffective | 88 | 153 |
| Dysgeusia | 2 | 2 |
| Dyspnoea | 5 | 7 |
| Ear pain | 2 | 4 |
| Eczema | | 1 |
| Erythema | 4 | 6 |
| Escherichia infection | 1 | 1 |
| Exposure during pregnancy | | 1 |
| Eye haemorrhage | 1 | 1 |
| Eye pain | | 1 |
| Eye swelling | 1 | 1 |
| Facial pain | | 1 |
| Facial paresis | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 55 | 91 |
| Feeling abnormal | 3 | 3 |
| Feeling cold | 5 | 7 |
| Feeling hot | 4 | 5 |
| Feeling of body temperature change | 1 | 2 |
| Femoral artery embolism | 1 | 1 |
| Flushing | 1 | 1 |
| Gait disturbance | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | |
| 3 | 3 | 82 | 127 |
| | 1 | | |
| | | 8 | 11 |
| 1 | 1 | | |
| 1 | 1 | | |
| 5 | 7 | | |
| 2 | 2 | | |
| 3 | 5 | | |
| 12 | 23 | 1 | 1 |
| 1 | 1 | 87 | 152 |
| 2 | 2 | | |
| 4 | 5 | 1 | 2 |
| 2 | 4 | | |
| | 1 | | |
| 4 | 6 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 54 | 90 | 1 | 1 |
| 3 | 3 | | |
| 5 | 7 | | |
| 4 | 5 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Headache | 71 | 104 |
| Head discomfort | 1 | 2 |
| Hepatitis cholestatic | 1 | 1 |
| Herpes zoster | 3 | 3 |
| Herpes zoster oticus | 1 | 1 |
| Herpes zoster reactivation | 1 | 1 |
| Hot flush | 3 | 3 |
| Hyperaesthesia | | 1 |
| Hyperhidrosis | 4 | 4 |
| Hypersensitivity | 3 | 6 |
| Hypersomnia | 1 | 1 |
| Hypertension | 1 | 2 |
| Hypoaesthesia | 5 | 6 |
| Hypoaesthesia oral | 1 | 1 |
| Illness | | 1 |
| Inappropriate schedule of product administration | 3 | 6 |
| Incorrect route of product administration | 1 | 2 |
| Increased upper airway secretion | | 1 |
| Influenza like illness | 2 | 4 |
| Initial insomnia | 2 | 2 |
| Insomnia | 3 | 3 |
| Limb discomfort | 5 | 6 |
| Liver function test increased | 1 | 1 |
| Localised infection | 1 | 1 |
| Local reaction | 1 | 1 |
| Lymphadenopathy | 11 | 17 |
| Lymph node pain | 5 | 6 |
| Malaise | 8 | 12 |
| Maternal exposure during pregnancy | 7 | 18 |
| Menorrhagia | 1 | 1 |
| Menstrual disorder | 5 | 5 |
| Middle insomnia | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 71 | 104 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| | 1 | | |
| 4 | 4 | | |
| 3 | 6 | | |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 5 | 6 | | |
| 1 | 1 | | |
| | 1 | | |
| 3 | 6 | | |
| 1 | 2 | | |
| | 1 | | |
| 2 | 4 | | |
| 2 | 2 | | |
| 3 | 3 | | |
| 5 | 6 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 11 | 17 | | |
| 5 | 6 | | |
| 8 | 12 | | |
| 7 | 18 | | |
| 1 | 1 | | |
| 5 | 5 | | |
| 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Mobility decreased | 2 | 3 |
| Movement disorder | 1 | 1 |
| Muscle spasms | 2 | 2 |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 2 | 3 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 29 | 49 |
| Myoclonus | 1 | 1 |
| Nasopharyngitis | 4 | 5 |
| Nausea | 18 | 28 |
| Neck pain | 2 | 3 |
| Neuralgia | 3 | 3 |
| Neurodermatitis | 1 | 1 |
| Night sweats | 2 | 2 |
| No adverse event | 2 | 3 |
| Occupational exposure to product | | 1 |
| Off label use | 4 | 8 |
| Oral discomfort | 1 | 1 |
| Oropharyngeal pain | 4 | 8 |
| Pain | 5 | 8 |
| Pain in extremity | 54 | 72 |
| Pain in jaw | 2 | 2 |
| Pain of skin | 1 | 1 |
| Palpitations | 3 | 3 |
| Paraesthesia | 8 | 9 |
| Paraesthesia oral | 1 | 1 |
| Peripheral embolism | | 1 |
| Peripheral swelling | 2 | 4 |
| Platelet count decreased | 1 | 1 |
| Pneumonia | 1 | 1 |
| Poor quality product administered | 4 | 5 |
| Poor quality sleep | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 1 | | |
| 29 | 49 | | |
| 1 | 1 | | |
| 4 | 5 | | |
| 18 | 28 | | |
| 2 | 3 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 2 | 3 | | |
| | 1 | | |
| 4 | 8 | | |
| 1 | 1 | | |
| 4 | 8 | | |
| 5 | 8 | | |
| 54 | 72 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| 8 | 9 | | |
| 1 | 1 | | |
| | 1 | | |
| 2 | 4 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | | |
| 2 | 2 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Presyncope | 2 | 2 |
| Product complaint | 1 | 1 |
| Product leakage | | 1 |
| Product preparation error | | 2 |
| Product preparation issue | 8 | 8 |
| Product storage error | 1 | 1 |
| Product temperature excursion issue | 3 | 3 |
| Product use issue | 4 | 9 |
| Pruritus | 2 | 3 |
| Pustule | 2 | 2 |
| Pyrexia | 45 | 54 |
| Rash | 4 | 8 |
| Rash erythematous | 1 | 1 |
| Rash macular | 1 | 2 |
| Respiratory distress | 1 | 1 |
| Rhinitis allergic | 1 | 1 |
| Rhinorrhoea | 3 | 6 |
| SARS-CoV-2 ant body test negative | 9 | 9 |
| SARS-CoV-2 ant body test positive | 4 | 7 |
| SARS-CoV-2 test false positive | 1 | 4 |
| SARS-CoV-2 test positive | 9 | 35 |
| Sensation of foreign body | | 1 |
| Sensitive skin | 1 | 1 |
| Sinus congestion | 2 | 2 |
| Skin burning sensation | 2 | 2 |
| Sleep disorder | 1 | 2 |
| Somnolence | | 1 |
| Sudden hearing loss | | 1 |
| Suspected COVID-19 | | 4 |
| Swelling of eyelid | 1 | 1 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 4 | 4 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | |
| 8 | 8 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| 4 | 9 | | |
| 2 | 2 | | 1 |
| 1 | 1 | 1 | 1 |
| 45 | 54 | | |
| 3 | 7 | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 6 | | |
| 9 | 9 | | |
| 4 | 7 | | |
| 1 | 4 | | |
| 4 | 10 | 5 | 25 |
| | | | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 2 | | |
| | 1 | | |
| | | | 1 |
| | | | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Temporomandibular joint syndrome | 1 | 1 | 1 | 1 | | |
| Tenosynovitis | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | 2 | 2 | 2 | 2 | | |
| Throat irritation | 1 | 3 | 1 | 3 | | |
| Tinnitus | 2 | 2 | 2 | 2 | | |
| Tongue discomfort | 1 | 2 | 1 | 2 | | |
| Underdose | 9 | 18 | 9 | 18 | | |
| Urticaria | 2 | 2 | 2 | 2 | | |
| Vaccination site bruising | 1 | 3 | 1 | 3 | | |
| Vaccination site discomfort | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 4 | 5 | 4 | 5 | | |
| Vaccination site haematoma | 2 | 3 | 1 | 2 | 1 | 1 |
| Vaccination site haemorrhage | 2 | 2 | 2 | 2 | | |
| Vaccination site hyperaesthesia | 1 | 2 | 1 | 2 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 1 | 4 | 1 | 4 | | |
| Vaccination site pain | 85 | 161 | 85 | 161 | | |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 5 | 8 | 5 | 8 | | |
| Vaccination site warmth | 4 | 4 | 4 | 4 | | |
| Vertigo | | 1 | | 1 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Visual impairment | 2 | 2 | 2 | 2 | | |
| Vomiting | 4 | 7 | 4 | 7 | | |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 964 | 1,481 | 749 | 1121 | 215 | 360 |

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* I=Interval, C=Cumulative
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Country Where Event Occurred

GIBRALTAR

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Death | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

GREECE

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Fall | 1 | 1 | 1 | 1 |
| Skin lesion | 1 | 1 | 1 | 1 |
| Syncope | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 4 | 4 | | | 4 | 4 |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | 1 | 1 | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 3 | 3 | 1 | 1 | 2 | 2 |
| C-reactive protein increased | 2 | 2 | 2 | 2 | | |
| Diabetes mellitus inadequate control | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 3 | 3 | 3 | 3 | | |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Erythema | 3 | 3 | 2 | 2 | 1 | 1 |
| Fatigue | 4 | 5 | 1 | 2 | 3 | 3 |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Headache | 3 | 3 | 3 | 3 | | |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Insulin resistance | 1 | 1 | | | 1 | 1 |
| Laryngospasm | 1 | 1 | | | 1 | 1 |
| Livedo reticularis | 1 | 1 | 1 | 1 | | |
| Lymphadenitis | 4 | 4 | 2 | 2 | 2 | 2 |
| Lymphadenopathy | 3 | 3 | 2 | 2 | 1 | 1 |
| Lymph node pain | 1 | 1 | | | 1 | 1 |
| Lymphopenia | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 6 | 1 | 1 | 5 | 5 |
| Nausea | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oedema peripheral | 1 | 1 | 1 | 1 | | |
| Oral herpes | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain in extremity | 2 | 3 | 2 | 3 | | |
| Palpitations | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 5 | 6 | 1 | 2 | 4 | 4 |
| Rash | 6 | 7 | 3 | 4 | 3 | 3 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Tachycardia | 1 | 2 | | 1 | 1 | 1 |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Throat irritation | | 1 | | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 87 | 93 | 42 | 48 | 45 | 45 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Abdominal pain upper | 3 | 4 | 3 | 4 | | |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | 1 | 2 | 1 | 1 | | 1 |
| Anaphylactic reaction | 3 | 5 | | | 3 | 5 |
| Angioedema | 3 | 5 | | | 3 | 5 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 4 | 4 | | | 4 | 4 |
| Arthralgia | 24 | 25 | 10 | 11 | 14 | 14 |
| Aspartate aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Asthenia | 6 | 6 | 4 | 4 | 2 | 2 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | | 1 | | | | 1 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Blepharospasm | 1 | 1 | 1 | 1 | | |
| Blister | 2 | 2 | 2 | 2 | | |
| Blood pressure decreased | 2 | 4 | | 2 | 2 | 2 |
| Blood pressure diastolic increased | | 1 | | 1 | | |
| Blood pressure increased | 11 | 11 | 8 | 8 | 3 | 3 |
| Body dysmorphic disorder | 1 | 1 | | | 1 | 1 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 3 | 5 | | | 3 | 5 |
| Burning sensation | 4 | 6 | 3 | 5 | 1 | 1 |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Cachexia | 2 | 2 | | | 2 | 2 |
| Capillary disorder | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 3 | 3 | 1 | 1 | 2 | 2 |
| Chest pain | 2 | 4 | 1 | 2 | 1 | 2 |
| Chills | 26 | 29 | 10 | 12 | 16 | 17 |
| Cholinergic syndrome | 3 | 3 | | | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Complex regional pain syndrome | 1 | 1 |
| Confusional state | 2 | 2 |
| Cough | 6 | 9 |
| COVID-19 | 6 | 6 |
| Cyanosis | | 1 |
| Decreased appetite | 1 | 1 |
| Defaecation urgency | | 1 |
| Diarrhoea | 5 | 7 |
| Diastolic hypertension | | 1 |
| Discomfort | 1 | 2 |
| Dizziness | 18 | 25 |
| Drowning | 1 | 1 |
| Drug ineffective | 7 | 7 |
| Drug interaction | | 1 |
| Dry mouth | 2 | 4 |
| Dry throat | 1 | 3 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 2 | 6 |
| Dyskinesia | 1 | 1 |
| Dysphagia | 2 | 6 |
| Dysphonia | 4 | 7 |
| Dyspnoea | 5 | 7 |
| Ear pain | 2 | 2 |
| Eructation | 2 | 2 |
| Erythema | 21 | 22 |
| Extrasystoles | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eyelid ptosis | 1 | 1 |
| Eye oedema | | 1 |
| Eye pruritus | | 1 |
| Face oedema | 1 | 1 |
| Facial paresis | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | 4 | 7 |
| | | 6 | 6 |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 3 | 4 | 2 | 3 |
| | | | 1 |
| | 1 | 1 | 1 |
| 11 | 16 | 7 | 9 |
| | | 1 | 1 |
| | | 7 | 7 |
| | | | 1 |
| 1 | 3 | 1 | 1 |
| | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 3 | 1 | 3 |
| | | 1 | 1 |
| | 1 | 2 | 5 |
| 1 | 1 | 3 | 6 |
| 3 | 3 | 2 | 4 |
| 2 | 2 | | |
| 2 | 2 | | |
| 16 | 16 | 5 | 6 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Fatigue | 20 | 23 |
| Feeling abnormal | 1 | 1 |
| Feeling hot | | 1 |
| Flatulence | 1 | 2 |
| Flushing | 14 | 17 |
| Gait disturbance | 1 | 2 |
| Gamma-glutamyltransferase increased | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| Gastrointestinal disorder | 5 | 5 |
| Gastrointestinal hypermotility | | 1 |
| Guillain-Barre syndrome | 2 | 2 |
| Headache | 40 | 46 |
| Heart rate increased | 11 | 11 |
| Herpes zoster | 1 | 1 |
| Hyperhidrosis | 6 | 8 |
| Hypersensitivity | 10 | 14 |
| Hypertension | 8 | 11 |
| Hypertensive crisis | 3 | 3 |
| Hypertensive emergency | | 1 |
| Hypoaesthesia | 23 | 27 |
| Hypoaesthesia oral | 4 | 8 |
| Hypotension | 5 | 5 |
| Illness | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Inflammation | 1 | 1 |
| Joint range of motion decreased | | 1 |
| Laryngeal oedema | | 1 |
| Laryngeal pain | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Lethargy | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Lip oedema | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 8 | 10 | 12 | 13 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 2 |
| 9 | 10 | 5 | 7 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 5 | 5 | | |
| | | | 1 |
| | | 2 | 2 |
| 23 | 28 | 17 | 18 |
| 9 | 9 | 2 | 2 |
| 1 | 1 | | |
| 5 | 7 | 1 | 1 |
| 2 | 4 | 8 | 10 |
| 3 | 5 | 5 | 6 |
| | | 3 | 3 |
| | | | 1 |
| 14 | 17 | 9 | 10 |
| 1 | 2 | 3 | 6 |
| 2 | 2 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Lip swelling | 1 | 1 |
| Localised oedema | 3 | 3 |
| Local reaction | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenitis | 4 | 4 |
| Lymphadenopathy | 7 | 7 |
| Lymph node pain | 1 | 1 |
| Malaise | 7 | 7 |
| Mechanical urticaria | 1 | 1 |
| Meningism | 1 | 1 |
| Middle insomnia | 1 | 1 |
| Migraine | 1 | 1 |
| Mucosal dryness | | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle spasms | 3 | 3 |
| Muscle tightness | 1 | 1 |
| Muscular weakness | | 1 |
| Musculoskeletal discomfort | 1 | 1 |
| Myalgia | 31 | 33 |
| Myelitis | 1 | 1 |
| Nasal pruritus | | 1 |
| Nausea | 15 | 19 |
| Neck pain | 1 | 1 |
| Oedema | 1 | 1 |
| Off label use | 1 | 1 |
| Oral herpes | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 9 | 10 |
| Pain in extremity | 7 | 10 |
| Pallor | 1 | 1 |
| Palpitations | 9 | 10 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 4 | 4 |
| 1 | 1 | 6 | 6 |
| 1 | 1 | | |
| 2 | 2 | 5 | 5 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 16 | 17 | 15 | 16 |
| | | 1 | 1 |
| | 1 | | |
| 12 | 15 | 3 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 8 | 8 |
| 5 | 8 | 2 | 2 |
| 1 | 1 | | |
| 7 | 8 | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------|------------------------------------|--------------------------------------|
| Pancreatitis | 1 | 1 |
| Panic reaction | 1 | 1 |
| Paralysis | 1 | 1 |
| Peripheral coldness | 1 | 1 |
| Polyneuropathy | 1 | 1 |
| Poor quality sleep | | 1 |
| Post herpetic neuralgia | 1 | 1 |
| Presyncope | 6 | 9 |
| Product use issue | 1 | 1 |
| Pruritus | 22 | 23 |
| Pyrexia | 41 | 45 |
| Rash | 17 | 22 |
| Rash erythematous | 2 | 2 |
| Rash macular | 1 | 1 |
| Rash pruritic | 6 | 6 |
| Seizure | | 1 |
| Shock | 1 | 1 |
| Skin burning sensation | | 1 |
| Skin reaction | 1 | 1 |
| Somnolence | 4 | 5 |
| Spinal pain | 2 | 2 |
| Swelling | 1 | 1 |
| Swelling face | 1 | 1 |
| Syncope | 3 | 3 |
| Tachycardia | 17 | 22 |
| Throat irritation | 4 | 5 |
| Tinnitus | 3 | 3 |
| Tongue discomfort | 1 | 1 |
| Tongue oedema | 1 | 1 |
| Tremor | 5 | 7 |
| Trigeminal neuralgia | 1 | 1 |
| Urticaria | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 3 | 4 | 3 | 5 |
| 1 | 1 | | |
| 15 | 15 | 7 | 8 |
| 19 | 22 | 22 | 23 |
| 7 | 10 | 10 | 12 |
| 2 | 2 | | |
| 1 | 1 | | |
| 3 | 3 | 3 | 3 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 2 | 3 | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| 8 | 10 | 9 | 12 |
| 2 | 3 | 2 | 2 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 1 | 3 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site hyperaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 2 | 2 | 2 | 2 | | |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 3 | 3 | 3 | 3 | | |
| Vaccination site pain | 22 | 28 | 17 | 23 | 5 | 5 |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vertigo | 4 | 4 | 4 | 4 | | |
| Viral infection | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 4 | 6 | 2 | 4 | 2 | 2 |
| | 688 | 828 | 344 | 422 | 344 | 406 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 4 | 4 | 2 | 2 | 2 | 2 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Acute respiratory distress syndrome | | 1 | | | | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 2 | 5 | | | 2 | 5 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 4 | 4 | | | 4 | 4 |
| Anxiety | | 1 | | 1 | | |
| Arthralgia | 11 | 11 | 4 | 4 | 7 | 7 |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Arthritis enteropathic | 1 | 1 | | | 1 | 1 |
| Asthenia | 6 | 8 | 2 | 4 | 4 | 4 |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blister | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure diastolic increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 6 | 6 | 4 | 4 | 2 | 2 |
| Blood pressure systolic increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Burning sensation | 4 | 4 | 3 | 3 | 1 | 1 |
| Cardiac arrest | | 1 | | | | 1 |
| Cardiac discomfort | 1 | 1 | | | 1 | 1 |
| Cardiac valve disease | | 1 | | | | 1 |
| Chest pain | 3 | 4 | 1 | 1 | 2 | 3 |
| Chills | 11 | 12 | 1 | 2 | 10 | 10 |
| Complex regional pain syndrome | 1 | 1 | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Condition aggravated | 1 | 2 |
| Confusional state | 2 | 2 |
| Cough | 4 | 4 |
| COVID-19 | 2 | 2 |
| Deafness | 1 | 1 |
| Diarrhoea | 6 | 6 |
| Dizziness | 10 | 13 |
| Drug ineffective | 1 | 1 |
| Dry mouth | 1 | 1 |
| Dry throat | 1 | 1 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 1 | 1 |
| Dyspepsia | 2 | 2 |
| Dysphagia | 4 | 4 |
| Dysphonia | 3 | 3 |
| Dyspnoea | 6 | 7 |
| Enlarged uvula | 1 | 1 |
| Eructation | 1 | 1 |
| Erythema | 12 | 13 |
| Extrasystoles | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eyelids pruritus | 1 | 1 |
| Eye pruritus | 1 | 1 |
| Face oedema | 1 | 1 |
| Fall | | 1 |
| Fatigue | 17 | 19 |
| Feeling cold | 1 | 2 |
| Feeling hot | 1 | 1 |
| Gait disturbance | | 1 |
| Gastrointestinal disorder | 1 | 1 |
| Headache | 16 | 19 |
| Head discomfort | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| | | 2 | 2 |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| 3 | 3 | 3 | 3 |
| 6 | 8 | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 3 | 3 |
| 2 | 2 | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 8 | 5 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 6 | 7 | 11 | 12 |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 7 | 10 | 9 | 9 |
| 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Heart rate increased | 5 | 5 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 7 | 8 |
| Hypersensitivity | 4 | 4 |
| Hypertension | 8 | 8 |
| Hypertensive crisis | 2 | 3 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 8 | 9 |
| Hypoaesthesia oral | 6 | 6 |
| Hypotension | 2 | 2 |
| Hypothermia | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Inflammation | 1 | 1 |
| Insomnia | 1 | 1 |
| Irritability | 1 | 1 |
| Laryngeal oedema | 3 | 3 |
| Laryngospasm | 2 | 2 |
| Leukocytosis | | 1 |
| Lip oedema | 2 | 2 |
| Lip swelling | 1 | 1 |
| Loss of consciousness | | 1 |
| Lymphadenitis | 3 | 3 |
| Lymphadenopathy | 2 | 2 |
| Lymph node pain | 1 | 1 |
| Lymphoedema | 1 | 1 |
| Malaise | 2 | 3 |
| Muscular weakness | 1 | 1 |
| Myalgia | 24 | 25 |
| Nasal congestion | | 1 |
| Nausea | 6 | 7 |
| Neck pain | 1 | 1 |
| Nervousness | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | 2 | 2 |
| | | 1 | 1 |
| | | 7 | 8 |
| 3 | 3 | 1 | 1 |
| 5 | 5 | 3 | 3 |
| | | 2 | 3 |
| | | 1 | 1 |
| 5 | 6 | 3 | 3 |
| 4 | 4 | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 2 | 2 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | 2 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| 14 | 15 | 10 | 10 |
| | 1 | | |
| 3 | 3 | 3 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Ocular hyperaemia | 1 | 1 |
| Oedema | 2 | 2 |
| Off label use | 1 | 1 |
| Oral herpes | | 1 |
| Oropharyngeal pain | 1 | 1 |
| Orthostatic hypotension | | 1 |
| Pain | 3 | 3 |
| Pain in extremity | 2 | 2 |
| Pain in jaw | 1 | 1 |
| Palpitations | 6 | 6 |
| Pneumonia | | 1 |
| Presyncope | 1 | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 9 | 10 |
| Pulmonary embolism | 1 | 1 |
| Pyrexia | 21 | 26 |
| Rash | 9 | 10 |
| Rash maculo-papular | 3 | 3 |
| Rash pruritic | 2 | 2 |
| Respiratory tract infection | | 1 |
| Rheumatoid arthritis | 1 | 2 |
| Rhinitis allergic | | 1 |
| Rhinorrhoea | | 1 |
| SARS-CoV-2 test positive | 1 | 1 |
| Somnolence | 5 | 5 |
| Stress | 1 | 1 |
| Swelling face | 1 | 1 |
| Syncope | 1 | 1 |
| Tachycardia | 5 | 6 |
| Taste disorder | 2 | 2 |
| Temporomandibular joint syndrome | 1 | 1 |
| Tension | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 3 | 3 |
| 2 | 2 | | |
| 1 | 1 | | |
| 3 | 3 | 3 | 3 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 6 | 4 | 4 |
| | | 1 | 1 |
| 11 | 15 | 10 | 11 |
| 6 | 7 | 3 | 3 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| | | 1 | 2 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 2 | 3 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Throat irritation | | 1 | | 1 | | |
| Tinnitus | 1 | 1 | | | 1 | 1 |
| Tongue ulceration | | 1 | | 1 | | |
| Tonsillar hypertrophy | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 3 | 1 | 1 | 2 | 2 |
| Trismus | 1 | 1 | 1 | 1 | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site irritation | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | | 1 | | 1 | | |
| Vaccination site pain | 13 | 19 | 10 | 16 | 3 | 3 |
| Vaccination site pruritus | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 2 | 2 | | | 2 | 2 |
| | 383 | 442 | 170 | 206 | 213 | 236 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Fatigue | | 1 | | 1 | | |
| Headache | | 1 | | 1 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypotension | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| | 17 | 19 | 4 | 6 | 13 | 13 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Acute respiratory failure | | 1 | | | | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 3 | 1 | 1 | 2 | 2 |
| Asthenia | 3 | 3 | 2 | 2 | 1 | 1 |
| Auscultation | | 1 | | 1 | | |
| Blood glucose abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure inadequately controlled | | 1 | | 1 | | |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | | 2 | | | | 2 |
| Central nervous system stimulation | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | 2 | 2 | 2 | 2 |
| Complex regional pain syndrome | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| Death | 2 | 2 | | | 2 | 2 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | | | 2 | 2 |
| Dysphoria | | 1 | | | | 1 |
| Dyspnoea | 3 | 5 | | 1 | 3 | 4 |
| Erythema | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # | Cumulative Total # |
|-----------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Facial paralysis | 1 | 1 |
| Fatigue | 3 | 3 |
| Gastrointestinal disorder | 1 | 1 |
| Headache | 1 | 1 |
| Hemiparesis | 1 | 1 |
| Herpes dermatitis | 1 | 1 |
| Hypersensitivity | 1 | 1 |
| Hypertensive crisis | 1 | 1 |
| Hypoaesthesia | 3 | 3 |
| Hypoaesthesia oral | 1 | 1 |
| Lethargy | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Malaise | 3 | 3 |
| Migraine | 1 | 1 |
| Myalgia | 2 | 2 |
| Myocardial infarction | | 1 |
| Nasopharyngitis | 1 | 1 |
| Nausea | | 1 |
| Off label use | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Orthostatic hypotension | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Polydipsia | 1 | 1 |
| Polyuria | 1 | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 3 | 3 |
| Pyrexia | 3 | 3 |
| Rash | 2 | 2 |
| Somnolence | 1 | 1 |
| Sudden death | 1 | 3 |
| Suspected COVID-19 | 1 | 1 |
| Syncope | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachypnoea | | 1 | | 1 | | |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Viral infection | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 2 | | 1 | 1 | 1 |
| Wheezing | 1 | 1 | 1 | 1 | | |
| | 88 | 103 | 34 | 41 | 54 | 62 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Antibody test abnormal | 1 | 2 | 1 | 2 | | |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 3 | 1 | 3 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blister | | 1 | | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 4 | 2 | 3 | | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chills | 4 | 5 | 2 | 3 | 2 | 2 |
| Circumstance or information capable of leading to medication error | 2 | 2 | 2 | 2 | | |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Cough | 4 | 4 | 4 | 4 | | |
| COVID-19 | 4 | 5 | 1 | 1 | 3 | 4 |
| Cyanosis | 1 | 1 | 1 | 1 | | |
| Deafness unilateral | | 1 | | | | 1 |
| Diarrhoea | 1 | 2 | | 1 | 1 | 1 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dizziness | 9 | 9 | 7 | 7 | 2 | 2 |
| Drug ineffective | 3 | 4 | | | 3 | 4 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 2 | 3 | | 1 | 2 | 2 |
| Dyskinesia | 2 | 2 | 2 | 2 | | |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Dysphonia | 2 | 2 | | | 2 | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Dyspnoea | 3 | 4 |
| Erythema | 4 | 4 |
| Eye irritation | | 1 |
| Eyelid ptosis | | 1 |
| Fatigue | 4 | 7 |
| Fibrin D dimer increased | 1 | 1 |
| Flushing | 2 | 2 |
| Gastrointestinal disorder | | 2 |
| Headache | 3 | 5 |
| Heart rate increased | 1 | 1 |
| Hemiparesis | 1 | 1 |
| Hypersensitivity | 3 | 8 |
| Hypertension | | 2 |
| Hypoaesthesia | 6 | 7 |
| Hypoaesthesia oral | 4 | 7 |
| Hypotension | 3 | 4 |
| Incomplete course of vaccination | | 1 |
| Incorrect route of product administration | 1 | 1 |
| Injury | | 1 |
| Lethargy | 1 | 1 |
| Limb discomfort | | 1 |
| Liquid product physical issue | 1 | 4 |
| Local reaction | | 1 |
| Lymphadenopathy | 1 | 2 |
| Lymph node pain | | 1 |
| Malaise | 2 | 2 |
| Maternal exposure during pregnancy | | 1 |
| Migraine | | 1 |
| Muscle spasms | | 1 |
| Myalgia | 3 | 3 |
| Nausea | 1 | 1 |
| No adverse event | 5 | 7 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | 2 | 2 |
| 4 | 4 | | |
| | 1 | | |
| | | | 1 |
| 4 | 7 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| | 2 | | |
| 2 | 4 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 6 | 1 | 2 |
| | 2 | | |
| 6 | 7 | | |
| 1 | 4 | 3 | 3 |
| | 1 | 3 | 3 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | 1 | 1 |
| | 1 | | |
| 1 | 4 | | |
| | 1 | | |
| | 1 | 1 | 1 |
| | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 5 | 7 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oedema | 1 | 1 | 1 | 1 | | |
| Off label use | | 1 | | 1 | | |
| Oral discomfort | | 1 | | 1 | | |
| Oropharyngeal discomfort | 2 | 2 | 2 | 2 | | |
| Oxygen saturation decreased | 1 | 1 | 1 | 1 | | |
| Pain | 9 | 9 | 9 | 9 | | |
| Pain in extremity | 1 | 3 | 1 | 3 | | |
| Palpitations | | 1 | | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Periorbital oedema | 1 | 2 | 1 | 2 | | |
| Pollakiuria | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | 1 | 4 | 1 | 4 | | |
| Pruritus | 5 | 5 | 4 | 4 | 1 | 1 |
| Pulmonary thrombosis | 1 | 2 | | | 1 | 2 |
| Pyrexia | 7 | 9 | 5 | 7 | 2 | 2 |
| Rash | 6 | 7 | 1 | 2 | 5 | 5 |
| Rash macular | | 1 | | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| Reaction to excipient | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 2 | 1 | 2 | | |
| Tachycardia | 6 | 9 | 3 | 6 | 3 | 3 |
| Therapeutic response unexpected | | 1 | | 1 | | |
| Throat irritation | 1 | 1 | 1 | 1 | | |
| Tinnitus | | 2 | | 2 | | |
| Tremor | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site pain | 8 | 12 | 8 | 12 | | |
| Vaccination site warmth | | 1 | | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 1 | 2 | | 1 | 1 | 1 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 162 | 241 | 112 | 183 | 50 | 58 |

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Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenia | 1 | 1 | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 |
| Oedema peripheral | 2 | 2 | 2 | 2 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| Periorbital oedema | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 8 | 8 | 8 | 8 |

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Country Where Event Occurred

HUNGARY

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Exposure via breast milk | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | | 1 | | 1 | | |
| Back pain | | 1 | | 1 | | |
| Chest pain | 1 | 3 | 1 | 3 | | |
| Confusional state | | 1 | | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 4 | 1 | 4 | | |
| Drug hypersensitivity | 1 | 1 | 1 | 1 | | |
| Ear discomfort | | 1 | | 1 | | |
| Ear pain | | 1 | | 1 | | |
| Ear pruritus | | 1 | | 1 | | |
| Erythema | | 1 | | 1 | | |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Feeling hot | | 1 | | 1 | | |
| Headache | | 3 | | 2 | | 1 |
| Hypoaesthesia | 1 | 2 | 1 | 2 | | |
| Hypoaesthesia oral | | 1 | | 1 | | |
| Hypoglycaemia | | 1 | | 1 | | |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 2 | 3 | 2 | 2 | | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | | 2 | | 1 | | 1 |
| Migraine | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 3 | 2 | 3 | | |
| Nausea | 1 | 2 | 1 | 2 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 1 | 4 | 1 | 4 | | |
| Palpitations | | 1 | | 1 | | |
| Panic attack | | 1 | | 1 | | |
| Peripheral nerve paresis | 1 | 1 | | | 1 | 1 |
| Polyarthritits | 1 | 1 | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pulpitis dental | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 4 | 2 | 3 | | 1 |
| Rash | | 1 | | 1 | | |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Retching | 1 | 1 | 1 | 1 | | |
| Skin burning sensation | 1 | 1 | 1 | 1 | | |
| Tremor | | 1 | | 1 | | |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site erythema | | 2 | | 2 | | |
| Vaccination site hypoaesthesia | | 1 | | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vaginal discharge | | 1 | | 1 | | |
| Vision blurred | | 1 | | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 28 | 72 | 25 | 65 | 3 | 7 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Ageusia | | 2 | | 2 | | |
| Allergy to vaccine | | 1 | | | | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Anosmia | 2 | 3 | 2 | 3 | | |
| Arthralgia | 3 | 4 | 3 | 4 | | |
| Asthenia | 11 | 17 | 10 | 15 | 1 | 2 |
| Axillary pain | | 1 | | 1 | | |
| Back pain | 1 | 2 | 1 | 2 | | |
| Blister | | 1 | | 1 | | |
| Blood glucose increased | | 1 | | 1 | | |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | | 2 | | 1 | | 1 |
| Body temperature increased | | 1 | | 1 | | |
| Burning sensation | 2 | 2 | 2 | 2 | | |
| Chest pain | 2 | 2 | 2 | 2 | | |
| Chills | 8 | 12 | 8 | 12 | | |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 1 | | | | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Depression | | 1 | | 1 | | |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Dizziness | 5 | 9 | 4 | 7 | 1 | 2 |
| Drug hypersensitivity | 1 | 1 | 1 | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Dry mouth | | 1 | | | | 1 |
| Dysgeusia | 2 | 2 | 2 | 2 | | |
| Dysphagia | 4 | 4 | 1 | 1 | 3 | 3 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Ear pruritus | | 1 | | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | 1 | 1 | | |
| Fatigue | 6 | 9 | 6 | 9 | | |
| Feeling abnormal | 2 | 3 | 2 | 3 | | |
| Feeling hot | | 2 | | 1 | | 1 |
| Flushing | 1 | 1 | 1 | 1 | | |
| Gait disturbance | | 1 | | 1 | | |
| Haemorrhage | | 1 | | | | 1 |
| Headache | 11 | 18 | 11 | 17 | | 1 |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | | 2 | | 2 | | |
| Herpes virus infection | | 1 | | 1 | | |
| Hyperaesthesia | | 2 | | 2 | | |
| Hyperhidrosis | 1 | 2 | 1 | 2 | | |
| Hypersensitivity | | 1 | | 1 | | |
| Hypoaesthesia | | 2 | | 2 | | |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Incorrect route of product administration | | 1 | | 1 | | |
| Injection site discomfort | 1 | 1 | 1 | 1 | | |
| Lacrimation increased | | 1 | | 1 | | |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 9 | 11 | 6 | 8 | 3 | 3 |
| Lymph node pain | 1 | 2 | | 1 | 1 | 1 |
| Malaise | 4 | 8 | 4 | 8 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Micturition urgency | | 1 | | 1 | | |
| Mobility decreased | | 1 | | 1 | | |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | 6 | 10 | 6 | 10 | | |
| Nausea | 5 | 7 | 5 | 6 | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 6 | 9 | | |
| 2 | 3 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| 11 | 17 | | 1 |
| 1 | 1 | | |
| | 2 | | |
| | 1 | | |
| | 2 | | |
| 1 | 2 | | |
| | 1 | | |
| | 2 | | |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | | |
| | | | |
| | | | |
| 1 | 1 | | |
| 6 | 8 | 3 | 3 |
| | 1 | 1 | 1 |
| 4 | 8 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 6 | 10 | | |
| 5 | 6 | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # | Cumulative Total # | Spontaneous | | | |
|--------------------------------------|------------------|--------------------|-------------|----|---------|---|
| | Spontaneous AE | Spontaneous AE | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nipple pain | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| Oxygen saturation decreased | | 1 | | 1 | | |
| Pain | | 1 | | 1 | | |
| Pain in extremity | 7 | 13 | 7 | 13 | | |
| Pallor | | 1 | | 1 | | |
| Palpitations | 1 | 1 | 1 | 1 | | |
| Paraesthesia | | 2 | | 1 | | 1 |
| Peripheral swelling | 1 | 3 | 1 | 3 | | |
| Pruritus | 1 | 3 | 1 | 3 | | |
| Pyrexia | 11 | 17 | 11 | 17 | | |
| Rash | 2 | 2 | 2 | 2 | | |
| Retching | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 2 | 2 | 2 | 2 | | |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Skin lesion | | 1 | | 1 | | |
| Somnolence | 1 | 3 | 1 | 3 | | |
| Stress | | 1 | | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 5 | 5 | 3 | 3 | 2 | 2 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Thirst | | 1 | | | | 1 |
| Throat irritation | | 1 | | 1 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 2 | 1 | 1 | | 1 |
| Urticaria | | 1 | | 1 | | |
| Vaccination site coldness | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 4 | 1 | 4 | | |
| Vaccination site movement impairment | | 2 | | 2 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site nodule | | 1 | | 1 | | |
| Vaccination site oedema | | 1 | | 1 | | |
| Vaccination site pain | 7 | 12 | 7 | 12 | | |
| Vaccination site swelling | 1 | 3 | 1 | 3 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Vomiting | 2 | 5 | 2 | 4 | | 1 |
| | 160 | 282 | 137 | 244 | 23 | 38 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Arthralgia | 2 | 3 | 2 | 2 | | 1 |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthenia | 6 | 8 | 5 | 7 | 1 | 1 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 4 | 3 | 3 | 1 | 1 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | | 1 | | 1 | | |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Cartilage injury | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 2 | 1 | 2 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 7 | 10 | 7 | 9 | | 1 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cold sweat | | 1 | | 1 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Craniofacial fracture | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Depressed mood | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 4 | 2 | 2 | 2 | 2 |
| Drug ineffective | | 1 | | | | 1 |
| Dysgeusia | 2 | 3 | 2 | 3 | | |
| Dysphagia | 2 | 2 | 1 | 1 | 1 | 1 |
| Dyspnoea | 3 | 4 | 2 | 2 | 1 | 2 |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Ear pruritus | 1 | 1 | 1 | 1 | | |
| Erythema | 2 | 2 | 2 | 2 | | |
| Extrasystoles | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eye oedema | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fall | 2 | 2 | 1 | 1 | 1 | 1 |
| Fatigue | 5 | 7 | 5 | 7 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Flushing | 2 | 2 | 2 | 2 | | |
| Gait disturbance | | 1 | | 1 | | |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Headache | 6 | 11 | 5 | 9 | 1 | 2 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hyperaemia | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | 2 | 2 | 2 | 2 | | |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 | | |
| Hypokinesia | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Insomnia | 2 | 2 | 2 | 2 | | |
| Lacrimation increased | 1 | 1 | 1 | 1 | | |
| Laryngeal oedema | | 1 | | | | 1 |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Localised oedema | 1 | 1 | 1 | 1 | | |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 5 | 6 | 5 | 6 | | |
| Lymph node pain | 3 | 4 | 3 | 4 | | |
| Malaise | 6 | 9 | 6 | 8 | | 1 |
| Metabolic acidosis | 1 | 1 | | | 1 | 1 |
| Mood altered | 2 | 2 | 2 | 2 | | |
| Muscle strain | 2 | 2 | 2 | 2 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 4 | 6 | 4 | 5 | | 1 |
| Nausea | 3 | 5 | 2 | 4 | 1 | 1 |
| Neoplasm progression | 1 | 1 | | | 1 | 1 |
| No adverse event | | 1 | | 1 | | |
| Odynophagia | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | | 1 | | | | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 5 | 5 | 5 | 5 | | |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Poor quality sleep | 1 | 1 | 1 | 1 | | |
| Pruritus | 2 | 3 | 1 | 2 | 1 | 1 |
| Pulseless electrical activity | 1 | 1 | | | 1 | 1 |
| Pyrexia | 11 | 15 | 11 | 14 | | 1 |
| Rash | 1 | 2 | | 1 | 1 | 1 |
| Rash erythematous | 3 | 3 | 3 | 3 | | |
| Rash maculo-papular | 1 | 2 | 1 | 1 | | 1 |
| Rash pruritic | 2 | 3 | 2 | 3 | | |
| Rash vesicular | | 1 | | 1 | | |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Sensation of foreign body | 1 | 2 | | | 1 | 2 |
| Sensitive skin | 1 | 1 | 1 | 1 | | |
| Sinusitis | 1 | 1 | 1 | 1 | | |
| Skin burning sensation | 2 | 2 | 1 | 1 | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Stress | 1 | 1 | 1 | 1 | | |
| Swelling face | | 1 | | 1 | | |
| Tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Taste disorder | 1 | 1 | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tension | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | |
| Throat irritation | 1 | 1 | 1 | 1 | | |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Urticaria | 2 | 3 | 1 | 2 | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site nodule | | 1 | | 1 | | |
| Vaccination site pain | 4 | 5 | 3 | 4 | 1 | 1 |
| Vaccination site swelling | 3 | 3 | 3 | 3 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| White coat hypertension | 1 | 1 | 1 | 1 | | |
| | 176 | 224 | 137 | 171 | 39 | 53 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Asthenia | 3 | 3 | 3 | 3 | | |
| Cervical neuritis | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 2 | 2 | 2 | 2 | | |
| Eye haemorrhage | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 2 | 2 | 2 | | |
| Herpes zoster | 3 | 3 | 3 | 3 | | |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypotension | 1 | 1 | 1 | 1 | | |
| Illness | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Nausea | 2 | 2 | 2 | 2 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 2 | 1 | 2 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | | 1 | | 1 | | |
| | 33 | 35 | 27 | 29 | 6 | 6 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Asthenia | 1 | 1 | 1 | 1 |
| Death | 1 | 1 | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 |
| Feeding disorder | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthenia | 2 | 3 | 2 | 3 | | |
| Back pain | | 1 | | 1 | | |
| Blood pressure increased | 1 | 2 | | 1 | 1 | 1 |
| Burning sensation | 1 | 3 | 1 | 3 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Chronic obstructive pulmonary disease | 1 | 1 | 1 | 1 | | |
| COVID-19 | 5 | 6 | 2 | 2 | 3 | 4 |
| Dermatitis allergic | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Drug ineffective | 4 | 5 | | | 4 | 5 |
| Eczema | | 1 | | 1 | | |
| Erythema | 3 | 4 | 3 | 4 | | |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Eye haemorrhage | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Feeling abnormal | | 2 | | 2 | | |
| Feeling hot | 1 | 2 | 1 | 2 | | |
| Headache | 5 | 9 | 5 | 9 | | |
| Herpes zoster | 1 | 4 | 1 | 4 | | |
| Hypersensitivity | 2 | 2 | 2 | 2 | | |
| Hypoaesthesia | | 1 | | 1 | | |
| Hypoaesthesia oral | | 1 | | 1 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Lymphoedema | | 1 | | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Migraine | 1 | 1 | 1 | 1 | | |
| Muscle fatigue | | 1 | | 1 | | |
| Myalgia | 3 | 4 | 3 | 4 | | |
| Nasopharyngitis | | 1 | | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nausea | 3 | 4 | 3 | 4 | | |
| Neuralgia | 1 | 1 | 1 | 1 | | |
| Off label use | | 2 | | 2 | | |
| Pain | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 1 | 4 | 1 | 4 | | |
| Pain of skin | | 1 | | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 2 | 1 | 2 | | |
| Pyrexia | 7 | 8 | 7 | 8 | | |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Rash macular | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test positive | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Sensitive skin | 1 | 1 | 1 | 1 | | |
| Skin disorder | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Swelling face | | 1 | | 1 | | |
| Tinnitus | | 1 | | 1 | | |
| Vaccination site erythema | | 2 | | 2 | | |
| Vaccination site pain | 2 | 6 | 2 | 6 | | |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vasculitis | 1 | 1 | 1 | 1 | | |
| | 68 | 115 | 57 | 102 | 11 | 13 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Country Where Event Occurred

ICELAND

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | | 1 | | 1 | | |
| Bone pain | | 1 | | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Discomfort | | 1 | | 1 | | |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Dizziness | | 1 | | 1 | | |
| Dry mouth | | 1 | | 1 | | |
| Dry throat | | 1 | | 1 | | |
| Fatigue | 1 | 2 | 1 | 2 | | |
| Feeling cold | | 1 | | 1 | | |
| Headache | 2 | 3 | 2 | 3 | | |
| Hypoaesthesia | | 3 | | 3 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 2 | | 2 | | |
| Pruritus | | 1 | | 1 | | |
| Pyrexia | 2 | 5 | 2 | 5 | | |
| Sensory loss | | 1 | | 1 | | |
| Thirst | | 1 | | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| | 15 | 38 | 14 | 37 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 2 | 1 | 2 | | |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | | 1 | | 1 | | |
| Bone pain | | 1 | | 1 | | |
| Bradycardia | | 1 | | | | 1 |
| Breast inflammation | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 2 | 1 | 2 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 3 | 4 | 3 | 4 | | |
| Cold sweat | | 1 | | 1 | | |
| Dizziness | 3 | 5 | 3 | 5 | | |
| Erythema | 1 | 2 | 1 | 2 | | |
| Fatigue | 4 | 8 | 4 | 8 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | | 1 | | 1 | | |
| Headache | 6 | 14 | 6 | 14 | | |
| Head discomfort | | 1 | | 1 | | |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hepatic enzyme increased | 1 | 1 | 1 | 1 | | |
| Hot flush | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 2 | 1 | 2 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Limb discomfort | | 1 | | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 4 | 8 | 4 | 8 | | |
| Migraine | | 1 | | 1 | | |
| Muscle twitching | 2 | 2 | 2 | 2 | | |
| Myalgia | 4 | 5 | 4 | 5 | | |
| Nausea | | 4 | | 4 | | |
| Ocular discomfort | | 1 | | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oropharyngeal pain | 2 | 2 | 2 | 2 | | |
| Pain | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 3 | 3 | 3 | 3 | | |
| Pallor | | 1 | | 1 | | |
| Periorbital swelling | 1 | 1 | 1 | 1 | | |
| Pharyngeal swelling | | 1 | | 1 | | |
| Pruritus | 2 | 2 | 2 | 2 | | |
| Pyrexia | 3 | 6 | 3 | 6 | | |
| Rash | 1 | 1 | 1 | 1 | | |
| Sensitive skin | 1 | 1 | 1 | 1 | | |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Sluggishness | 1 | 1 | 1 | 1 | | |
| Swelling | | 1 | | 1 | | |
| Tachycardia | | 1 | | 1 | | |
| Tremor | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 2 | 1 | 2 | | |
| Vaccination site inflammation | 2 | 2 | 2 | 2 | | |
| Vaccination site pain | 5 | 7 | 5 | 7 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 67 | 119 | 67 | 118 | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | | 1 | | 1 |
| Back pain | | 1 | | 1 |
| Cough | | 1 | | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 |
| Dyspnoea | 1 | 1 | 1 | 1 |
| Fatigue | 1 | 2 | 1 | 2 |
| Gastrointestinal pain | 1 | 1 | 1 | 1 |
| Headache | | 2 | | 2 |
| Heart rate increased | | 1 | | 1 |
| Myalgia | 1 | 2 | 1 | 2 |
| Nasopharyngitis | | 1 | | 1 |
| Pruritus | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 3 | 1 | 3 |
| Sensitive skin | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 3 | 1 | 3 |
| | 11 | 24 | 11 | 24 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anal incontinence | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 2 | 1 | 2 | | |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 2 | 1 | 2 | | |
| Death | | 1 | | | | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dyspnoea | | 1 | | 1 | | |
| Fluid overload | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Hepatic enzyme increased | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypoperfusion | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Nausea | | 1 | | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pyrexia | 2 | 3 | 1 | 2 | 1 | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Urinary incontinence | 1 | 1 | 1 | 1 | | |
| Urine flow decreased | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| | 24 | 31 | 12 | 18 | 12 | 13 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Aortic aneurysm | | 1 | | | | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 2 | 1 | 2 | | |
| Asthma | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Cardiac failure | | 2 | | | | 2 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Cough | | 1 | | | | 1 |
| Death | | 1 | | | | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Disease progression | | 1 | | | | 1 |
| Dizziness | | 1 | | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Fatigue | | 1 | | 1 | | |
| Headache | | 1 | | 1 | | |
| Hypercapnia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypoxia | 2 | 2 | | | 2 | 2 |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Lung infiltration | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 5 | 1 | 2 | 1 | 3 |
| Myocardial infarction | | 1 | | | | 1 |
| Nasopharyngitis | | 2 | | 2 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Peripheral artery thrombosis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 3 | | | 1 | 3 |
| Pyrexia | 1 | 6 | | 3 | 1 | 3 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Respiration abnormal | | 1 | | | | 1 | |
| Respiratory failure | 1 | 1 | | | 1 | 1 | |
| Rhinorrhoea | | 2 | | 2 | | | |
| Sepsis | | 1 | | | | 1 | |
| Sudden death | | 1 | | | | 1 | |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 | |
| Vaccination site erythema | | 2 | | 2 | | | |
| Vaccination site inflammation | | 1 | | 1 | | | |
| | 26 | 57 | 7 | 22 | 19 | 35 | |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Ear pain | | 1 | | 1 |
| Fatigue | 1 | 1 | 1 | 1 |
| Headache | | 1 | | 1 |
| Myalgia | 1 | 2 | 1 | 2 |
| Oropharyngeal pain | 1 | 2 | 1 | 2 |
| Painful respiration | 1 | 1 | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| Pulmonary pain | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 2 | 1 | 2 |
| | 7 | 12 | 7 | 12 |

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Country Where Event Occurred

INDIA

Age Range

Unknown

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| | |
|-------------|---|
| Spontaneous | |
| Nonserious | |
| I | C |
| | 1 |
| | 1 |

Suspected counterfeit product

1

1

1

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Country Where Event Occurred

IRELAND

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Exposure via breast milk | 1 | 1 | 1 | 1 |
| Rash | 1 | 1 | 1 | 1 |
| Urticaria | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | | | 2 | 2 |
| Asthenia | 5 | 5 | | | 5 | 5 |
| Blepharospasm | 1 | 1 | | | 1 | 1 |
| Blindness | | 1 | | | | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Burning sensation | 2 | 2 | | | 2 | 2 |
| Chest pain | 2 | 2 | | | 2 | 2 |
| Chills | 3 | 3 | | | 3 | 3 |
| Cold sweat | | 1 | | | | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Contusion | 1 | 1 | 1 | 1 | | |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Deafness | | 1 | | | | 1 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Dizziness | 5 | 6 | 1 | 1 | 4 | 5 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 3 | 4 | | | 3 | 4 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Fatigue | 8 | 8 | 1 | 1 | 7 | 7 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Feeling hot | 1 | 1 |
| Feeling of body temperature change | 1 | 1 |
| Flushing | 1 | 1 |
| Headache | 6 | 6 |
| Heart rate increased | | 1 |
| Hyperhidrosis | 4 | 4 |
| Hypersensitivity | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypotension | 1 | 1 |
| Inflammation | 1 | 1 |
| Influenza like illness | 1 | 1 |
| Insomnia | 2 | 2 |
| Lymphadenopathy | 1 | 1 |
| Lymph node pain | 2 | 2 |
| Malaise | 2 | 2 |
| Mastitis | 1 | 1 |
| Myalgia | 3 | 3 |
| Myokymia | 1 | 1 |
| Nausea | 7 | 7 |
| Neutropenia | 1 | 1 |
| Pain | 3 | 3 |
| Pain in extremity | 5 | 5 |
| Pallor | 1 | 1 |
| Palpitations | 4 | 4 |
| Paraesthesia | 2 | 2 |
| Pruritus | 1 | 1 |
| Pyrexia | 4 | 4 |
| Rash | 2 | 2 |
| Rash erythematous | 2 | 2 |
| Retching | 1 | 1 |
| Sinusitis | 1 | 1 |
| Syncope | 1 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 5 | 5 |
| | | | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 5 | 5 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | 4 | 4 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 4 | 4 | | | 4 | 4 |
| Tinnitus | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Urticaria | 2 | 2 | | | 2 | 2 |
| Urticarial vasculitis | 1 | 1 | | | 1 | 1 |
| Urticaria papular | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site pruritus | 2 | 2 | | | 2 | 2 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Vomiting | 5 | 5 | | | 5 | 5 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 140 | 147 | 17 | 17 | 123 | 130 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Ageusia | 3 | 3 | 1 | 1 | 2 | 2 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Arthralgia | 9 | 9 | 2 | 2 | 7 | 7 |
| Asthenia | 13 | 14 | 1 | 2 | 12 | 12 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | 3 | 3 | | | 3 | 3 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Blood pressure systolic increased | 1 | 1 | 1 | 1 | | |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cheilitis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 6 | 6 | | | 6 | 6 |
| Chest pain | 5 | 5 | | | 5 | 5 |
| Chills | 12 | 12 | 1 | 1 | 11 | 11 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 4 | 4 | | | 4 | 4 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 3 | 3 | | | 3 | 3 |
| Discomfort | 4 | 4 | | | 4 | 4 |
| Disease recurrence | 2 | 2 | | | 2 | 2 |
| Disorientation | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Disturbance in attention | 2 | 2 |
| Dizziness | 20 | 20 |
| Drug ineffective | 2 | 2 |
| Dry eye | 1 | 1 |
| Dry mouth | 1 | 1 |
| Dry throat | 1 | 1 |
| Dysarthria | 2 | 2 |
| Dysgeusia | 1 | 1 |
| Dysphagia | 1 | 1 |
| Dyspnoea | 6 | 6 |
| Ear pain | 1 | 1 |
| Emotional distress | 1 | 1 |
| Encephalitis | 1 | 1 |
| Erythema | 2 | 2 |
| Erythema of eyelid | 1 | 1 |
| Eyelids pruritus | 1 | 1 |
| Eye pain | 1 | 1 |
| Facial pain | 1 | 1 |
| Facial paralysis | 3 | 3 |
| Fatigue | 24 | 25 |
| Feeling abnormal | 4 | 4 |
| Feeling cold | 3 | 3 |
| Feeling drunk | 2 | 2 |
| Feeling hot | 4 | 4 |
| Feeling of body temperature change | 1 | 1 |
| Flank pain | 2 | 2 |
| Flushing | 2 | 2 |
| Gait disturbance | 1 | 1 |
| Headache | 40 | 41 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 2 | 2 |
| Herpes zoster | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 19 | 19 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| 2 | 3 | 22 | 22 |
| | | 4 | 4 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 4 | 5 | 36 | 36 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hyperaesthesia | 1 | 1 |
| Hyperhidrosis | 4 | 4 |
| Hypersensitivity | 1 | 1 |
| Hypertension | 8 | 8 |
| Hypoaesthesia | 9 | 9 |
| Hypoaesthesia oral | 3 | 3 |
| Hypoglycaemia | 1 | 1 |
| Hypotension | 1 | 1 |
| Illness | 1 | 1 |
| Impaired driving ability | 2 | 2 |
| Impaired work ability | 3 | 3 |
| Influenza like illness | 3 | 3 |
| Insomnia | 5 | 5 |
| Joint stiffness | 2 | 2 |
| Lacrimation decreased | 1 | 1 |
| Lethargy | 5 | 5 |
| Limb discomfort | 2 | 2 |
| Lip swelling | 3 | 3 |
| Lymphadenopathy | 5 | 6 |
| Malaise | 13 | 13 |
| Maternal exposure during breast feeding | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 1 |
| Menstrual disorder | 1 | 1 |
| Mobility decreased | 1 | 1 |
| Muscle tightness | 1 | 1 |
| Muscle twitching | 3 | 3 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 8 | 8 |
| Myelitis transverse | 1 | 1 |
| Nasal congestion | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 8 | 8 |
| 2 | 2 | 7 | 7 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 3 | 3 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | 1 | 1 |
| | | 3 | 3 |
| | 1 | 5 | 5 |
| 3 | 3 | 10 | 10 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 8 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nausea | 22 | 22 | 2 | 2 | 20 | 20 |
| Neck pain | 4 | 4 | | | 4 | 4 |
| Nerve injury | 1 | 1 | | | 1 | 1 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Off label use | 2 | 2 | 2 | 2 | | |
| Oropharyngeal pain | 4 | 4 | 1 | 1 | 3 | 3 |
| Pain | 14 | 14 | 2 | 2 | 12 | 12 |
| Pain in extremity | 10 | 10 | 2 | 2 | 8 | 8 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palpitations | 6 | 6 | 1 | 1 | 5 | 5 |
| Paraesthesia | 16 | 16 | 1 | 1 | 15 | 15 |
| Paraesthesia oral | 4 | 4 | | | 4 | 4 |
| Paranasal sinus discomfort | 1 | 1 | | | 1 | 1 |
| Periorbital oedema | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 2 | | | 2 | 2 |
| Pharyngeal swelling | 2 | 2 | | | 2 | 2 |
| Poor quality sleep | 1 | 1 | 1 | 1 | | |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Pruritus | 7 | 7 | 1 | 1 | 6 | 6 |
| Pyrexia | 16 | 17 | 1 | 2 | 15 | 15 |
| Quality of life decreased | 1 | 1 | | | 1 | 1 |
| Rash | 7 | 7 | 1 | 1 | 6 | 6 |
| Rash erythematous | 4 | 4 | 1 | 1 | 3 | 3 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Road traffic accident | 1 | 1 | | | 1 | 1 |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Stress | 1 | 1 | 1 | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Suspected COVID-19 | 1 | 1 | 1 | 1 | | |
| Swelling | 3 | 3 | | | 3 | 3 |
| Swelling face | 3 | 3 | 1 | 1 | 2 | 2 |
| Swelling of eyelid | 2 | 2 | 1 | 1 | 1 | 1 |
| Swollen tongue | 3 | 3 | | | 3 | 3 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 8 | 8 | | | 8 | 8 |
| Tenderness | 1 | 1 | | | 1 | 1 |
| Tension headache | 1 | 1 | | | 1 | 1 |
| Throat tightness | 3 | 3 | | | 3 | 3 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 2 | | | 2 | 2 |
| Trigeminal nerve disorder | 1 | 1 | | | 1 | 1 |
| Trigeminal neuralgia | 1 | 1 | | | 1 | 1 |
| Urticaria | 3 | 3 | | | 3 | 3 |
| Vaccination site bruising | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site irritation | 1 | 1 | | | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 7 | 7 | 1 | 1 | 6 | 6 |
| Vaccination site pruritus | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vitreous floaters | 2 | 2 | | | 2 | 2 |
| Vomiting | 7 | 7 | | | 7 | 7 |
| Wheezing | 2 | 2 | | | 2 | 2 |
| | 522 | 527 | 56 | 61 | 466 | 466 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Arthralgia | 4 | 4 | | | 4 | 4 |
| Asthenia | 6 | 6 | 1 | 1 | 5 | 5 |
| Back pain | 2 | 2 | | | 2 | 2 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Blindness transient | 1 | 1 | | | 1 | 1 |
| Blood pressure diastolic increased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Burning sensation | 2 | 2 | 1 | 1 | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | | | 2 | 2 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Dizziness | 7 | 7 | 1 | 1 | 6 | 6 |
| Dry eye | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Eye discharge | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 1 | 1 | | | 1 | 1 |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 6 | 7 | | 1 | 6 | 6 |
| Feeling abnormal | 3 | 3 | 2 | 2 | 1 | 1 |
| Feeling cold | 1 | 1 | | | 1 | 1 |
| Feeling hot | 4 | 4 | | | 4 | 4 |
| Flushing | 2 | 2 | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Gastric disorder | 1 | 1 | | | 1 | 1 |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Headache | 7 | 8 | 1 | 2 | 6 | 6 |
| Herpes zoster reactivation | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 2 | 2 | | | 2 | 2 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypertension | 2 | 2 | | | 2 | 2 |
| Hypoaesthesia | 3 | 3 | | | 3 | 3 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Impaired work ability | 1 | 1 | | | 1 | 1 |
| Incorrect dose administered | | 1 | | 1 | | |
| Influenza like illness | 2 | 2 | | | 2 | 2 |
| Injected limb mobility decreased | | 1 | | | | 1 |
| Insomnia | 1 | 1 | | | 1 | 1 |
| Joint swelling | 1 | 1 | | | 1 | 1 |
| Lethargy | 2 | 2 | | | 2 | 2 |
| Limb discomfort | 2 | 2 | | | 2 | 2 |
| Lip discolouration | 1 | 1 | | | 1 | 1 |
| Lip swelling | 2 | 2 | | | 2 | 2 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymph node pain | 1 | 1 | | | 1 | 1 |
| Malaise | 5 | 5 | | | 5 | 5 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 | | | 1 | 1 |
| Myalgia | 4 | 4 | | | 4 | 4 |
| Nausea | 5 | 5 | | | 5 | 5 |
| Night sweats | 1 | 1 | | | 1 | 1 |
| No adverse event | | 1 | | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 2 | | | 1 | 2 |
| Pain in extremity | 2 | 2 | | | 2 | 2 |
| Palpitations | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | 6 | 6 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 5 | 5 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Paraesthesia | 7 | 7 | 1 | 1 | 6 | 6 |
| Paraesthesia oral | 2 | 2 | | | 2 | 2 |
| Periarthritis | | 1 | | | | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Product preparation issue | | 1 | | 1 | | |
| Pruritus | 2 | 2 | | | 2 | 2 |
| Psychomotor hyperactivity | 1 | 1 | | | 1 | 1 |
| Pulse abnormal | 1 | 1 | | | 1 | 1 |
| Pyrexia | 6 | 6 | | | 6 | 6 |
| Rash | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | | | 2 | 2 |
| Suspected product quality issue | | 1 | | 1 | | |
| Swelling | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 2 | | | 1 | 2 |
| Tachycardia | 2 | 2 | | | 2 | 2 |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 3 | 3 | | | 3 | 3 |
| | 155 | 165 | 10 | 16 | 145 | 149 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Acute cardiac event | 1 | 1 | 1 | 1 |
| Agitation | 1 | 1 | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 |
| Cold sweat | 1 | 1 | 1 | 1 |
| Confusional state | 1 | 1 | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 |
| Eye movement disorder | 1 | 1 | 1 | 1 |
| Facial paralysis | 1 | 1 | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 |
| Gait disturbance | 1 | 1 | 1 | 1 |
| Hypertension | 1 | 1 | 1 | 1 |
| Hypoglycaemia | 1 | 1 | 1 | 1 |
| Hypotonia | 1 | 1 | 1 | 1 |
| Impaired work ability | 1 | 1 | 1 | 1 |
| Loss of consciousness | 1 | 1 | 1 | 1 |
| Presyncope | 1 | 1 | 1 | 1 |
| Respiratory rate increased | 1 | 1 | 1 | 1 |
| Sudden death | | 1 | | 1 |
| Supraventricular tachycardia | 1 | 1 | 1 | 1 |
| Tardive dyskinesia | 1 | 1 | 1 | 1 |
| Tongue movement disturbance | 1 | 1 | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 | 1 | 1 |
| | 22 | 23 | 22 | 23 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Cardiac failure congestive | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Cyanosis | | 1 | | 1 | | |
| Death | 2 | 3 | | | 2 | 3 |
| Depressed level of consciousness | | 1 | | | | 1 |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Dyspnoea at rest | 1 | 1 | | | 1 | 1 |
| Face injury | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Faeces discoloured | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | | | 1 | 1 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 4 | 4 | | | 4 | 4 |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Pancreatitis relapsing | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Rales | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Upper gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Urticaria | 2 | 2 | | | 2 | 2 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 41 | 44 | 3 | 4 | 38 | 40 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 3 | 1 | 1 | 2 | 2 |
| Asthenia | 3 | 3 | 1 | 1 | 2 | 2 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature abnormal | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Choking sensation | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 3 | 3 | | | 3 | 3 |
| Dyspnoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Emotional distress | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 3 | 3 | 1 | 1 | 2 | 2 |
| Feeling cold | 3 | 3 | 1 | 1 | 2 | 2 |
| Feeling hot | 3 | 3 | 1 | 1 | 2 | 2 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Haematochezia | 1 | 1 | | | 1 | 1 |
| Headache | 4 | 5 | 1 | 1 | 3 | 4 |
| Hyperhidrosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect dose administered | | 4 | | 4 | | |
| IVth nerve paralysis | 1 | 2 | | | 1 | 2 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Loss of personal independence in daily activities | 2 | 2 |
| Lymphadenopathy | 1 | 1 |
| Lymph node pain | 1 | 1 |
| Malaise | 1 | 2 |
| Metrorrhagia | 1 | 1 |
| Migraine | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Myalgia | 2 | 2 |
| Nausea | 7 | 8 |
| Neuropathy peripheral | 1 | 1 |
| Night sweats | 1 | 1 |
| No adverse event | 1 | 4 |
| Off label use | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 1 | 1 |
| Panic attack | 2 | 2 |
| Paraesthesia | 1 | 1 |
| Platelet count decreased | 1 | 1 |
| Presyncope | 1 | 1 |
| Product preparation issue | 1 | 5 |
| Pruritus | 2 | 2 |
| Pyrexia | 2 | 3 |
| Rhinitis | 1 | 1 |
| Skin tightness | 1 | 1 |
| Suspected COVID-19 | 1 | 1 |
| Suspected product quality issue | | 4 |
| Syncope | 1 | 1 |
| Tachycardia | 1 | 1 |
| Thirst | 1 | 1 |
| Throat tightness | 1 | 1 |
| Tremor | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 3 | 3 | 4 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 4 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 5 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 4 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site discolouration | 1 | 1 | | | 1 | 1 |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 |
| Visual impairment | | 1 | | | | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 100 | 121 | 31 | 46 | 69 | 75 |

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Country Where Event Occurred
ISRAEL

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposure via breast milk | | 3 | | 3 | | |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Product administered to patient of inappropriate age | 1 | 1 | 1 | 1 | | |
| | 4 | 7 | 2 | 5 | 2 | 2 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Anxiety | | 1 | | 1 | | | |
| Arthralgia | 1 | 1 | 1 | 1 | | | |
| Asthenia | 6 | 10 | 6 | 10 | | | |
| Asthma | 1 | 1 | | | 1 | | 1 |
| Back pain | 3 | 3 | 3 | 3 | | | |
| Cerebrovascular accident | | 1 | | | | | 1 |
| Chills | 3 | 3 | 3 | 3 | | | |
| Cough | 2 | 2 | 2 | 2 | | | |
| COVID-19 | 1 | 1 | | | 1 | | 1 |
| Dizziness | | 1 | | 1 | | | |
| Drug ineffective | 1 | 1 | | | 1 | | 1 |
| Dyspnoea | 1 | 1 | 1 | 1 | | | |
| Erythema | | 1 | | 1 | | | |
| Eye swelling | | 1 | | 1 | | | |
| Facial paralysis | | 1 | | | | | 1 |
| Fatigue | | 3 | | 3 | | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | | |
| Gingival pain | | 1 | | 1 | | | |
| Headache | 2 | 7 | 2 | 7 | | | |
| Heart rate increased | 1 | 3 | 1 | 3 | | | |
| Hypoaesthesia | | 4 | | 4 | | | |
| Infection | | 1 | | 1 | | | |
| Injection site pain | | 2 | | 2 | | | |
| Insomnia | 1 | 1 | 1 | 1 | | | |
| Joint noise | 1 | 1 | 1 | 1 | | | |
| Loss of consciousness | 1 | 1 | | | 1 | | 1 |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 | | | |
| Lung disorder | | 1 | | 1 | | | |
| Lymphadenopathy | | 1 | | 1 | | | |
| Malaise | 1 | 2 | 1 | 2 | | | |
| Muscle contractions involuntary | | 1 | | 1 | | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Myalgia | | 2 |
| Myocarditis | 1 | 1 |
| Nasopharyngitis | 1 | 1 |
| Neck pain | 1 | 1 |
| Neuritis | | 1 |
| Off label use | | 1 |
| Oropharyngeal pain | | 2 |
| Overdose | | 1 |
| Pain | 1 | 3 |
| Pain in extremity | 4 | 7 |
| Pain in jaw | | 1 |
| Palpitations | | 1 |
| Paraesthesia | | 2 |
| Paralysis | 1 | 1 |
| Peripheral swelling | | 1 |
| Product preparation error | | 1 |
| Product use issue | | 1 |
| Pyrexia | 4 | 9 |
| Seizure | 1 | 1 |
| Skin disorder | | 1 |
| Systemic inflammatory response syndrome | | 1 |
| Tenderness | | 1 |
| Tic | | 1 |
| Tinnitus | | 1 |
| Toothache | | 1 |
| Vaccination site bruising | | 1 |
| Vaccination site erythema | | 1 |
| Vaccination site joint movement impairment | | 1 |
| Vaccination site pain | 1 | 6 |
| Vaccination site pruritus | | 1 |
| Vaccination site reaction | | 1 |
| Vaccination site swelling | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 1 | | |
| 1 | 3 | | |
| 4 | 7 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 4 | 9 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 6 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 44 | 117 | 37 | 107 | 7 | 10 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | | 1 | | | | 1 | | |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 | | |
| Abortion spontaneous | 1 | 1 | | | | | 1 | 1 |
| Ageusia | | 1 | | | | 1 | | |
| Allergy to vaccine | | 1 | | | | | | 1 |
| Anaesthesia oral | | 1 | | | | 1 | | |
| Anaphylactic reaction | 1 | 2 | | | | | 1 | 2 |
| Anxiety | 1 | 1 | | | 1 | 1 | | |
| Arthralgia | 5 | 9 | | | 3 | 7 | 2 | 2 |
| Arthritis reactive | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 9 | 18 | | | 8 | 16 | 1 | 2 |
| Atrial fibrillation | 1 | 2 | | | | | 1 | 2 |
| Back pain | 1 | 3 | | | 1 | 3 | | |
| Blood chloride increased | | 1 | | | | | | 1 |
| Blood glucose increased | | 1 | | | | | | 1 |
| Blood pressure increased | | 2 | | | | | | 2 |
| Blood pressure systolic increased | | 1 | | | | 1 | | |
| Body temperature decreased | 1 | 1 | | | 1 | 1 | | |
| Breast inflammation | 1 | 1 | | | 1 | 1 | | |
| Cardiac arrest | | 1 | | | | | | 1 |
| Chills | 8 | 13 | | | 8 | 12 | | 1 |
| Choking | | 2 | | | | | | 2 |
| Cough | | 2 | | | | 2 | | |
| COVID-19 | 4 | 4 | | 1 | | | 4 | 4 |
| Decreased appetite | | 2 | | | | 1 | | 1 |
| Depressed mood | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Depression | 1 | 1 | | | | | 1 | 1 |
| Diarrhoea | 1 | 3 | | | 1 | 2 | | 1 |
| Disease recurrence | 1 | 3 | | | 1 | 2 | | 1 |
| Dizziness | 1 | 12 | | | 1 | 9 | | 3 |
| Drug ineffective | 4 | 4 | | 1 | | | 4 | 4 |
| Dysgeusia | 1 | 4 | | | 1 | 4 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Dyspepsia | 1 | 2 |
| Dysphagia | | 4 |
| Dyspnoea | 1 | 5 |
| Ear discomfort | 1 | 1 |
| Ear pain | 1 | 2 |
| Eosinophilic oesophagitis | | 1 |
| Erythema | 2 | 3 |
| Exposure during pregnancy | | 1 |
| Exposure to SARS-CoV-2 | | |
| Eye infection | 1 | 1 |
| Eye pain | 1 | 1 |
| Facial pain | 1 | 1 |
| Facial paralysis | 2 | 5 |
| Fatigue | 8 | 16 |
| Feeling abnormal | 1 | 3 |
| Feeling cold | 1 | 1 |
| Feeling hot | | 1 |
| Feeling of body temperature change | | 1 |
| Food craving | | 1 |
| Gait disturbance | 1 | 1 |
| Glomerular filtration rate decreased | | 1 |
| Hangover | | 1 |
| Headache | 11 | 24 |
| Heart rate increased | | 4 |
| Hepatitis | | 1 |
| Herpes zoster | 2 | 3 |
| Hyperhidrosis | 1 | 2 |
| Hypersensitivity | 2 | 3 |
| Hypertension | | 1 |
| Hypoaesthesia | 1 | 7 |
| Hypoaesthesia oral | | 4 |
| Illness | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | | 3 | | 1 |
| | | | 1 | 1 | 4 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | | |
| | 1 | | | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 5 |
| | | 8 | 15 | | 1 |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 10 | 20 | 1 | 4 |
| | | | 4 | | |
| | | | | | 1 |
| | | 2 | 3 | | |
| | | 1 | 2 | | |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | | 5 | 1 | 2 |
| | | | 3 | | 1 |
| | | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Impaired quality of life | | 1 |
| Inappropriate schedule of product administration | | 1 |
| Inflammatory marker increased | | 1 |
| Influenza like illness | 1 | 3 |
| Injection site inflammation | | 1 |
| Insomnia | | 1 |
| International normalised ratio increased | | 1 |
| Joint swelling | 1 | 2 |
| Leukocytosis | | 1 |
| Limb discomfort | | 1 |
| Loss of libido | 1 | 1 |
| Lymphadenopathy | | 2 |
| Lymphopenia | | 1 |
| Malaise | 2 | 6 |
| Maternal exposure during pregnancy | 2 | 2 |
| Mean cell haemoglobin decreased | | 1 |
| Migraine | | 1 |
| Miliaria | | 1 |
| Mobility decreased | 1 | 1 |
| Multiple sclerosis | | 1 |
| Multiple sclerosis relapse | | 1 |
| Muscle contractions involuntary | 1 | 1 |
| Muscle rigidity | 1 | 1 |
| Myalgia | 9 | 15 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 3 | 9 |
| Neuralgia | | 1 |
| Neutrophil count increased | | 1 |
| No adverse event | 1 | 1 |
| Odynophagia | | 2 |
| Off label use | 2 | 3 |
| Oral herpes | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | | | | 1 |
| | | 2 | 4 | | 2 |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 8 | 14 | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 8 | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 2 | 3 | | |
| | | | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Oropharyngeal pain | | 3 |
| Otitis media | | 1 |
| Oxygen saturation decreased | | 1 |
| Pain | 2 | 3 |
| Pain in extremity | 3 | 7 |
| Palpitations | | 3 |
| Paraesthesia | 1 | 8 |
| Paraesthesia oral | | 3 |
| Paralysis | 1 | 1 |
| Parosmia | 1 | 2 |
| Pelvic pain | | 1 |
| Pericarditis | | 1 |
| Peripheral coldness | 1 | 1 |
| Pharyngeal swelling | 1 | 2 |
| Pleuritic pain | | 1 |
| Poor quality product administered | | 1 |
| Presyncope | | 1 |
| Product use issue | 1 | 2 |
| Pruritus | | 2 |
| Pyrexia | 10 | 14 |
| Rash | | 3 |
| Rash pruritic | | 1 |
| Reduced facial expression | | 1 |
| Sensory disturbance | | 1 |
| Sinus tachycardia | | 1 |
| Sleep disorder due to general medical condition, insomnia type | | 1 |
| Sneezing | | 1 |
| Somnolence | 1 | 1 |
| Speech disorder | 1 | 2 |
| Suicidal ideation | 1 | 1 |
| Swelling | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 3 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 2 | 3 | | |
| | | 3 | 7 | | |
| | | | 3 | | |
| | | | 6 | 1 | 2 |
| | | | 2 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | 1 | | 1 |
| | | 9 | 12 | 1 | 2 |
| | | | 1 | | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Swollen tongue | | 2 | | | | | | 2 |
| Syncope | | 1 | | | | | | 1 |
| Tachycardia | | 1 | | | | | | 1 |
| Taste disorder | | 1 | | | | 1 | | |
| Throat tightness | | 1 | | | | | | 1 |
| Tongue discomfort | | 1 | | | | 1 | | |
| Urticaria | | 2 | | | | 1 | | 1 |
| Uveitis | 1 | 1 | | | | | 1 | 1 |
| Vaccination site cellulitis | | 1 | | | | 1 | | |
| Vaccination site erythema | | 1 | | | | 1 | | |
| Vaccination site pain | 4 | 19 | | | 4 | 19 | | |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 | | |
| Vision blurred | 1 | 2 | | | 1 | 2 | | |
| Vomiting | 1 | 3 | | | 1 | 2 | | 1 |
| Weight decreased | | 2 | | | | 1 | | 1 |
| Wrong technique in product usage process | | 1 | | | | 1 | | |
| Yawning | | 1 | | | | 1 | | |
| | 146 | 385 | | 3 | 107 | 284 | 39 | 101 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Allergy to vaccine | | 2 | | 1 | | 1 | |
| Anaphylactic reaction | 1 | 2 | | | 1 | 2 | |
| Anaphylactic shock | | 1 | | | | 1 | |
| Anger | | 1 | | 1 | | | |
| Angina pectoris | 1 | 2 | | | 1 | 2 | |
| Anosmia | | 1 | | 1 | | | |
| Aphonia | | 1 | | | | 1 | |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | | |
| Arrhythmia | 1 | 3 | | | 1 | 3 | |
| Arthralgia | 1 | 3 | 1 | 3 | | | |
| Asthenia | 5 | 14 | 4 | 13 | 1 | 1 | |
| Atelectasis | 1 | 1 | | | 1 | 1 | |
| Atrial f brillation | | 1 | | | | 1 | |
| Autoimmune haemolytic anaemia | 1 | 1 | | | 1 | 1 | |
| Back pain | | 3 | | 3 | | | |
| Blood chloride increased | | 1 | | 1 | | | |
| Blood glucose increased | | 2 | | 1 | | 1 | |
| Blood pressure increased | 1 | 3 | 1 | 2 | | 1 | |
| Bone pain | | 1 | | 1 | | | |
| Cardiac arrest | | 3 | | | | 3 | |
| Cardiac flutter | 1 | 1 | | | 1 | 1 | |
| Cerebellar haemorrhage | | 1 | | | | 1 | |
| Cerebral ischaemia | | 1 | | | | 1 | |
| Chest discomfort | | 1 | | 1 | | | |
| Chest pain | 1 | 2 | 1 | 2 | | | |
| Chills | 2 | 5 | 2 | 5 | | | |
| Confusional state | 1 | 1 | | | 1 | 1 | |
| Cough | | 1 | | 1 | | | |
| COVID-19 | 2 | 2 | | | 2 | 2 | |
| C-reactive protein increased | | 1 | | 1 | | | |
| Death | | 1 | | | | 1 | |
| Decreased appetite | 1 | 1 | 1 | 1 | | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Depressed level of consciousness | | 1 |
| Diarrhoea | | 1 |
| Dizziness | 4 | 6 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 2 | 4 |
| Dysarthria | 1 | 1 |
| Dysgeusia | | 1 |
| Dysmenorrhoea | 1 | 1 |
| Dyspnoea | 3 | 6 |
| Dyspnoea exertional | 1 | 1 |
| Dysstasia | 1 | 1 |
| Ear discomfort | | 1 |
| Ear pain | 1 | 1 |
| Epilepsy | 1 | 1 |
| Erythema | | 2 |
| Facial asymmetry | | 1 |
| Facial paralysis | 3 | 6 |
| Fatigue | 3 | 5 |
| Feeling abnormal | | 1 |
| Feeling cold | 1 | 2 |
| Feeling hot | | 2 |
| Formication | | 2 |
| General physical health deterioration | 1 | 1 |
| Headache | 5 | 11 |
| Head discomfort | 1 | 1 |
| Herpes zoster | 3 | 3 |
| Hyperhidrosis | | 1 |
| Hypersensitivity | | 2 |
| Hypertension | | 1 |
| Hypoaesthesia | 1 | 5 |
| Hypoaesthesia oral | | 1 |
| Hypotension | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | 1 | | |
| 3 | 5 | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 4 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | 2 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| | 1 | | |
| | | 3 | 6 |
| 3 | 5 | | |
| | 1 | | |
| 1 | 2 | | |
| | 2 | | |
| | 2 | | |
| | | 1 | 1 |
| 4 | 10 | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| | 1 | | |
| | 1 | | 1 |
| | | | 1 |
| 1 | 5 | | |
| | 1 | | |
| | | | 1 |

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 * AE=Adverse Event
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Age Range

51 - 64 years

| Preferred Term | Interval Total # | Cumulative Total # |
|--|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Immune thrombocytopenia | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 2 |
| Influenza | 1 | 2 |
| Influenza like illness | 1 | 3 |
| Lip pruritus | | 1 |
| Lip swelling | | 2 |
| Loss of consciousness | 1 | 2 |
| Lymphadenopathy | 1 | 1 |
| Lymphocyte count increased | | 1 |
| Malaise | | 7 |
| Mean cell haemoglobin concentration decreased | | 1 |
| Mean cell haemoglobin decreased | | 2 |
| Mean cell volume decreased | | 1 |
| Mean platelet volume increased | | 1 |
| Menorrhagia | 1 | 1 |
| Mobility decreased | 1 | 1 |
| Muscle twitching | | 1 |
| Muscular weakness | 1 | 2 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 2 | 5 |
| Myocardial infarction | | 1 |
| Nasopharyngitis | 1 | 2 |
| Nausea | 2 | 5 |
| Neck pain | 2 | 4 |
| Oral discomfort | 1 | 1 |
| Oral herpes | 1 | 1 |
| Oral pain | 1 | 1 |
| Oropharyngeal discomfort | | 1 |
| Oropharyngeal pain | | 1 |
| Pain | 2 | 6 |
| Pain in extremity | 3 | 10 |
| Palmar erythema | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 2 | | |
| 1 | 3 | | |
| | 1 | | |
| | 1 | | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| | 1 | | |
| | 6 | | 1 |
| | 1 | | |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| 2 | 5 | | |
| | | | 1 |
| 1 | 2 | | |
| 1 | 4 | 1 | 1 |
| 2 | 4 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 5 | 1 | 1 |
| 3 | 10 | | |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Palpitations | | 2 |
| Paraesthesia | | 7 |
| Paraesthesia oral | | 3 |
| Parosmia | | 1 |
| Peripheral swelling | | 1 |
| Pharyngeal paraesthesia | | 1 |
| Pharyngeal swelling | | 1 |
| Poor quality product administered | | 2 |
| Product deposit | | 1 |
| Product packaging quantity issue | | 1 |
| Pulse abnormal | | 1 |
| Pyrexia | 2 | 5 |
| Rash | 1 | 3 |
| Rash macular | | 1 |
| Red blood cell count increased | | 1 |
| Respiratory arrest | | 1 |
| Rhinorrhoea | | 1 |
| SARS-CoV-2 test positive | | 2 |
| Sensory disturbance | | 1 |
| Sensory loss | | 1 |
| Skin burning sensation | | 1 |
| Speech disorder | 1 | 1 |
| Sudden death | 1 | 1 |
| Swelling face | | 1 |
| Swollen tongue | | 1 |
| Tachycardia | 1 | 4 |
| Taste disorder | | 1 |
| Therapeutic response unexpected | | 1 |
| Thrombosis | | 1 |
| Tremor | | 1 |
| Urticaria | | 2 |
| Vaccination site cellulitis | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| | 7 | | |
| | 3 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| 1 | 4 | 1 | 1 |
| 1 | 3 | | |
| | 1 | | |
| | 1 | | 1 |
| | 1 | | |
| | | | 2 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| 1 | 4 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | 1 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | | 1 | | 1 | | |
| Vaccination site pain | 2 | 14 | 2 | 14 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Wheezing | | 1 | | | | 1 |
| | 91 | 283 | 62 | 214 | 29 | 69 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 2 | 1 | 2 | | |
| Abdominal pain upper | | 1 | | 1 | | |
| Alcohol intolerance | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | | 1 | | | | 1 |
| Arthralgia | 2 | 5 | 2 | 4 | | 1 |
| Asthenia | | 11 | | 10 | | 1 |
| Asthma | | 1 | | 1 | | |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure decreased | | 1 | | 1 | | |
| Blood pressure increased | | 4 | | 3 | | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | | 1 | | | | 1 |
| Cardiac disorder | | 1 | | | | 1 |
| Cardiac failure | | 1 | | | | 1 |
| Cerebrovascular accident | | 1 | | | | 1 |
| Chest pain | 1 | 3 | 1 | 2 | | 1 |
| Chills | | 5 | | 5 | | |
| Cold sweat | | 1 | | 1 | | |
| Cough | | 1 | | 1 | | |
| COVID-19 | 3 | 6 | | | 3 | 6 |
| Death | | 2 | | | | 2 |
| Decreased appetite | | 2 | | 2 | | |
| Depression | | 1 | | 1 | | |
| Diarrhoea | 1 | 3 | 1 | 3 | | |
| Dizziness | | 6 | | 5 | | 1 |
| Drug ineffective | 3 | 6 | | | 3 | 6 |
| Dysgeusia | | 2 | | 2 | | |
| Dyspepsia | | 3 | | 3 | | |
| Dyspnoea | 1 | 6 | 1 | 4 | | 2 |
| Dyspnoea exertional | | 1 | | 1 | | |
| Dysstasia | | 1 | | | | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------|------------------------------------|--------------------------------------|
| Ear discomfort | | 1 |
| Ear pain | | 1 |
| Erythema | | 2 |
| Eye haemorrhage | | 1 |
| Eye pain | | 1 |
| Eye swelling | 1 | 1 |
| Facial paralysis | | 4 |
| Fall | 1 | 2 |
| Fatigue | 4 | 7 |
| Feeling abnormal | 1 | 6 |
| Feeling cold | | 2 |
| Feeling hot | | 2 |
| Food refusal | 1 | 1 |
| Formication | 1 | 1 |
| Gait disturbance | | 2 |
| Haemolytic anaemia | | 1 |
| Headache | 4 | 9 |
| Head discomfort | | 1 |
| Heart rate increased | | 1 |
| Hepatitis acute | 1 | 1 |
| Hip fracture | | 1 |
| Hyperhidrosis | | 1 |
| Hypertension | | 2 |
| Hypoaesthesia | | 4 |
| Hypoaesthesia teeth | | 1 |
| Hypotension | | 1 |
| Hypoventilation | | 1 |
| Illness | | 1 |
| Influenza | | 1 |
| Influenza like illness | | 1 |
| Insomnia | 1 | 2 |
| Jaundice | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | | 4 |
| | | 1 | 2 |
| 4 | 7 | | |
| 1 | 3 | | 3 |
| | 2 | | |
| | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 2 |
| | | | 1 |
| 4 | 9 | | |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | | 2 |
| | 3 | | 1 |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lip disorder | | 1 | | 1 | | |
| Loss of consciousness | | 2 | | | | 2 |
| Lymphocytosis | | 1 | | 1 | | |
| Malaise | | 1 | | 1 | | |
| Movement disorder | | 1 | | | | 1 |
| Multiple sclerosis relapse | | 1 | | | | 1 |
| Myalgia | 1 | 5 | 1 | 4 | | 1 |
| Myocardial infarction | | 1 | | | | 1 |
| Nausea | 1 | 7 | 1 | 5 | | 2 |
| Overdose | | 1 | | 1 | | |
| Oxygen saturation decreased | | 1 | | 1 | | |
| Pain in extremity | 2 | 7 | 2 | 7 | | |
| Pain in jaw | | 1 | | 1 | | |
| Palpitations | | 2 | | 2 | | |
| Pancreatitis | | 1 | | | | 1 |
| Paraesthesia | 1 | 3 | 1 | 3 | | |
| Paraesthesia oral | | 1 | | 1 | | |
| Pelvic fracture | | 1 | | | | 1 |
| Product preparation error | | 1 | | 1 | | |
| Pulpitis dental | | 1 | | 1 | | |
| Pyrexia | 2 | 7 | 1 | 6 | 1 | 1 |
| Rash | | 2 | | 2 | | |
| Respiratory rate increased | | 1 | | | | 1 |
| Rhinorrhoea | | 1 | | 1 | | |
| Rib fracture | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| Skin burning sensation | | 1 | | 1 | | |
| Speech disorder | | 1 | | 1 | | |
| Swelling face | | 1 | | 1 | | |
| Syncope | | 2 | | | | 2 |
| Thrombosis | | 2 | | | | 2 |
| Toothache | | 1 | | 1 | | |

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Age Range

65 - 79 years

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | | 1 |
| | 3 | | |
| | 1 | | |
| | 1 | | 1 |
| | | | 1 |
| | 3 | | |
| 26 | 149 | 12 | 71 |

38

220

26

149

12

71

Tooth injury

Torticollis

Tremor

Underdose

Urticaria

Vertigo

Vomiting

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 1 | 1 | 1 | 1 | | |
| Aspiration | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Brain injury | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 1 | 2 | | | 1 | 2 |
| Cardiac disorder | | 1 | | | | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | | 1 | | | | 1 |
| Circulatory collapse | | 1 | | | | 1 |
| Contusion | | 1 | | | | 1 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Crying | | 1 | | 1 | | |
| Death | 1 | 3 | | | 1 | 3 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 2 | | | 1 | 2 |
| Drug hypersensitivity | | 1 | | | | 1 |
| Drug ineffective | 2 | 3 | | | 2 | 3 |
| Dyskinesia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dyspepsia | | 1 | | 1 | | |
| Dyspnoea | 1 | 3 | | 1 | 1 | 2 |
| Endocarditis | 1 | 1 | | | 1 | 1 |
| Eye irritation | | 2 | | 1 | | 1 |
| Fall | | 1 | | | | 1 |
| Fatigue | 2 | 2 | 1 | 1 | 1 | 1 |
| Feeling cold | | 1 | | 1 | | |
| Gastric haemorrhage | 1 | 1 | | | 1 | 1 |
| Gastrointestinal necrosis | 1 | 1 | | | 1 | 1 |
| Headache | | 1 | | 1 | | |
| Hypertension | | 1 | | | | 1 |
| Inflammation | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ischaemic stroke | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | | 2 | | 1 | | 1 |
| Malaise | | 1 | | 1 | | |
| Movement disorder | | 1 | | 1 | | |
| Myalgia | 1 | 2 | 1 | 2 | | |
| Oedema | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 2 | 1 | 2 | | |
| Personality change | | 1 | | 1 | | |
| Pleural effusion | | 1 | | | | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Psychomotor hyperactivity | 1 | 1 | 1 | 1 | | |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory distress | | 1 | | | | 1 |
| Restlessness | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Sepsis | | 1 | | | | 1 |
| Suffocation feeling | | 1 | | 1 | | |
| Syncope | | 1 | | | | 1 |
| Vomiting | | 1 | | | | 1 |
| | 35 | 69 | 9 | 22 | 26 | 47 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Adverse event | | 1 | | 1 | | |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Alopecia | | 1 | | 1 | | |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 2 | 1 | 2 | | |
| Antibody test abnormal | | 1 | | 1 | | |
| Application site hypersensitivity | | 1 | | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 6 | 8 | 5 | 6 | 1 | 2 |
| Arthropathy | | 1 | | 1 | | |
| Asthenia | 5 | 32 | 5 | 32 | | |
| Asthenopia | 1 | 1 | 1 | 1 | | |
| Back pain | | 1 | | 1 | | |
| Balance disorder | | 1 | | 1 | | |
| Blood pressure increased | 1 | 2 | 1 | 1 | | 1 |
| Body temperature decreased | 1 | 2 | 1 | 2 | | |
| Cartilage injury | 1 | 1 | | | 1 | 1 |
| Chest pain | 2 | 2 | 2 | 2 | | |
| Chills | 8 | 20 | 8 | 20 | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 2 | 3 | 1 | 2 | 1 | 1 |
| Confusional state | | 1 | | 1 | | |
| Coronavirus infection | 1 | 2 | 1 | 1 | | 1 |
| Coronavirus test positive | | 1 | | | | 1 |
| Cough | | 2 | | 2 | | |
| COVID-19 | 4 | 7 | 1 | 1 | 3 | 6 |
| Depressed mood | | 1 | | 1 | | |
| Diarrhoea | | 2 | | 2 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Disease recurrence | 1 | 1 |
| Dizziness | 2 | 9 |
| Drug ineffective | 3 | 12 |
| Dry mouth | | 1 |
| Dyschromatopsia | 1 | 1 |
| Dysgeusia | | 2 |
| Dysphagia | | 1 |
| Dyspnoea | 2 | 3 |
| Dyspnoea exertional | 1 | 1 |
| Ear pain | | 1 |
| Exposure via breast milk | 1 | 2 |
| Eye infection | | 1 |
| Eye pain | 2 | 3 |
| Facial paralysis | 3 | 4 |
| Fall | | 1 |
| Fatigue | 4 | 20 |
| Feeling abnormal | | 2 |
| Feeling cold | 3 | 6 |
| Gastroenteritis viral | | 1 |
| Hallucination | 1 | 1 |
| Headache | 10 | 27 |
| Head discomfort | | 2 |
| Head injury | | 1 |
| Heart rate increased | 1 | 2 |
| Hemiplegia | 1 | 1 |
| Herpes zoster | 4 | 4 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | | 1 |
| Hypertension | 1 | 1 |
| Hypoaesthesia | | 7 |
| Hypoaesthesia oral | | 3 |
| Inappropriate schedule of product administration | | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 2 | 9 | | |
| 1 | 1 | 2 | 11 |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| | 1 | | |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| 2 | 2 | | 1 |
| | | 3 | 4 |
| | 1 | | |
| 4 | 20 | | |
| | 2 | | |
| 3 | 6 | | |
| | 1 | | |
| | | 1 | 1 |
| 10 | 26 | | 1 |
| | 2 | | |
| | | | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | 7 | | |
| | 3 | | |
| | 3 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Incomplete course of vaccination | | 1 |
| Influenza like illness | 1 | 4 |
| Initial insomnia | | 1 |
| Injection site erythema | | 1 |
| Injection site pain | 1 | 2 |
| Insomnia | 1 | 1 |
| Intentional dose omission | | 1 |
| Leukocytosis | 1 | 1 |
| Limb discomfort | | 1 |
| Lip pruritus | | 1 |
| Liquid product physical issue | 1 | 15 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 1 | 3 |
| Malaise | 2 | 7 |
| Maternal exposure during pregnancy | 2 | 2 |
| Mechanical urticaria | 1 | 1 |
| Menstrual disorder | 1 | 1 |
| Mental disorder | 1 | 1 |
| Migraine | 1 | 1 |
| Mobility decreased | | 1 |
| Mood altered | 1 | 1 |
| Motor dysfunction | | 1 |
| Multiple sclerosis relapse | | 1 |
| Muscle contractions involuntary | 1 | 2 |
| Muscular weakness | 1 | 1 |
| Myalgia | 3 | 19 |
| Myasthenia gravis | 1 | 1 |
| Myocarditis | 1 | 1 |
| Nasopharyngitis | | 1 |
| Nausea | 5 | 14 |
| Neck pain | | 1 |
| Neuralgic amyotrophy | | 2 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 4 | | |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 15 | | |
| | | 1 | 1 |
| 1 | 3 | | |
| 2 | 6 | | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| 3 | 18 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 5 | 14 | | |
| | 1 | | |
| | 2 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| No adverse event | 1 | 1 |
| Off label use | 1 | 1 |
| Oral herpes | | 3 |
| Oropharyngeal pain | 1 | 3 |
| Overdose | | 2 |
| Pain | 2 | 6 |
| Pain in extremity | 2 | 13 |
| Pain in jaw | | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | 3 | 6 |
| Paraesthesia oral | 2 | 6 |
| Paralysis | | 1 |
| Paraplegia | | 1 |
| Pericarditis | 1 | 2 |
| Photopsia | | 1 |
| Pneumonia | 2 | 2 |
| Poor quality product administered | 1 | 27 |
| Poor quality sleep | | 1 |
| Presyncope | 1 | 1 |
| Product complaint | | 1 |
| Product packaging quantity issue | | 11 |
| Product preparation error | | 2 |
| Product preparation issue | | 1 |
| Product use issue | 1 | 1 |
| Pruritus | | 1 |
| Pyrexia | 8 | 29 |
| Rash | | 3 |
| Rhinalgia | | 1 |
| Rhinorrhoea | | 1 |
| SARS-CoV-2 ant body test negative | 2 | 2 |
| SARS-CoV-2 test positive | 1 | 4 |
| Seizure | 8 | 8 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | | |
| | 2 | | 1 |
| 1 | 3 | | |
| | 2 | | |
| 1 | 5 | 1 | 1 |
| 2 | 13 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 5 | 1 | 1 |
| 1 | 5 | 1 | 1 |
| | | | 1 |
| | | | 1 |
| | | 1 | 2 |
| | 1 | | |
| | | 2 | 2 |
| 1 | 27 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 11 | | |
| | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 8 | 27 | | 2 |
| | 2 | | 1 |
| | 1 | | |
| | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | 3 |
| | | 8 | 8 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Sneezing | | 1 | | 1 | | |
| Somnolence | | 1 | | 1 | | |
| Stress | | 1 | | 1 | | |
| Sudden cardiac death | | 1 | | | | 1 |
| Suspected COVID-19 | | 1 | | | | 1 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swollen tongue | | 1 | | | | 1 |
| Syncope | | 3 | | | | 3 |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | | 1 | | 1 | | |
| Thinking abnormal | 1 | 1 | 1 | 1 | | |
| Tracheal oedema | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Underdose | | 2 | | 2 | | |
| Urinary tract infection | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 3 | 6 | 3 | 6 | | |
| Vaccination site hypersensitivity | | 1 | | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | | 1 | | 1 | | |
| Vaccination site pain | 5 | 32 | 5 | 32 | | |
| Vaccination site swelling | | 7 | | 7 | | |
| Vaginal haemorrhage | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 3 | 1 | 3 | | |
| Vomiting | 1 | 5 | 1 | 5 | | |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 168 | 545 | 127 | 461 | 41 | 84 |

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Country Where Event Occurred

ITALY

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Exposure via breast milk | | 1 | | 1 |
| Product administered to patient of inappropriate age | | 1 | | 1 |
| | | 2 | | 2 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 6 | 7 | 6 | 7 | | |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 2 | 2 | 1 | 1 | 1 | 1 |
| Anaesthesia oral | 1 | 1 | 1 | 1 | | |
| Anal incontinence | | 1 | | 1 | | |
| Anaphylactic reaction | 1 | 3 | | | 1 | 3 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Anuria | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 21 | 27 | 14 | 20 | 7 | 7 |
| Asthenia | 28 | 42 | 18 | 31 | 10 | 11 |
| Asthenopia | 1 | 1 | 1 | 1 | | |
| Asthma | 2 | 2 | | | 2 | 2 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Back pain | 5 | 6 | 2 | 3 | 3 | 3 |
| Blood pressure decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Blood pressure systolic increased | 2 | 2 | 2 | 2 | | |
| Bone pain | 3 | 3 | 3 | 3 | | |
| Bradycardia | 2 | 2 | | | 2 | 2 |
| Bronchospasm | 1 | 2 | | | 1 | 2 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 3 | 4 | | 1 | 3 | 3 |
| Chills | 29 | 36 | 22 | 29 | 7 | 7 |
| Clonus | 1 | 1 | | | 1 | 1 |
| Cold burn | 1 | 1 | 1 | 1 | | |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Confusional state | 3 | 4 | 1 | 1 | 2 | 3 |
| Contusion | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Coordination abnormal | 1 | 1 |
| Cough | 4 | 4 |
| COVID-19 | 5 | 5 |
| Cystitis haemorrhagic | 1 | 1 |
| Decreased appetite | 1 | 1 |
| Depressed level of consciousness | 4 | 5 |
| Diarrhoea | 9 | 15 |
| Disorientation | 1 | 1 |
| Dizziness | 22 | 25 |
| Drug ineffective | 4 | 4 |
| Dry mouth | 1 | 2 |
| Dysentery | 8 | 8 |
| Dysgeusia | | 3 |
| Dysmetria | 1 | 1 |
| Dyspepsia | 1 | 2 |
| Dysphagia | 4 | 5 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 7 | 8 |
| Ear pain | 2 | 2 |
| Encephalopathy | 1 | 1 |
| Erythema | 5 | 8 |
| Face oedema | 1 | 1 |
| Facial nerve disorder | 1 | 1 |
| Facial paralysis | 2 | 2 |
| Facial paresis | 2 | 2 |
| Fatigue | 16 | 19 |
| Febrile convulsion | 1 | 1 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | 2 | 2 |
| Feeling hot | 3 | 4 |
| Feeling of body temperature change | 1 | 2 |
| Flushing | 1 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 2 | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 5 |
| 4 | 10 | 5 | 5 |
| | | 1 | 1 |
| 8 | 11 | 14 | 14 |
| 1 | 1 | 3 | 3 |
| | 1 | 1 | 1 |
| | | 8 | 8 |
| | 3 | | |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | 4 | 4 |
| | | 1 | 1 |
| | 1 | 7 | 7 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 2 | 4 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| 11 | 14 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | 3 | 3 |
| | 1 | 1 | 1 |
| | 1 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Gastritis | | 1 |
| Gastrointestinal disorder | 2 | 2 |
| Gastrointestinal pain | 1 | 1 |
| Gingival swelling | 1 | 1 |
| Goitre | 1 | 1 |
| Haematuria | 1 | 1 |
| Headache | 48 | 73 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 1 | 1 |
| Hemianaesthesia | 1 | 1 |
| Hemiparaesthesia | 1 | 1 |
| Hot flush | | 2 |
| Hyperaemia | 1 | 1 |
| Hyperhidrosis | 5 | 8 |
| Hyperpyrexia | 17 | 17 |
| Hypersensitivity | 3 | 3 |
| Hypertensive crisis | 2 | 2 |
| Hyperthermia | 1 | 1 |
| Hypoaesthesia | 3 | 5 |
| Hypoaesthesia oral | 1 | 2 |
| Hypotension | 8 | 12 |
| Hypotonia | 2 | 2 |
| Illness | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Influenza like illness | 3 | 4 |
| Insomnia | 2 | 2 |
| Laryngeal oedema | 4 | 5 |
| Laryngeal pain | | 1 |
| Limb discomfort | | 2 |
| Lip oedema | 2 | 3 |
| Lip swelling | 1 | 2 |
| Localised oedema | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 33 | 58 | 15 | 15 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |
| 2 | 4 | 3 | 4 |
| | | 17 | 17 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| 2 | 4 | 1 | 1 |
| 1 | 2 | | |
| 1 | 4 | 7 | 8 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | 2 | 2 |
| | | 2 | 2 |
| | | 4 | 5 |
| | 1 | | |
| | 2 | | |
| | | 2 | 3 |
| | 1 | 1 | 1 |
| 2 | 2 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Loss of consciousness | 13 | 14 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 13 | 16 |
| Lymph node pain | 1 | 2 |
| Lymphoedema | 1 | 1 |
| Macroglossia | 1 | 1 |
| Malaise | 7 | 11 |
| Maternal exposure during pregnancy | 1 | 1 |
| Mechanical urticaria | 1 | 2 |
| Menstrual disorder | 1 | 1 |
| Middle insomnia | 2 | 2 |
| Migraine | 1 | 2 |
| Mouth swelling | 1 | 1 |
| Mouth ulceration | 1 | 1 |
| Muscle oedema | 1 | 1 |
| Muscle rigidity | 1 | 1 |
| Muscle spasms | 3 | 3 |
| Muscular weakness | 2 | 2 |
| Musculoskeletal pain | 8 | 9 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 26 | 31 |
| Myocarditis | 1 | 1 |
| Nausea | 26 | 35 |
| Neck pain | 2 | 2 |
| Neuralgia | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Nuchal rigidity | 1 | 1 |
| Obstructive airways disorder | 1 | 2 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 2 | 2 |
| Orthostatic hypotension | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 13 | 14 |
| | | 1 | 1 |
| 4 | 7 | 9 | 9 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 8 | 3 | 3 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| 1 | 1 | 1 | 1 |
| 6 | 7 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 18 | 23 | 8 | 8 |
| | | 1 | 1 |
| 15 | 24 | 11 | 11 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Overdose | 3 | 4 |
| Oxygen saturation decreased | 2 | 2 |
| Pain | 8 | 9 |
| Pain in extremity | 10 | 16 |
| Pallor | 1 | 2 |
| Palpitations | 2 | 2 |
| Paraesthesia | 15 | 17 |
| Paraesthesia oral | 4 | 5 |
| Paralysis | 1 | 1 |
| Pericardial effusion | 1 | 1 |
| Pericarditis | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal erythema | | 1 |
| Pharyngeal swelling | 1 | 1 |
| Pharyngitis | 1 | 1 |
| Presyncope | 8 | 11 |
| Product administered at inappropriate site | 2 | 2 |
| Product preparation issue | 1 | 1 |
| Pruritus | 8 | 11 |
| Pyrexia | 74 | 92 |
| Quality of life decreased | 1 | 1 |
| Rash | 8 | 12 |
| Rash erythematous | 3 | 3 |
| Rash pruritic | 1 | 1 |
| Respiratory fatigue | 1 | 1 |
| Rhinitis allergic | 1 | 1 |
| Rhinorrhoea | | 1 |
| SARS-CoV-2 test positive | 2 | 2 |
| Sensation of foreign body | 1 | 2 |
| Sensory loss | 1 | 1 |
| Sinus tachycardia | 1 | 2 |
| Soft tissue infection | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 4 | | |
| | | 2 | 2 |
| 3 | 4 | 5 | 5 |
| 4 | 10 | 6 | 6 |
| | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 4 | 6 | 11 | 11 |
| 1 | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 4 | 7 | 7 |
| 2 | 2 | | |
| 1 | 1 | | |
| 2 | 4 | 6 | 7 |
| 41 | 58 | 33 | 34 |
| 1 | 1 | | |
| 2 | 5 | 6 | 7 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Somnolence | 5 | 9 |
| Swelling | | 1 |
| Swelling face | 1 | 2 |
| Swollen tongue | 1 | 1 |
| Syncope | 17 | 17 |
| Tachycardia | 8 | 15 |
| Tachycardia paroxysmal | | 1 |
| Terminal insomnia | 1 | 1 |
| Thermal burns of eye | 1 | 1 |
| Throat irritation | 2 | 2 |
| Throat tightness | 2 | 3 |
| Thyroid pain | 1 | 1 |
| Tongue oedema | 1 | 1 |
| Tonic clonic movements | | 1 |
| Tonsillitis | 1 | 1 |
| Toothache | 1 | 1 |
| Tremor | 6 | 7 |
| Troponin T increased | 1 | 1 |
| Underdose | 1 | 2 |
| Urinary incontinence | 1 | 1 |
| Urticaria | 5 | 8 |
| Vaccination complication | | 1 |
| Vaccination site discomfort | | 2 |
| Vaccination site erythema | 6 | 8 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site hypoaesthesia | 2 | 2 |
| Vaccination site induration | 1 | 2 |
| Vaccination site joint warmth | | 1 |
| Vaccination site lymphadenopathy | 2 | 2 |
| Vaccination site mass | 1 | 1 |
| Vaccination site movement impairment | 1 | 2 |
| Vaccination site oedema | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 6 | 3 | 3 |
| | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 17 | 17 |
| | 7 | 8 | 8 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 3 | 4 | 4 |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 3 | 4 | 5 |
| | 1 | | |
| | 2 | | |
| 1 | 3 | 5 | 5 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 37 | 56 | 26 | 45 | 11 | 11 |
| Vaccination site paraesthesia | 3 | 6 | 1 | 4 | 2 | 2 |
| Vaccination site pruritus | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site swelling | 6 | 9 | 3 | 6 | 3 | 3 |
| Vaccination site vesicles | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vasodilatation | 1 | 1 | | | 1 | 1 |
| Vertigo | 6 | 9 | 1 | 4 | 5 | 5 |
| Vision blurred | 3 | 5 | 1 | 3 | 2 | 2 |
| Vomiting | 7 | 8 | 2 | 3 | 5 | 5 |
| | 788 | 1,025 | 344 | 561 | 444 | 464 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | | 1 | | | | 1 | | |
| Abdominal distension | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Abdominal pain | 24 | 32 | | | 10 | 17 | 14 | 15 |
| Abdominal pain upper | 15 | 20 | | | 5 | 10 | 10 | 10 |
| Abortion | 1 | 1 | | | | | 1 | 1 |
| Acquired macroglossia | 1 | 1 | | | | | 1 | 1 |
| Ageusia | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Agitation | 7 | 10 | | | 3 | 6 | 4 | 4 |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 | | |
| Allergic cough | 1 | 1 | | | | | 1 | 1 |
| Allergy to vaccine | 2 | 2 | | | | | 2 | 2 |
| Allodynia | | 1 | | | | 1 | | |
| Amylase increased | 1 | 1 | | | | | 1 | 1 |
| Anaemia | 1 | 1 | | | 1 | 1 | | |
| Anaesthesia | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Anaesthesia oral | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Anal sphincter atony | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 10 | 17 | | | | | 10 | 17 |
| Anaphylactic shock | 4 | 7 | | | | | 4 | 7 |
| Anaphylactoid reaction | 1 | 1 | | | | | 1 | 1 |
| Angina pectoris | 3 | 3 | | | | | 3 | 3 |
| Angioedema | 17 | 19 | | | | | 17 | 19 |
| Angiomyolipoma | 1 | 1 | | | | | 1 | 1 |
| Anosmia | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Anterograde amnesia | 1 | 1 | | | | | 1 | 1 |
| Anxiety | 3 | 3 | | | | | 3 | 3 |
| Apathy | 1 | 1 | | | | | 1 | 1 |
| Aphasia | 1 | 1 | | | | | 1 | 1 |
| Aphthous ulcer | 2 | 2 | | | | | 2 | 2 |
| Arrhythmia | 2 | 2 | | | | | 2 | 2 |
| Arthralgia | 106 | 125 | 2 | 2 | 48 | 67 | 58 | 58 |
| Arthropod sting | 1 | 1 | | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Asphyxia | | 1 |
| Asthenia | 112 | 128 |
| Asthenopia | 2 | 2 |
| Asthmatic crisis | 3 | 3 |
| Asymptomatic COVID-19 | 1 | 1 |
| Atrial f brillation | 1 | 1 |
| Aura | | 1 |
| Autoimmune thyroiditis | 1 | 1 |
| Axillary pain | 11 | 14 |
| Azotaemia | 1 | 1 |
| Back pain | 12 | 14 |
| Balance disorder | 4 | 5 |
| Band sensation | 2 | 3 |
| Barotrauma | 1 | 1 |
| Basedow's disease | 1 | 1 |
| Blindness | 2 | 2 |
| Blood glucose increased | 1 | 2 |
| Blood potassium decreased | 1 | 1 |
| Blood pressure decreased | 5 | 6 |
| Blood pressure diastolic increased | | 1 |
| Blood pressure fluctuation | 1 | 1 |
| Blood pressure increased | 12 | 17 |
| Body temperature decreased | | 2 |
| Body temperature increased | 1 | 3 |
| Bone pain | 12 | 14 |
| Bradycardia | 2 | 3 |
| Brain neoplasm | 1 | 1 |
| Breast pain | 1 | 1 |
| Breath sounds | 1 | 1 |
| Breath sounds abnormal | 1 | 1 |
| Bronchospasm | 6 | 6 |
| Bronchostenosis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| 3 | 3 | 50 | 65 | 62 | 63 |
| | | 2 | 2 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 7 | 9 | 4 | 5 |
| | | | | 1 | 1 |
| 1 | 1 | 6 | 7 | 6 | 7 |
| | | | 1 | 4 | 4 |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 3 | 2 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 5 | 10 | 12 |
| | | | 2 | | |
| | | | 2 | 1 | 1 |
| | | 7 | 9 | 5 | 5 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 6 |
| | | | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Burning sensation | 4 | 4 |
| Carotid artery dissection | 1 | 1 |
| Central cord syndrome | 1 | 1 |
| Chest discomfort | 16 | 19 |
| Chest expansion decreased | 1 | 1 |
| Chest pain | 12 | 14 |
| Chills | 119 | 137 |
| Choking | 1 | 1 |
| Circumoral swelling | 1 | 1 |
| Clonus | 1 | 1 |
| Cold sweat | 2 | 2 |
| Confusional state | 12 | 14 |
| Conjunctival haemorrhage | 1 | 1 |
| Conjunctivitis | 3 | 3 |
| Constipation | | 1 |
| Cough | 29 | 35 |
| COVID-19 | 7 | 10 |
| Cranial nerve disorder | 1 | 2 |
| Cranial nerve paralysis | 1 | 1 |
| C-reactive protein increased | 2 | 2 |
| Cyanosis | 3 | 3 |
| Cystitis haemorrhagic | 1 | 1 |
| Deafness neurosensory | 1 | 1 |
| Decreased appetite | 6 | 7 |
| Dehydration | 1 | 1 |
| Delirium | 1 | 1 |
| Demyelinating polyneuropathy | 1 | 1 |
| Depressed level of consciousness | 16 | 16 |
| Dermatitis | | 1 |
| Dermatitis allergic | 2 | 2 |
| Dermatitis atopic | 1 | 1 |
| Dermatitis bullous | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 4 | 6 | 12 | 13 |
| | | 1 | 1 | | |
| 1 | 1 | | 2 | 12 | 12 |
| 1 | 1 | 56 | 74 | 63 | 63 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 5 | 7 | 7 | 7 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | | |
| | | 3 | 8 | 26 | 27 |
| | | 3 | 3 | 4 | 7 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 5 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 15 | 15 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Dermatitis exfoliative generalised | 1 | 1 |
| Diaphragmatic spasm | 1 | 1 |
| Diarrhoea | 44 | 58 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diastolic hypotension | 1 | 1 |
| Diplegia | 1 | 1 |
| Diplopia | 3 | 3 |
| Discomfort | 3 | 4 |
| Disease recurrence | 2 | 3 |
| Disorientation | 3 | 3 |
| Disturbance in attention | 4 | 4 |
| Dizziness | 45 | 50 |
| Drug hypersensitivity | 2 | 2 |
| Drug ineffective | 3 | 6 |
| Dry mouth | 11 | 17 |
| Dry skin | 2 | 2 |
| Dry throat | 1 | 2 |
| Dysaesthesia | 3 | 6 |
| Dysaesthesia pharynx | 1 | 1 |
| Dysentery | 46 | 46 |
| Dysgeusia | 9 | 18 |
| Dyskinesia | 1 | 1 |
| Dyspepsia | 2 | 2 |
| Dysphagia | 10 | 17 |
| Dysphonia | 7 | 8 |
| Dyspnoea | 65 | 74 |
| Dyspnoea at rest | 1 | 1 |
| Dyspnoea exertional | 1 | 1 |
| Ear discomfort | 2 | 2 |
| Ear infection | 1 | 1 |
| Ear pain | 6 | 6 |
| Ear pruritus | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 15 | 29 | 29 | 29 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 3 | 4 | | |
| | | | 1 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 4 | 4 |
| | | 19 | 24 | 26 | 26 |
| | | | | 2 | 2 |
| | | 1 | 1 | 2 | 5 |
| 1 | 1 | 2 | 6 | 9 | 11 |
| | | | | 2 | 2 |
| | | 1 | 2 | | |
| | | 2 | 5 | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | | | 46 | 46 |
| | | 5 | 12 | 4 | 6 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| 1 | 1 | 5 | 9 | 5 | 8 |
| | | 1 | 2 | 6 | 6 |
| 1 | 1 | 9 | 15 | 56 | 59 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | 4 | 4 |
| | | 2 | 2 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Ear swelling | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Enanthema | 1 | 1 |
| Eosinophil count decreased | 1 | 1 |
| Epilepsy | 1 | 1 |
| Epistaxis | 3 | 3 |
| Erythema | 38 | 52 |
| Erythema multiforme | 1 | 1 |
| Exposure to SARS-CoV-2 | 1 | 1 |
| Extrasystoles | 2 | 2 |
| Extremity contracture | | 1 |
| Eye colour change | 1 | 1 |
| Eye irritation | 4 | 5 |
| Eyelid myoclonus | 1 | 1 |
| Eyelid oedema | 4 | 5 |
| Eyelid ptosis | 2 | 2 |
| Eye oedema | 2 | 2 |
| Eye pain | 6 | 8 |
| Eye pruritus | 1 | 3 |
| Eye swelling | 3 | 3 |
| Face oedema | 3 | 4 |
| Facial nerve disorder | 1 | 1 |
| Facial pain | 4 | 4 |
| Facial paralysis | 16 | 17 |
| Facial paresis | 4 | 4 |
| Facial spasm | | 1 |
| Faeces soft | 1 | 1 |
| Fatigue | 72 | 85 |
| Feeling abnormal | 3 | 3 |
| Feeling cold | 7 | 11 |
| Feeling hot | 24 | 33 |
| Flatulence | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 9 | 21 | 29 | 31 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 3 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 5 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 4 | 4 | 4 |
| | | | 1 | 1 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 16 | 17 |
| | | | | 4 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 27 | 40 | 45 | 45 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 4 | 6 | 7 |
| 1 | 1 | 9 | 16 | 15 | 17 |
| | | | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Flushing | 12 | 17 |
| Foreign body in throat | 1 | 1 |
| Gait disturbance | 3 | 3 |
| Gastrointestinal disorder | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Glossodynia | 1 | 1 |
| Haematochezia | 1 | 1 |
| Haematoma | | 1 |
| Hallucination | 1 | 1 |
| Hallucination, auditory | 1 | 1 |
| Hallucination, olfactory | 1 | 1 |
| Hallucination, visual | 1 | 1 |
| Haptoglobin increased | 1 | 1 |
| Headache | 219 | 278 |
| Head injury | 1 | 1 |
| Heart rate abnormal | 1 | 1 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 3 | 3 |
| Hemianaesthesia | 3 | 3 |
| Hemianopia heteronymous | 1 | 1 |
| Hemidysaesthesia | 2 | 2 |
| Hemihyperaesthesia | 1 | 1 |
| Hemiparaesthesia | 14 | 14 |
| Hemiparesis | 4 | 4 |
| Hemiplegia | 2 | 2 |
| Hepatitis acute | 1 | 1 |
| Herpes simplex | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Herpes zoster infection neurological | 1 | 1 |
| Herpes zoster oticus | 1 | 1 |
| Hot flush | 7 | 12 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 7 | 10 | 10 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 3 | 3 | 87 | 145 | 132 | 133 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 14 | 14 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 6 | 6 | 6 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyperaesthesia | 1 | 1 |
| Hyperglycaemia | 1 | 1 |
| Hyperhidrosis | 19 | 26 |
| Hyperpyrexia | 61 | 61 |
| Hyperreflexia | 1 | 1 |
| Hypersensitivity | 12 | 13 |
| Hypersomnia | 1 | 1 |
| Hypertension | 19 | 23 |
| Hypertensive crisis | 22 | 25 |
| Hyperthermia | 3 | 3 |
| Hyperventilation | 3 | 3 |
| Hypoaesthesia | 20 | 27 |
| Hypoaesthesia oral | 4 | 8 |
| Hypokinesia | 1 | 1 |
| Hyposmia | 1 | 1 |
| Hypotension | 22 | 25 |
| Hypotensive crisis | 2 | 2 |
| Hypothermia | 4 | 4 |
| Hypoxia | 1 | 1 |
| Idiosyncratic drug reaction | 1 | 1 |
| Illness | 1 | 2 |
| Immobile | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect dose administered | | 2 |
| Incorrect route of product administration | 5 | 6 |
| Inflammation | 1 | 1 |
| Inflammatory pain | 1 | 1 |
| Influenza | 3 | 3 |
| Influenza like illness | 2 | 4 |
| Initial insomnia | 1 | 1 |
| Injection site pain | 3 | 3 |
| Injection site pruritus | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 7 | 13 | 12 | 13 |
| | | | | 61 | 61 |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 1 | 11 | 12 |
| | | 1 | 1 | | |
| | | 1 | 3 | 18 | 20 |
| | | | | 22 | 25 |
| | | 1 | 1 | 2 | 2 |
| 1 | 1 | | | 3 | 3 |
| 1 | 1 | 7 | 13 | 13 | 14 |
| | | 3 | 7 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 6 | 8 | 16 | 17 |
| | | | | 2 | 2 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 5 | 6 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 3 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Injection site rash | 1 | 1 |
| Insomnia | 11 | 13 |
| Interstitial lung disease | 2 | 2 |
| Intestinal pseudo-obstruction | 1 | 1 |
| Intranasal hypoaesthesia | 1 | 1 |
| Joint range of motion decreased | 1 | 2 |
| Lacrimation increased | 1 | 3 |
| Laryngeal dyspnoea | 1 | 1 |
| Laryngeal obstruction | 2 | 2 |
| Laryngeal oedema | 17 | 20 |
| Laryngeal stenosis | 1 | 1 |
| Laryngospasm | 3 | 4 |
| Limb discomfort | 6 | 8 |
| Lip oedema | 10 | 15 |
| Lip pruritus | 3 | 4 |
| Lip swelling | 5 | 5 |
| Localised oedema | 2 | 3 |
| Loss of consciousness | 21 | 21 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenitis | 10 | 12 |
| Lymphadenopathy | 81 | 95 |
| Lymphangitis | 2 | 2 |
| Lymph node pain | 12 | 14 |
| Lymphocyte count increased | 1 | 1 |
| Lymphocytosis | 1 | 1 |
| Lymphoedema | | 1 |
| Lymphopenia | 1 | 1 |
| Malaise | 33 | 43 |
| Mastitis | 2 | 2 |
| Maternal exposure during pregnancy | 1 | 1 |
| Mechanical urticaria | 1 | 1 |
| Mental disorder | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 4 | 6 | 7 | 7 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 3 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 17 | 20 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | 3 | 5 | 3 | 3 |
| | | 1 | 5 | 9 | 10 |
| | | 2 | 3 | 1 | 1 |
| | | 1 | 1 | 4 | 4 |
| | | 1 | 2 | 1 | 1 |
| | | | | 21 | 21 |
| | | 1 | 1 | | |
| | | 3 | 5 | 7 | 7 |
| | | 24 | 38 | 57 | 57 |
| | | | | 2 | 2 |
| | | 6 | 8 | 6 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 12 | 21 | 21 | 22 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| 1 | 1 | 1 | 1 | | |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Mental impairment | 1 | 1 |
| Metrorrhagia | 1 | 1 |
| Migraine | 15 | 20 |
| Mobility decreased | 1 | 1 |
| Monocyte count decreased | 1 | 1 |
| Monoparesis | | 1 |
| Monoplegia | 1 | 1 |
| Mood altered | 2 | 2 |
| Mouth ulceration | 1 | 1 |
| Movement disorder | 4 | 4 |
| Mucosal dryness | | 1 |
| Mucosal hyperaemia | 1 | 1 |
| Muscle contractions involuntary | 1 | 2 |
| Muscle contracture | 1 | 1 |
| Muscle rigidity | 2 | 3 |
| Muscle spasms | 3 | 4 |
| Muscular weakness | 9 | 11 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal pain | 27 | 31 |
| Musculoskeletal stiffness | 5 | 7 |
| Myalgia | 138 | 164 |
| Myalgia intercostal | 1 | 1 |
| Myasthenia gravis crisis | 1 | 1 |
| Myoclonus | 1 | 1 |
| Nasal congestion | 2 | 3 |
| Nasal obstruction | 1 | 1 |
| Nasal oedema | 1 | 1 |
| Nasopharyngitis | 1 | 3 |
| Nausea | 111 | 131 |
| Neck pain | 6 | 8 |
| Neuralgia | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 10 | 10 | 10 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | 1 | 3 | 3 |
| | | 3 | 5 | 6 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 11 | 15 | 16 | 16 |
| 1 | 1 | 1 | 3 | 4 | 4 |
| 2 | 2 | 66 | 91 | 72 | 73 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | 1 |
| | | 42 | 60 | 69 | 71 |
| | | 2 | 4 | 4 | 4 |
| | | 1 | 2 | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Neuritis | 1 | 2 |
| Neurological symptom | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Neurotoxicity | 1 | 1 |
| Neutrophil count increased | 1 | 1 |
| Nightmare | 1 | 1 |
| Night sweats | 1 | 2 |
| No adverse event | 1 | 1 |
| Nuchal rigidity | 3 | 5 |
| Obstructive airways disorder | 2 | 2 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | 2 | 4 |
| Odynophagia | 1 | 1 |
| Oedema | 1 | 1 |
| Oedema mucosal | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Oesophageal pain | 1 | 1 |
| Oesophageal spasm | 1 | 1 |
| Off label use | 7 | 7 |
| Ophthalmic herpes simplex | 1 | 1 |
| Optic neuritis | 3 | 3 |
| Optic neuropathy | 1 | 1 |
| Oral discomfort | 2 | 2 |
| Oral herpes | 2 | 3 |
| Oral pruritus | 2 | 2 |
| Oropharyngeal discomfort | 6 | 6 |
| Oropharyngeal pain | 12 | 14 |
| Overdose | 9 | 10 |
| Oxygen saturation decreased | 9 | 9 |
| Pain | 39 | 48 |
| Pain in extremity | 39 | 58 |
| Pain in jaw | 4 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 3 | 4 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 2 | 3 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 6 | 6 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | 2 | 2 | 4 | 4 |
| | | 2 | 4 | 10 | 10 |
| | | 9 | 10 | | |
| | | | | 9 | 9 |
| | | 22 | 30 | 17 | 18 |
| | | 15 | 34 | 24 | 24 |
| | | 1 | 1 | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Palatal oedema | 2 | 3 |
| Palatal swelling | | 1 |
| Pallor | 2 | 3 |
| Palpitations | 7 | 9 |
| Panic attack | 1 | 1 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 70 | 87 |
| Paraesthesia oral | 36 | 50 |
| Paralysis | 2 | 2 |
| Paraparesis | 1 | 1 |
| Paresis | 1 | 1 |
| Paresis cranial nerve | | 1 |
| Parosmia | | 1 |
| Pericarditis | 1 | 1 |
| Periorbital discomfort | 1 | 1 |
| Periorbital oedema | | 1 |
| Peripheral coldness | 1 | 3 |
| Peripheral swelling | 5 | 5 |
| Petechiae | 1 | 1 |
| Pharyngeal erythema | 2 | 2 |
| Pharyngeal hypoesthesia | 1 | 1 |
| Pharyngeal oedema | 3 | 3 |
| Pharyngeal paraesthesia | 2 | 3 |
| Pharyngeal swelling | 5 | 5 |
| Pharyngitis | 1 | 2 |
| Photophobia | 1 | 1 |
| Photopsia | 1 | 1 |
| Photosensitivity reaction | 1 | 1 |
| Polyuria | 1 | 1 |
| Presyncope | 21 | 25 |
| Product administered at inappropriate site | 1 | 1 |
| Product preparation issue | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | | 1 | 2 | 2 |
| | | 4 | 6 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | 21 | 36 | 49 | 51 |
| 2 | 2 | 9 | 20 | 27 | 30 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| 1 | 1 | | 2 | 1 | 1 |
| | | 3 | 3 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | 1 | 2 | 2 |
| | | 2 | 2 | 3 | 3 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 7 | 17 | 18 |
| | | 1 | 1 | | |
| | | 2 | 2 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Product use issue | 6 | 6 |
| Pruritus | 30 | 44 |
| Psoriasis | 1 | 1 |
| Pyrexia | 254 | 304 |
| Q fever | 4 | 4 |
| Quality of life decreased | 1 | 1 |
| Radiculopathy | 1 | 1 |
| Rales | 1 | 1 |
| Rash | 43 | 56 |
| Rash erythematous | 2 | 3 |
| Rash macular | 1 | 1 |
| Rash morbilliform | 1 | 1 |
| Rash pruritic | 9 | 10 |
| Reduced facial expression | | 1 |
| Renal pain | 1 | 2 |
| Respiratory disorder | 1 | 2 |
| Respiratory distress | 2 | 3 |
| Respiratory fatigue | 4 | 4 |
| Respiratory rate increased | 1 | 1 |
| Retching | 4 | 6 |
| Retrograde amnesia | 1 | 1 |
| Rhinitis | 1 | 1 |
| Rhinorrhoea | 1 | 2 |
| Rosacea | 1 | 1 |
| Salivary hypersecretion | 2 | 2 |
| SARS-CoV-2 test positive | 1 | 2 |
| Seasonal allergy | 1 | 1 |
| Sedation | 1 | 1 |
| Seizure | 3 | 3 |
| Sensation of foreign body | 2 | 2 |
| Sense of oppression | 2 | 2 |
| Sensory disturbance | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 4 | 2 | 2 |
| | | 8 | 20 | 22 | 24 |
| | | | | 1 | 1 |
| 3 | 3 | 84 | 133 | 170 | 171 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 10 | 21 | 33 | 35 |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 3 | 7 | 7 |
| | | | | | 1 |
| | | 1 | 2 | | |
| | | | 1 | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | 2 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Sensory loss | 2 | 2 |
| Sinus bradycardia | 1 | 1 |
| Sinus headache | 1 | 1 |
| Sinus tachycardia | 3 | 3 |
| Sjogren's syndrome | 1 | 1 |
| Skin reaction | 3 | 4 |
| Skin tightness | 1 | 1 |
| Skin warm | 3 | 3 |
| Somnolence | 15 | 24 |
| Sopor | 1 | 1 |
| Speech disorder | | 1 |
| Spinal pain | 2 | 6 |
| Stupor | 3 | 3 |
| Suffocation feeling | 1 | 1 |
| Swelling | 7 | 9 |
| Swelling face | 6 | 7 |
| Swelling of eyelid | 2 | 3 |
| Swollen tongue | 3 | 6 |
| Syncope | 35 | 35 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 61 | 73 |
| Tachycardia paroxysmal | | 1 |
| Tachypnoea | 3 | 4 |
| Taste disorder | 4 | 4 |
| Tenderness | 1 | 1 |
| Tension headache | 1 | 1 |
| Terminal insomnia | 1 | 1 |
| Throat irritation | 9 | 12 |
| Throat tightness | 14 | 22 |
| Thyroid disorder | 1 | 1 |
| Thyroid hormones increased | 1 | 1 |
| Tinnitus | 4 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 7 | 16 | 8 | 8 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 5 | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 3 | 5 | 4 | 4 |
| | | 1 | 1 | 5 | 6 |
| | | 2 | 3 | | |
| | | | 2 | 3 | 4 |
| | | | | 35 | 35 |
| | | 1 | 1 | | |
| 2 | 2 | 12 | 22 | 49 | 51 |
| | | | 1 | | |
| | | 1 | 2 | 2 | 2 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 3 | 8 | 9 |
| | | 1 | 5 | 13 | 17 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Tongue discolouration | 1 | 1 |
| Tongue discomfort | 1 | 1 |
| Tongue disorder | | 1 |
| Tongue dry | | 3 |
| Tongue erythema | 1 | 1 |
| Tongue oedema | 5 | 7 |
| Tongue pruritus | 1 | 1 |
| Tonic clonic movements | 1 | 1 |
| Tonic convulsion | 1 | 1 |
| Tonsillar erythema | | 1 |
| Tonsillar hypertrophy | | 1 |
| Torticollis | 1 | 1 |
| Toxic skin eruption | 1 | 1 |
| Tracheitis | 1 | 1 |
| Transaminases increased | 1 | 1 |
| Tremor | 20 | 26 |
| Trigeminal nerve disorder | 4 | 4 |
| Type I hypersensitivity | 2 | 2 |
| Underdose | 3 | 4 |
| Upper respiratory tract inflammation | 1 | 1 |
| Urine output decreased | 1 | 1 |
| Urticaria | 41 | 57 |
| Use of accessory respiratory muscles | 1 | 1 |
| Vaccination complication | 5 | 5 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | 1 | 1 |
| Vaccination site discomfort | | 1 |
| Vaccination site erythema | 9 | 15 |
| Vaccination site induration | 2 | 2 |
| Vaccination site inflammation | 1 | 1 |
| Vaccination site ischaemia | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 4 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 6 | 19 | 20 |
| | | 1 | 1 | 3 | 3 |
| | | | | 2 | 2 |
| | | 3 | 4 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 20 | 36 | 37 |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 1 | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 6 | 11 | 3 | 4 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Vaccination site joint swelling | | 1 |
| Vaccination site lymphadenopathy | 1 | 1 |
| Vaccination site movement impairment | 2 | 3 |
| Vaccination site oedema | 9 | 11 |
| Vaccination site pain | 113 | 180 |
| Vaccination site paraesthesia | 3 | 3 |
| Vaccination site pruritus | 3 | 6 |
| Vaccination site reaction | 1 | 1 |
| Vaccination site swelling | 17 | 22 |
| Vaccination site urticaria | 1 | 6 |
| Vaccination site warmth | 6 | 10 |
| Vascular rupture | 1 | 1 |
| Vasoconstriction | 3 | 4 |
| Vasomotor rhinitis | | 1 |
| Ventricular extrasystoles | 1 | 1 |
| Vertigo | 27 | 40 |
| Vertigo positional | 1 | 1 |
| Vision blurred | 4 | 5 |
| Visual impairment | 1 | 2 |
| Vocal cord dysfunction | 1 | 1 |
| Volvulus | 1 | 1 |
| Vomiting | 40 | 49 |
| Vomiting projectile | 2 | 2 |
| Wheezing | 3 | 3 |
| White blood cell count increased | 2 | 2 |
| Wound | 1 | 1 |
| Wrong technique in product usage process | | 1 |
| | 3,517 | 4,353 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|-----|---------|------|------|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | | 1 | | | | |
| | | 1 | 1 | | | | |
| | | 2 | 3 | | | | |
| | | 3 | 5 | 6 | 6 | | |
| 2 | 2 | 60 | 125 | 53 | 55 | | |
| | | 1 | 1 | 2 | 2 | | |
| | | 2 | 5 | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | 10 | 14 | 7 | 8 | | |
| | | | 4 | 1 | 2 | | |
| | | 3 | 6 | 3 | 4 | | |
| | | | | 1 | 1 | | |
| | | | 1 | 3 | 3 | | |
| | | | 1 | | | | |
| | | | | 1 | 1 | | |
| | | 11 | 23 | 16 | 17 | | |
| | | | | 1 | 1 | | |
| | | 1 | 2 | 3 | 3 | | |
| | | | 1 | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | 10 | 19 | 30 | 30 | | |
| | | | | 2 | 2 | | |
| | | | | 3 | 3 | | |
| | | | | 2 | 2 | | |
| | | | | 1 | 1 | | |
| | | | 1 | | | | |
| | | 38 | 38 | 1094 | 1817 | 2423 | 2536 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal distension | 1 | 1 | | | | | 1 | 1 |
| Abdominal pain | 18 | 23 | | | 9 | 14 | 9 | 9 |
| Abdominal pain upper | 9 | 12 | | | 3 | 6 | 6 | 6 |
| Accommodation disorder | 1 | 1 | | | | | 1 | 1 |
| Acute coronary syndrome | | 1 | | | | | | 1 |
| Acute myocardial infarction | | 1 | | | | | | 1 |
| Acute respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Administration site movement impairment | 1 | 1 | | | | | 1 | 1 |
| Administration site reaction | | 1 | | | | | | 1 |
| Ageusia | 6 | 6 | | | 4 | 4 | 2 | 2 |
| Agitation | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 | | |
| Allergy to vaccine | 2 | 3 | | | | | 2 | 3 |
| Amnesia | 1 | 1 | | | 1 | 1 | | |
| Anaesthesia | 1 | 2 | | | 1 | 2 | | |
| Anaphylactic reaction | 1 | 3 | | | | | 1 | 3 |
| Anaphylactic shock | 2 | 4 | | | | | 2 | 4 |
| Anaphylactoid reaction | 1 | 1 | | | | | 1 | 1 |
| Angioedema | 8 | 8 | | | | | 8 | 8 |
| Anosmia | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Anterograde amnesia | 1 | 1 | | | | | 1 | 1 |
| Anuria | 1 | 1 | | | | | 1 | 1 |
| Anxiety | 1 | 4 | | | 1 | 4 | | |
| Aphasia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Aphonia | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Aphthous ulcer | 1 | 1 | | | 1 | 1 | | |
| Apnoea | 1 | 1 | | | | | 1 | 1 |
| Arrhythmia | 5 | 5 | | | | | 5 | 5 |
| Arthralgia | 100 | 116 | | | 38 | 52 | 62 | 64 |
| Asthenia | 94 | 102 | | | 32 | 40 | 62 | 62 |
| Asthma | 3 | 3 | | | | | 3 | 3 |
| Asthmatic crisis | 2 | 2 | | | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Atrial f brillation | 1 | 1 |
| Atrial tachycardia | 1 | 1 |
| Axillary pain | 6 | 9 |
| Back pain | 9 | 10 |
| Balance disorder | | 1 |
| Blepharospasm | 1 | 1 |
| Blindness | 1 | 1 |
| Blood alkaline phosphatase increased | 1 | 1 |
| Blood pressure decreased | | |
| Blood pressure increased | 10 | 11 |
| Body temperature increased | 2 | 4 |
| Bone pain | 20 | 21 |
| Bradycardia | 3 | 3 |
| Breast abscess | 1 | 1 |
| Breast discomfort | | 1 |
| Breast pain | | 1 |
| Breast swelling | | 1 |
| Bronchospasm | 6 | 6 |
| Burning sensation | 2 | 3 |
| Butterfly rash | 1 | 1 |
| Catarrh | 1 | 1 |
| Cerebral disorder | 1 | 1 |
| Cerebral venous sinus thrombosis | 1 | 1 |
| Cervicobrachial syndrome | 1 | 1 |
| Chest discomfort | 4 | 6 |
| Chest pain | 9 | 10 |
| Chills | 82 | 100 |
| Chromaturia | 1 | 1 |
| Chronic respiratory failure | 1 | 1 |
| Clonus | 1 | 1 |
| Coagulopathy | 1 | 1 |
| Cold sweat | 4 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 4 | 5 | 5 |
| 2 | 2 | 1 | 2 | 8 | 8 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | | 1 | 1 |
| | | | 1 | 10 | 10 |
| | | 1 | 2 | 1 | 2 |
| | | 10 | 11 | 10 | 10 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| 1 | 1 | | | 6 | 6 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 4 | 2 | 2 |
| | | 1 | 2 | 8 | 8 |
| 1 | 2 | 27 | 43 | 55 | 57 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Condition aggravated | 1 | 1 |
| Confusional state | 7 | 9 |
| Conjunctival haemorrhage | 2 | 2 |
| Conjunctival hyperaemia | 1 | 1 |
| Conjunctival irritation | 1 | 1 |
| Conjunctivitis | 3 | 3 |
| Corneal bleeding | | 1 |
| Cough | 21 | 22 |
| COVID-19 | 8 | 10 |
| Crying | | 1 |
| Cyanosis | 1 | 1 |
| Cystitis | 1 | 1 |
| Cystitis haemorrhagic | 1 | 1 |
| Deafness | 2 | 2 |
| Death | | 1 |
| Decreased appetite | 4 | 5 |
| Deep vein thrombosis | 1 | 1 |
| Depressed level of consciousness | 6 | 8 |
| Dermatitis allergic | 1 | 1 |
| Dermatitis bullous | 4 | 4 |
| Dermatitis exfoliative | 1 | 1 |
| Diarrhoea | 30 | 35 |
| Diplopia | 1 | 1 |
| Disease recurrence | 1 | 1 |
| Disorientation | 1 | 2 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 26 | 37 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 6 | 7 |
| Dry eye | 1 | 1 |
| Dry mouth | 4 | 7 |
| Dry skin | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 3 | 5 | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | | 1 |
| 1 | 1 | 5 | 6 | 16 | 16 |
| | | | 1 | 8 | 9 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | 1 | 2 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 6 | 8 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 11 | 16 | 19 | 19 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 13 | 23 | 13 | 14 |
| | | | | 1 | 1 |
| | | | | 6 | 7 |
| | | 1 | 1 | | |
| | | 2 | 5 | 2 | 2 |
| | | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dysaesthesia | | 1 |
| Dysentery | 41 | 41 |
| Dysgeusia | 6 | 8 |
| Dysgraphia | 1 | 1 |
| Dyspepsia | 4 | 4 |
| Dysphagia | 14 | 15 |
| Dysphonia | 7 | 7 |
| Dyspnoea | 35 | 37 |
| Dyspnoea exertional | 2 | 2 |
| Dysstasia | 1 | 1 |
| Dysuria | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear infection | 1 | 1 |
| Ear pain | 3 | 4 |
| Ear pruritus | | 1 |
| Eosinophil count increased | 1 | 1 |
| Epiglottic oedema | 1 | 1 |
| Epilepsy | 4 | 4 |
| Episcleritis | 1 | 1 |
| Epistaxis | 4 | 4 |
| Erythema | 26 | 35 |
| Erythema of eyelid | 1 | 1 |
| Euphoric mood | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 |
| Extrasystoles | 4 | 4 |
| Eye haematoma | 1 | 1 |
| Eye irritation | 5 | 6 |
| Eyelid oedema | 2 | 2 |
| Eye pain | 3 | 3 |
| Eye pruritus | 1 | 2 |
| Face oedema | 5 | 6 |
| Facial bones fracture | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 41 | 41 |
| | | 1 | 3 | 5 | 5 |
| | | | | 1 | 1 |
| | | 3 | 3 | 1 | 1 |
| 1 | 1 | 4 | 5 | 10 | 10 |
| | | 3 | 3 | 4 | 4 |
| 1 | 2 | 3 | 3 | 32 | 34 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | |
| | | 1 | 1 | | |
| | | 2 | 3 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 3 | 3 | 1 | 1 |
| | | 2 | 9 | 24 | 26 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 4 | | |
| | | | | 1 | 1 |
| 1 | 1 | 2 | 3 | 3 | 3 |
| 1 | 1 | | | 2 | 2 |
| | | 2 | 2 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | 4 | 4 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Facial nerve disorder | 1 | 1 |
| Facial neuralgia | 1 | 1 |
| Facial pain | | 1 |
| Facial paralysis | 7 | 8 |
| Facial paresis | 2 | 2 |
| Fall | 1 | 1 |
| Fatigue | 60 | 70 |
| Feeling abnormal | 1 | 3 |
| Feeling cold | 12 | 13 |
| Feeling drunk | 1 | 1 |
| Feeling hot | 10 | 16 |
| Feeling of body temperature change | 2 | 2 |
| Fluid retention | 1 | 1 |
| Flushing | 6 | 8 |
| Gait disturbance | 4 | 4 |
| Gait inability | 1 | 1 |
| Gamma-glutamyltransferase increased | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| Gastrointestinal disorder | 1 | 3 |
| Gingival swelling | | 1 |
| Haematochezia | 1 | 1 |
| Hallucination | 1 | 1 |
| Hallucinations, mixed | 1 | 1 |
| Headache | 167 | 205 |
| Head discomfort | 3 | 4 |
| Heart rate decreased | | 1 |
| Heart rate increased | 5 | 5 |
| Hemianaesthesia | 1 | 1 |
| Hemiparaesthesia | 5 | 5 |
| Hemiparesis | 3 | 3 |
| Hemiplegia | 1 | 1 |
| Herpes ophthalmic | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 7 | 8 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | 1 | 18 | 27 | 42 | 43 |
| | | 1 | 2 | | 1 |
| | 1 | 4 | 5 | 8 | 8 |
| | | 1 | 1 | | |
| | | 2 | 7 | 8 | 9 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 2 | 4 | 4 | 4 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | | 1 | | |
| 2 | 3 | 69 | 105 | 98 | 100 |
| | | 2 | 3 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Herpes virus infection | 2 | 2 |
| Herpes zoster | 3 | 3 |
| Hot flush | 6 | 7 |
| Hyperaesthesia | | 1 |
| Hyperhidrosis | 15 | 18 |
| Hyperkinesia | 1 | 1 |
| Hyperpyrexia | 59 | 61 |
| Hypersensitivity | 6 | 7 |
| Hypertension | 16 | 18 |
| Hypertensive crisis | 17 | 21 |
| Hyperthermia | 3 | 4 |
| Hypertransaminasaemia | 2 | 2 |
| Hypertrophy of tongue papillae | 1 | 1 |
| Hyperventilation | 3 | 3 |
| Hypoacusis | 2 | 2 |
| Hypoesthesia | 4 | 7 |
| Hypoesthesia oral | 2 | 4 |
| Hypoglycaemia | | 1 |
| Hyporeflexia | 1 | 1 |
| Hypotension | 7 | 10 |
| Hypotensive crisis | 1 | 1 |
| Hypothermia | 5 | 5 |
| Hypotonia | 1 | 1 |
| Hypoxia | 1 | 1 |
| Immunisation anxiety related reaction | 1 | 1 |
| Incorrect route of product administration | 1 | 3 |
| Inflammation | 1 | 2 |
| Influenza | 3 | 3 |
| Influenza like illness | 8 | 10 |
| Initial insomnia | 1 | 1 |
| Injection site pain | 3 | 6 |
| Injection site urticaria | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | 6 | 6 |
| | | | 1 | | |
| | | 3 | 6 | 12 | 12 |
| | | 1 | 1 | | |
| | | | | 59 | 61 |
| | | | 1 | 6 | 6 |
| | | 2 | 2 | 14 | 16 |
| | | | | 17 | 21 |
| | | 1 | 1 | 2 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 4 | 3 | 3 |
| | | | 2 | 2 | 2 |
| | | | 1 | | |
| 1 | 1 | 1 | 3 | 6 | 7 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 3 | | |
| | | | | 1 | 2 |
| | | 3 | 3 | | |
| | | 4 | 6 | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 4 | 2 | 2 |
| | | 1 | 1 | 1 | 1 |

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* I=Interval, C=Cumulative
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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Insomnia | 3 | 4 |
| Intranasal paraesthesia | | 1 |
| Irritability | 1 | 2 |
| Joint lock | 1 | 1 |
| Joint range of motion decreased | 3 | 3 |
| Joint stiffness | 1 | 1 |
| Joint swelling | 1 | 1 |
| Joint warmth | 1 | 1 |
| Labyrinthitis | 2 | 2 |
| Lack of vaccination site rotation | | |
| Lacrimation increased | 1 | 1 |
| Laryngeal dyspnoea | 1 | 1 |
| Laryngeal obstruction | 1 | 1 |
| Laryngeal oedema | 10 | 13 |
| Laryngeal stenosis | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Limb discomfort | 1 | 2 |
| Lipodystrophy acquired | 1 | 1 |
| Lip oedema | 4 | 4 |
| Lip pain | 1 | 1 |
| Lip pruritus | 3 | 4 |
| Lip swelling | 1 | 2 |
| Localised oedema | | 1 |
| Loss of consciousness | 5 | 5 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenopathy | 40 | 50 |
| Lymphangitis | | 1 |
| Lymph node pain | 2 | 4 |
| Lymphoedema | 3 | 3 |
| Macular rupture | 1 | 1 |
| Malaise | 30 | 37 |
| Mastitis | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | 1 | 1 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 1 | 1 | | | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 10 | 13 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | | 1 | 3 | 3 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | | 5 | 5 |
| | | 1 | 1 | | |
| | | 12 | 19 | 28 | 31 |
| | | | | | 1 |
| | | | 2 | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 10 | 15 | 20 | 22 |
| | | | | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Maternal exposure during pregnancy | 1 | 1 |
| Mechanical urticaria | 2 | 2 |
| Memory impairment | 1 | 1 |
| Mental impairment | 1 | 1 |
| Metrorrhagia | 1 | 1 |
| Migraine | 10 | 12 |
| Miosis | 1 | 1 |
| Mobility decreased | 2 | 2 |
| Monoplegia | 3 | 3 |
| Movement disorder | 3 | 3 |
| Mucous stools | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Muscle contracture | 2 | 2 |
| Muscle spasms | 5 | 6 |
| Muscle swelling | 1 | 1 |
| Muscle tightness | 1 | 1 |
| Muscular weakness | 5 | 6 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 |
| Musculoskeletal pain | 15 | 17 |
| Musculoskeletal stiffness | 3 | 3 |
| Myalgia | 99 | 114 |
| Myocardial necrosis marker increased | 1 | 1 |
| Myocarditis | 1 | 1 |
| Myositis | | |
| Narcolepsy | 1 | 1 |
| Nasal congestion | 1 | 2 |
| Nasopharyngitis | 2 | 2 |
| Nausea | 81 | 100 |
| Neck pain | 10 | 11 |
| Neuralgia | 3 | 4 |
| Neuralgic amyotrophy | | |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| 1 | 1 | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 6 | 6 | 6 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 14 | 14 |
| | | 1 | 1 | 2 | 2 |
| 1 | 1 | 35 | 49 | 64 | 65 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | | | |
| | | 1 | 2 | | |
| | | 1 | 1 | 1 | 1 |
| 2 | 2 | 23 | 41 | 58 | 59 |
| | | 3 | 4 | 7 | 7 |
| | | 1 | 2 | 2 | 2 |
| 1 | 1 | | | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Neuropathy peripheral | 3 | 3 |
| Night sweats | 1 | 1 |
| Nystagmus | 1 | 1 |
| Ocular hyperaemia | 2 | 2 |
| Oculogyric crisis | 1 | 1 |
| Odynophagia | 1 | 1 |
| Oedema | 2 | 2 |
| Oedema mouth | 1 | 2 |
| Oedema mucosal | 1 | 1 |
| Oedema peripheral | 3 | 4 |
| Off label use | 4 | 6 |
| Oral candidiasis | 1 | 1 |
| Oral discomfort | 3 | 4 |
| Oral dysaesthesia | | 1 |
| Oral herpes | 4 | 5 |
| Oral mucosal erythema | 1 | 1 |
| Oral pain | 1 | 1 |
| Oral pruritus | 1 | 1 |
| Orbital oedema | 1 | 1 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 7 | 9 |
| Orthopnoea | 1 | 1 |
| Overdose | 16 | 17 |
| Oxygen saturation decreased | 12 | 12 |
| Pain | 23 | 26 |
| Pain in extremity | 43 | 51 |
| Palatal oedema | 2 | 2 |
| Palatal swelling | 1 | 1 |
| Pallor | 2 | 2 |
| Palpitations | 1 | 2 |
| Panniculitis | 1 | 1 |
| Papule | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 2 | 3 | 1 | 1 |
| | | 4 | 6 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 3 |
| | | | 1 | | |
| | | 1 | 2 | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 5 | 4 | 4 |
| | | | | 1 | 1 |
| | | 16 | 17 | | |
| | | 2 | 2 | 10 | 10 |
| | | 9 | 11 | 14 | 15 |
| | | 17 | 23 | 26 | 28 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Paraesthesia | 42 | 53 |
| Paraesthesia oral | 14 | 20 |
| Paresis | 1 | 1 |
| Parosmia | 2 | 2 |
| Partial seizures | 1 | 1 |
| Pericarditis | 2 | 2 |
| Periorbital oedema | 1 | 1 |
| Periorbital swelling | | 1 |
| Peripheral coldness | 3 | 4 |
| Peripheral sensorimotor neuropathy | 1 | 1 |
| Peripheral swelling | 6 | 8 |
| Peripheral venous disease | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal erythema | 1 | 1 |
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 4 |
| Pharyngeal swelling | | 1 |
| Pharyngitis | 1 | 1 |
| Photophobia | 3 | 4 |
| Photopsia | 2 | 2 |
| Pityriasis | 1 | 1 |
| Pleurisy | 1 | 1 |
| Plicated tongue | 1 | 1 |
| Pneumonia | 2 | 2 |
| Pneumonia bacterial | 1 | 1 |
| Pneumonitis | 2 | 2 |
| Polyuria | | 1 |
| Presyncope | 14 | 17 |
| Product administered at inappropriate site | 3 | 3 |
| Productive cough | 1 | 1 |
| Product preparation issue | 3 | 3 |
| Product use issue | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 9 | 19 | 33 | 34 |
| | | 2 | 6 | 12 | 14 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 5 | 5 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 3 | 6 | 11 | 11 |
| | | 3 | 3 | | |
| | | | | 1 | 1 |
| | | 3 | 3 | | |
| | | 2 | 3 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Pruritus | 25 | 36 |
| Pulmonary pain | 1 | 1 |
| Pulse abnormal | 1 | 1 |
| Pyrexia | 201 | 234 |
| Q fever | 2 | 2 |
| Rash | 20 | 26 |
| Rash erythematous | | 2 |
| Rash pruritic | 1 | 1 |
| Rash vesicular | 2 | 2 |
| Reaction to excipient | 1 | 1 |
| Respiratory depression | 1 | 1 |
| Respiratory disorder | 1 | 1 |
| Respiratory distress | 2 | 2 |
| Respiratory failure | 1 | 1 |
| Respiratory fatigue | 1 | 1 |
| Respiratory tract infection | 1 | 1 |
| Respiratory tract oedema | 1 | 1 |
| Restless legs syndrome | 1 | 1 |
| Restlessness | 3 | 3 |
| Retching | 1 | 1 |
| Retinal degeneration | 1 | 1 |
| Retinal detachment | 2 | 2 |
| Retinal disorder | 1 | 1 |
| Retinal vascular thrombosis | 1 | 1 |
| Retrograde amnesia | 1 | 1 |
| Rheumatic disorder | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 |
| Rhinalgia | 1 | 1 |
| Rhinitis | 2 | 2 |
| Rhinorrhoea | 3 | 5 |
| Rhonchi | 1 | 1 |
| SARS-CoV-2 ant body test negative | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 3 | 13 | 22 | 23 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 2 | 76 | 107 | 125 | 127 |
| | | | | 2 | 2 |
| 1 | 1 | 3 | 9 | 17 | 17 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 3 | 5 | | |
| | | 1 | 1 | | |
| | | | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Scab | 1 | 1 |
| Sciatica | 1 | 2 |
| Sedation | 1 | 1 |
| Seizure | 1 | 1 |
| Seizure like phenomena | 1 | 1 |
| Sensation of foreign body | 4 | 5 |
| Sensory loss | 1 | 1 |
| Septic shock | 1 | 1 |
| Severe acute respiratory syndrome | 1 | 1 |
| Sinus rhythm | 1 | 1 |
| Sinus tachycardia | | 2 |
| Skin burning sensation | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Skin lesion | 1 | 1 |
| Skin reaction | 1 | 1 |
| Skin swelling | 1 | 1 |
| Skin warm | 1 | 1 |
| Sneezing | | 1 |
| Somnolence | 12 | 15 |
| Speech disorder | 1 | 1 |
| Spinal pain | 1 | 1 |
| Stoma site pain | 1 | 1 |
| Stupor | 1 | 3 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling | 3 | 4 |
| Swelling face | 3 | 3 |
| Swollen tongue | 3 | 3 |
| Syncope | 14 | 15 |
| Tachycardia | 26 | 33 |
| Tachycardia paroxysmal | 1 | 1 |
| Tachypnoea | 1 | 1 |
| Temporomandibular joint syndrome | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 4 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 6 | 9 | 6 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 2 |
| | | 1 | 1 | | |
| | | 2 | 2 | 1 | 2 |
| 1 | 1 | | | 3 | 3 |
| | | | | 3 | 3 |
| | | | | 14 | 15 |
| 1 | 1 | 6 | 10 | 20 | 23 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Tenderness | | 1 |
| Tension | 1 | 1 |
| Throat irritation | 9 | 10 |
| Throat tightness | 11 | 16 |
| Thrombocytopenia | 1 | 1 |
| Thrombophlebitis superficial | 1 | 1 |
| Tinnitus | 5 | 5 |
| Tongue discomfort | | 1 |
| Tongue disorder | 1 | 1 |
| Tongue oedema | 4 | 5 |
| Tongue pruritus | 2 | 3 |
| Transaminases increased | 1 | 1 |
| Tremor | 12 | 15 |
| Trigeminal neuralgia | 1 | 1 |
| Type I hypersensitivity | 2 | 2 |
| Underdose | 1 | 2 |
| Upper airway obstruction | 1 | 1 |
| Urinary retention | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urticaria | 19 | 28 |
| Uveitis | 1 | 1 |
| Vaccination complication | 10 | 11 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | 1 | 1 |
| Vaccination site cellulitis | 1 | 1 |
| Vaccination site discolouration | | 1 |
| Vaccination site erythema | 14 | 19 |
| Vaccination site hypersensitivity | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 1 |
| Vaccination site induration | 1 | 1 |
| Vaccination site inflammation | | 1 |
| Vaccination site lymphadenopathy | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 3 | 7 | 7 |
| 2 | 2 | 1 | 5 | 10 | 11 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | 2 | 3 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 5 | 8 | 7 | 7 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 4 | 12 | 15 | 16 |
| | | | | 1 | 1 |
| | | 3 | 4 | 7 | 7 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 5 | 10 | 9 | 9 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Vaccination site movement impairment | | 1 |
| Vaccination site oedema | 4 | 7 |
| Vaccination site pain | 68 | 128 |
| Vaccination site paraesthesia | 2 | 4 |
| Vaccination site pruritus | 2 | 3 |
| Vaccination site rash | | 1 |
| Vaccination site reaction | 4 | 4 |
| Vaccination site swelling | 12 | 16 |
| Vaccination site urticaria | 1 | 1 |
| Vaccination site vesicles | 1 | 1 |
| Vaccination site warmth | 2 | 4 |
| Vaginal haemorrhage | 1 | 1 |
| Venous thrombosis limb | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 |
| Ventricular tachycardia | 1 | 1 |
| Vertigo | 28 | 33 |
| Vision blurred | 4 | 6 |
| Visual acuity reduced | 1 | 1 |
| Visual impairment | 5 | 5 |
| Vitreous disorder | 1 | 1 |
| Vitreous floaters | 2 | 2 |
| Vomiting | 34 | 36 |
| Vulvovaginal burning sensation | 1 | 1 |
| Wandering pacemaker | 1 | 1 |
| Wheezing | 2 | 2 |
| White blood cell count decreased | 1 | 1 |
| Xanthopsia | 1 | 1 |
| | 2,540 | 3,084 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 3 | 4 | 4 |
| 1 | 1 | 33 | 92 | 35 | 36 |
| | | 1 | 3 | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | | 2 | 2 | 2 |
| | | 3 | 7 | 9 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 11 | 16 | 17 | 17 |
| | | 1 | 3 | 3 | 3 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 8 | 9 | 26 | 27 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 28 | 34 | 1795 | 1879 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | | | 1 | 1 |
| Abdominal pain | 1 | 1 | | | | | 1 | 1 |
| Angioedema | 2 | 2 | | | | | 2 | 2 |
| Aphonia | 1 | 1 | | | 1 | 1 | | |
| Application site coldness | 1 | 1 | | | 1 | 1 | | |
| Arthralgia | 7 | 7 | | | 1 | 1 | 6 | 6 |
| Asthenia | 4 | 7 | | | | 3 | 4 | 4 |
| Atrial f brillation | 1 | 1 | | | | | 1 | 1 |
| Back pain | 1 | 1 | | | | | 1 | 1 |
| Blood pressure decreased | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Blood pressure increased | 1 | 2 | | | 1 | 2 | | |
| Bone pain | 1 | 2 | | | | 1 | 1 | 1 |
| Bradycardia | 1 | 1 | 1 | 1 | | | 1 | 1 |
| Catarrh | 1 | 1 | | | | | 1 | 1 |
| Cervical radiculopathy | 1 | 1 | | | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 | | |
| Chills | 8 | 8 | | | 6 | 6 | 2 | 2 |
| Clonus | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Confusional state | 1 | 2 | | | | 1 | 1 | 1 |
| Conjunctival irritation | 1 | 1 | | | | | 1 | 1 |
| Coronary artery disease | 1 | 1 | | | | | 1 | 1 |
| Cough | 1 | 3 | | | 1 | 3 | | |
| COVID-19 | 1 | 2 | | | | 1 | 1 | 1 |
| Cystitis haemorrhagic | 1 | 1 | | | | | 1 | 1 |
| Decreased appetite | 1 | 1 | | | | | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | | | 1 | 1 |
| Dehydration | 1 | 1 | | | | | 1 | 1 |
| Depressed level of consciousness | 2 | 2 | | | | | 2 | 2 |
| Diarrhoea | 1 | 2 | | | | 1 | 1 | 1 |
| Diplopia | 2 | 2 | | | | | 2 | 2 |
| Dizziness | 3 | 3 | | | 3 | 3 | | |
| Drug hypersensitivity | 1 | 1 | | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Drug ineffective | 1 | 1 |
| Dry mouth | | 1 |
| Dysentery | 2 | 2 |
| Dysphagia | 2 | 2 |
| Dysphonia | 1 | 2 |
| Dyspnoea | 3 | 4 |
| Ear pain | 1 | 1 |
| Ear pruritus | 1 | 1 |
| Encephalitis | 1 | 1 |
| Erythema | | 2 |
| Eye disorder | 1 | 1 |
| Eyelid retraction | 1 | 1 |
| Facial paralysis | 3 | 3 |
| Facial paresis | 1 | 1 |
| Fall | 1 | 1 |
| Flatulence | | 1 |
| Flushing | | 1 |
| Gastrointestinal sounds abnormal | | 1 |
| Haematuria | 1 | 1 |
| Headache | 8 | 11 |
| Hemiparaesthesia | 1 | 1 |
| Hemiplegia | 1 | 1 |
| Herpes zoster | | 1 |
| Hot flush | 1 | 1 |
| Hyperaemia | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hyperpyrexia | 1 | 1 |
| Hypersensitivity | 2 | 2 |
| Hypertension | 4 | 4 |
| Hypertensive crisis | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoglossal nerve disorder | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 7 | 4 | 4 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypotension | | 1 |
| Insomnia | 1 | 1 |
| Inspiratory capacity abnormal | | 1 |
| Intervertebral discitis | 1 | 1 |
| Laryngeal oedema | 1 | 2 |
| Laryngospasm | 1 | 1 |
| Lip oedema | 1 | 1 |
| Listeriosis | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenopathy | | 1 |
| Lymphangitis | 1 | 1 |
| Macroglossia | 1 | 1 |
| Malaise | 3 | 4 |
| Metamorphopsia | 1 | 1 |
| Middle insomnia | 1 | 1 |
| Migraine | | 1 |
| Muscle contracture | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal pain | 2 | 2 |
| Myalgia | 5 | 8 |
| Nausea | 3 | 6 |
| Neck pain | | 1 |
| Neurogenic bladder | 1 | 1 |
| Oedema mouth | 1 | 3 |
| Oedema peripheral | 1 | 1 |
| Optic neuritis | 1 | 1 |
| Oral pain | 1 | 1 |
| Oropharyngeal pain | 2 | 2 |
| Overdose | 1 | 1 |
| Oxygen saturation decreased | 1 | 2 |
| Pain in extremity | 5 | 6 |
| Palatal oedema | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | 3 | 5 | 5 |
| | | 1 | 4 | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 3 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | 4 | 5 | 1 | 1 |
| | | | 1 | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Pallor | 1 | 1 |
| Panic attack | 1 | 1 |
| Papilloedema | 1 | 1 |
| Paraesthesia | 2 | 2 |
| Paraesthesia oral | 1 | 2 |
| Parotid gland enlargement | | 1 |
| Periorbital swelling | 1 | 2 |
| Peripheral coldness | | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngitis | | 2 |
| Pruritus | 3 | 3 |
| Pulmonary embolism | 1 | 1 |
| Pyrexia | 20 | 26 |
| Quadripareisis | 1 | 1 |
| Rash erythematous | 1 | 1 |
| Seizure | 2 | 2 |
| Sepsis | 1 | 1 |
| Skin reaction | 1 | 1 |
| Speech disorder | 1 | 1 |
| Stertor | 1 | 1 |
| Sudden death | 1 | 1 |
| Syncope | 3 | 3 |
| Tachycardia | 3 | 4 |
| Tachypnoea | 1 | 1 |
| Taste disorder | 1 | 1 |
| Tongue oedema | 1 | 1 |
| Torticollis | | 1 |
| Tracheal pain | 1 | 1 |
| Tremor | 2 | 4 |
| Urticaria | 4 | 4 |
| Uveitis | 1 | 1 |
| Vaccination site erythema | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | 2 | | |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | 6 | 12 | 14 | 14 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | 2 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 2 | 2 | 2 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Vaccination site oedema | 1 | 1 |
| Vaccination site pain | 5 | 18 |
| Vaccination site pruritus | 1 | 1 |
| Vaccination site swelling | 1 | 1 |
| Vaccination site warmth | 1 | 1 |
| Vasculitis | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 |
| Vertigo | 3 | 4 |
| Vlth nerve paralysis | 1 | 1 |
| Vlth nerve paresis | 1 | 1 |
| Vitreous detachment | 1 | 1 |
| Vomiting | | 1 |
| | 216 | 287 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 4 | 17 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| 2 | 2 | 69 | 138 | 147 | 149 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute coronary syndrome | | 1 | | | | | | 1 |
| Acute myocardial infarction | | 1 | | | | | | 1 |
| Acute respiratory failure | 2 | 3 | | | | | 2 | 3 |
| Allergic respiratory symptom | | 1 | | | | | | 1 |
| Allergy to vaccine | 1 | 1 | | | | | 1 | 1 |
| Altered state of consciousness | 1 | 1 | | | | | 1 | 1 |
| Anaemia | 1 | 1 | | | 1 | 1 | | |
| Anaesthesia | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | | 1 | | | | | | 1 |
| Arteriosclerosis | | 1 | | | | | | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 | | |
| Asthenia | 2 | 3 | | | 2 | 2 | | 1 |
| Atrioventricular block complete | | 1 | | | | | | 1 |
| Balance disorder | 1 | 1 | | | | | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 | | |
| Body temperature increased | 1 | 2 | | | 1 | 2 | | |
| Bradycardia | | 1 | | | | | | 1 |
| Cardiac arrest | 3 | 3 | | | | | 3 | 3 |
| Cardiac failure | 1 | 2 | | | | | 1 | 2 |
| Cerebellar haemorrhage | | 1 | | | | | | 1 |
| Cerebrovascular accident | | 1 | | | | | | 1 |
| Circulatory collapse | 1 | 2 | | | | | 1 | 2 |
| Cold sweat | 1 | 1 | | | | | 1 | 1 |
| Coma | 2 | 2 | | | | | 2 | 2 |
| Coma scale abnormal | | 1 | | | | | | 1 |
| Condition aggravated | 1 | 2 | | | | | 1 | 2 |
| Confusional state | 1 | 1 | | | | | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 | | |
| Death | 1 | 2 | | | | | 1 | 2 |
| Deep vein thrombosis | | 1 | | | | | | 1 |
| Dehydration | | 1 | | | | | | 1 |
| Depressed level of consciousness | 1 | 1 | | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Dermatitis allergic | | 1 |
| Dermatitis exfoliative generalised | | 1 |
| Diarrhoea | 1 | 1 |
| Disease recurrence | 1 | 1 |
| Disorientation | 1 | 1 |
| Dizziness | 2 | 2 |
| Dysphagia | | 1 |
| Dyspnoea | 3 | 7 |
| Dysuria | | 1 |
| Epilepsy | 1 | 1 |
| Erythema | 2 | 2 |
| Facial paralysis | 1 | 1 |
| Fall | | 1 |
| Feeding disorder | 1 | 1 |
| Fibrin D dimer increased | 1 | 1 |
| General physical health deterioration | | 1 |
| Haemorrhage subcutaneous | 1 | 1 |
| Headache | 1 | 1 |
| Hemiparesis | | 1 |
| Hyperpyrexia | 4 | 4 |
| Hypertensive crisis | 2 | 2 |
| Hyperthermia | 2 | 2 |
| Hypotension | 5 | 5 |
| Hypotonia | 1 | 1 |
| Hypoxia | 1 | 1 |
| International normalised ratio increased | 1 | 1 |
| Ischaemic stroke | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Loss of consciousness | 3 | 3 |
| Lymphocyte count decreased | 1 | 1 |
| Malaise | 4 | 4 |
| Mean cell volume increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 3 | 7 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Monocyte count increased | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Muscle contractions involuntary | 1 | 1 |
| Myalgia | 1 | 1 |
| Myocardial infarction | | 1 |
| Myocardial ischaemia | | 1 |
| Off label use | 2 | 2 |
| Oxygen saturation decreased | 2 | 3 |
| Pallor | 1 | 1 |
| Paraesthesia | 1 | 1 |
| Paraesthesia oral | 1 | 1 |
| Pemphigoid | 1 | 1 |
| Productive cough | 1 | 1 |
| Product use issue | 2 | 2 |
| Pulmonary embolism | | 1 |
| Purpura | 1 | 1 |
| Pyrexia | 10 | 12 |
| Rash | | 1 |
| Rash macular | 1 | 1 |
| Red blood cell count decreased | 1 | 1 |
| Red cell distribution width increased | 1 | 1 |
| Regurgitation | 1 | 1 |
| Renal failure | 1 | 3 |
| Respiratory arrest | 1 | 2 |
| Restlessness | | 1 |
| Scleral discolouration | 1 | 1 |
| Sepsis | 1 | 1 |
| Somnolence | 3 | 3 |
| Sopor | 1 | 1 |
| Sudden death | 3 | 4 |
| Syncope | 4 | 4 |
| Systolic hypertension | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 2 | 2 | 8 | 10 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| 1 | 1 | | | 4 | 4 |
| | | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Thrombocytopenia | 1 | 1 | | | | | 1 | 1 |
| Tremor | 1 | 1 | | | | | 1 | 1 |
| Urticaria | 1 | 2 | | | | | 1 | 2 |
| Vaccination site inflammation | 1 | 1 | | | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 | | |
| Vertigo | 1 | 1 | | | | | 1 | 1 |
| Vomiting | 5 | 6 | | | 1 | 1 | 4 | 5 |
| Weight decreased | | 1 | | | | | | 1 |
| | 124 | 170 | 2 | 2 | 29 | 31 | 95 | 139 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Acute coronary syndrome | | 1 | | | | 1 |
| Anaphylactic reaction | 1 | 4 | | | 1 | 4 |
| Anaphylactic shock | | 2 | | | | 2 |
| Arthralgia | 3 | 6 | 3 | 6 | | |
| Asthenia | 2 | 6 | 2 | 6 | | |
| Asthenopia | | 1 | | 1 | | |
| Back pain | | 2 | | 1 | | 1 |
| Blister | 1 | 1 | 1 | 1 | | |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Bone pain | 2 | 3 | 2 | 3 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 3 | 5 | 3 | 5 | | |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Confusional state | | 1 | | 1 | | |
| Conjunctival hyperaemia | 1 | 1 | | | 1 | 1 |
| COVID-19 | 39 | 44 | | 1 | 39 | 43 |
| Deafness bilateral | | 1 | | | | 1 |
| Deafness neurosensory | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 3 | 5 | 3 | 5 | | |
| Diplopia | 1 | 1 | 1 | 1 | | |
| Dizziness | 3 | 6 | 2 | 5 | 1 | 1 |
| Drug ineffective | 41 | 46 | | | 41 | 46 |
| Dry mouth | | 2 | | 2 | | |
| Dysentery | 1 | 1 | | | 1 | 1 |
| Dysgeusia | | 1 | | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Dyspnoea | 1 | 1 |
| Dysuria | 1 | 1 |
| Enterocolitis | 1 | 1 |
| Erythema | 2 | 6 |
| Exposure during pregnancy | | 1 |
| Eye pain | 1 | 1 |
| Facial paralysis | 1 | 2 |
| Fatigue | 3 | 4 |
| Feeling hot | | 1 |
| Feeling of body temperature change | 1 | 1 |
| Flushing | 1 | 2 |
| Gait disturbance | 1 | 1 |
| Gait inability | 2 | 2 |
| Glossodynia | 1 | 1 |
| Haematuria | 1 | 1 |
| Headache | 9 | 18 |
| Head discomfort | 1 | 1 |
| Hemidysaesthesia | 1 | 1 |
| Hemiparaesthesia | 1 | 1 |
| Herpes zoster | 1 | 2 |
| Hyperhidrosis | | 2 |
| Hyperpyrexia | 4 | 4 |
| Hypersensitivity | | 1 |
| Hypertension | 1 | 1 |
| Hypertensive crisis | 1 | 1 |
| Hyperthermia | 1 | 2 |
| Hyperventilation | | 1 |
| Hypoaesthesia oral | | 1 |
| Hypothermia | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect dose administered | | 1 |
| Influenza like illness | | 2 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 5 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 2 |
| 3 | 4 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 8 | 17 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| | 2 | | |
| | | 4 | 4 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Injection site hypersensitivity | 1 | 1 |
| Insomnia | | 1 |
| Laryngeal oedema | | 1 |
| Limb discomfort | | 1 |
| Lip oedema | 1 | 4 |
| Lip pain | 1 | 1 |
| Lymphadenopathy | 3 | 10 |
| Malaise | 1 | 2 |
| Maternal exposure during pregnancy | 3 | 3 |
| Meningeal disorder | 1 | 1 |
| Migraine | 1 | 2 |
| Muscle tightness | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 |
| Musculoskeletal pain | 1 | 3 |
| Myalgia | 5 | 7 |
| Nausea | 4 | 5 |
| Neuralgia | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Night sweats | 1 | 1 |
| Nuchal rigidity | 1 | 1 |
| Off label use | 3 | 4 |
| Pain | 1 | 2 |
| Pain in extremity | 7 | 10 |
| Pallor | | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | 1 | 4 |
| Paraesthesia oral | 2 | 2 |
| Peripheral coldness | | 1 |
| Peripheral sensory neuropathy | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | 3 | 1 | 1 |
| 1 | 1 | | |
| 3 | 10 | | |
| 1 | 2 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 3 | | |
| 5 | 7 | | |
| 3 | 4 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 4 | | |
| 1 | 2 | | |
| 6 | 9 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 4 | | |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Photophobia | 1 | 1 |
| Pityriasis rosea | | 1 |
| Poor quality product administered | | 1 |
| Product administered at inappropriate site | | 1 |
| Product administration error | | 1 |
| Product label confusion | | 1 |
| Product preparation issue | | 1 |
| Product use issue | 2 | 3 |
| Pruritus | 3 | 3 |
| Pyrexia | 7 | 17 |
| Rash | 1 | 3 |
| Root canal infection | 1 | 1 |
| SARS-CoV-2 ant body test positive | 3 | 5 |
| SARS-CoV-2 test positive | 1 | 3 |
| Skin reaction | | 1 |
| Somnolence | | 1 |
| Spinal pain | 1 | 1 |
| Stomatitis | 1 | 1 |
| Swelling face | 1 | 2 |
| Syncope | 1 | 2 |
| Tachycardia | | 1 |
| Tongue oedema | 1 | 2 |
| Tooth infection | 1 | 1 |
| Tremor | 1 | 1 |
| Underdose | | 2 |
| Urticaria | 1 | 7 |
| Vaccination site erythema | | 1 |
| Vaccination site oedema | | 2 |
| Vaccination site pain | 6 | 22 |
| Vaccination site paraesthesia | | 1 |
| Vaccination site rash | 1 | 1 |
| Vaccination site reaction | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 2 | 3 | | |
| | | 3 | 3 |
| 6 | 16 | 1 | 1 |
| | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | 2 | 2 |
| 1 | 2 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | | 1 | 2 |
| | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| 1 | 7 | | |
| | 1 | | |
| | 2 | | |
| 5 | 21 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

Unknown

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 2 | | 1 |
| | 1 | | |
| | 1 | | |
| 111 | 249 | 123 | 147 |

Vaccination site swelling

2

Vaccination site urticaria

1

2

Vaccination site warmth

1

1

Vertigo

1

3

Vomiting

1

Wrong technique in product usage process

1

234

396

111

249

123

147

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Country Where Event Occurred

JAPAN

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abortion | 1 | 1 | | | 1 | 1 |
| Affect lability | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Brain oedema | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Haemorrhage | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Hospitalisation | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Mouth haemorrhage | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Oral discomfort | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| | 35 | 35 | 16 | 16 | 19 | 19 |

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Country Where Event Occurred
JORDAN

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Muscle spasms | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Taste disorder | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred
KUWAIT

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Pain in extremity | 1 | 1 | 1 | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 |
| Tenderness | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | | 1 | | 1 |
| Lymphadenopathy | | 1 | | 1 |
| Myalgia | | 1 | | 1 |
| Neck pain | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| Swelling | | 1 | | 1 |
| Tenderness | | 1 | | 1 |
| Vaccination site pain | | 1 | | 1 |
| Vaccination site swelling | | 1 | | 1 |
| | | 9 | | 9 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| COVID-19 | 1 | 1 | 1 | 1 |
| Drug ineffective | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

LATVIA

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Arthralgia | 10 | 13 | 8 | 10 | 2 | 3 |
| Asthenia | 5 | 7 | 4 | 6 | 1 | 1 |
| Asthma | | 1 | | 1 | | |
| Bacille Calmette-Guerin scar reactivation | 1 | 1 | 1 | 1 | | |
| Back pain | 2 | 2 | 2 | 2 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 9 | 10 | 9 | 10 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Burning sensation | 1 | 2 | | | 1 | 2 |
| Chest pain | | 1 | | 1 | | |
| Chills | 12 | 12 | 12 | 12 | | |
| Condition aggravated | | 1 | | 1 | | |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Cough | | 1 | | 1 | | |
| COVID-19 | | 1 | | | | 1 |
| C-reactive protein increased | 1 | 1 | 1 | 1 | | |
| Depressed mood | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 3 | 3 | 1 | 1 | 2 | 2 |
| Dizziness | 4 | 4 | 3 | 3 | 1 | 1 |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Dyspnoea | 1 | 2 | | 1 | 1 | 1 |
| Erythema | 1 | 2 | 1 | 1 | | 1 |
| Eye pain | 2 | 2 | 2 | 2 | | |
| Fatigue | 14 | 16 | 10 | 12 | 4 | 4 |
| Headache | 20 | 22 | 18 | 19 | 2 | 3 |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hyperaesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 2 | 2 | 2 | 2 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Increased appetite | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 5 | 5 |
| Lymph node pain | 1 | 1 |
| Mental impairment | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 12 | 13 |
| Nasal congestion | 1 | 1 |
| Nausea | 6 | 6 |
| Neck pain | 2 | 2 |
| Neuralgia | | 1 |
| Pain | 2 | 2 |
| Pain in extremity | 1 | 2 |
| Palpitations | 1 | 1 |
| Paraesthesia | 1 | 2 |
| Peripheral sensory neuropathy | 1 | 1 |
| Photophobia | 1 | 1 |
| Pruritus | | 1 |
| Pyrexia | 20 | 21 |
| Rash | 1 | 1 |
| Rash pruritic | 2 | 2 |
| SARS-CoV-2 test positive | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Somnolence | 2 | 2 |
| Tachycardia | 3 | 3 |
| Throat irritation | 1 | 2 |
| Vaccination site erythema | 2 | 2 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 1 |
| Vaccination site mass | 1 | 1 |
| Vaccination site oedema | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 4 | 4 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| 10 | 11 | 2 | 2 |
| 1 | 1 | | |
| 6 | 6 | | |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 18 | 19 | 2 | 2 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 3 | 3 |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 22 | 25 | 20 | 23 | 2 | 2 |
| Vaccination site pruritus | 1 | 1 | | | 1 | 1 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 206 | 235 | 158 | 177 | 48 | 58 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 3 | 3 | 3 | 3 | | |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Abnormal sensation in eye | 1 | 1 | 1 | 1 | | |
| Anxiety | | 1 | | | | 1 |
| Arthralgia | 12 | 14 | 12 | 14 | | |
| Asthenia | 4 | 6 | 3 | 4 | 1 | 2 |
| Blepharitis | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | | 1 | | | | 1 |
| Body temperature increased | 16 | 19 | 16 | 18 | | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 13 | 14 | 13 | 14 | | |
| Cold sweat | | 1 | | | | 1 |
| Cough | 4 | 4 | 4 | 4 | | |
| Decreased appetite | 3 | 3 | 3 | 3 | | |
| Diarrhoea | 3 | 4 | 3 | 4 | | |
| Disturbance in attention | 2 | 2 | 1 | 1 | 1 | 1 |
| Dizziness | 5 | 5 | 3 | 3 | 2 | 2 |
| Dry mouth | 1 | 2 | 1 | 1 | | 1 |
| Dysgeusia | 2 | 3 | 1 | 1 | 1 | 2 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | | | 1 | 1 |
| Eye pain | 5 | 5 | 5 | 5 | | |
| Fatigue | 18 | 18 | 16 | 16 | 2 | 2 |
| Feeling hot | | 1 | | 1 | | |
| Headache | 16 | 17 | 14 | 15 | 2 | 2 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hyperaesthesia | 1 | 1 | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hyperhidrosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 2 | 2 | 2 | 2 | | |
| Lymph node pain | 2 | 3 | 1 | 1 | 1 | 2 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Musculoskeletal discomfort | 1 | 2 | 1 | 2 | | |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 13 | 15 | 11 | 13 | 2 | 2 |
| Nasal oedema | 1 | 1 | 1 | 1 | | |
| Nausea | 5 | 6 | 4 | 5 | 1 | 1 |
| Oropharyngeal pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Palatal swelling | | 1 | | 1 | | |
| Palpitations | 2 | 2 | | | 2 | 2 |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | | 2 | | 1 | | 1 |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pyrexia | 15 | 16 | 13 | 14 | 2 | 2 |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Somnolence | 5 | 5 | 3 | 3 | 2 | 2 |
| Syncope | | 1 | | | | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Thirst | 1 | 1 | | | 1 | 1 |
| Throat irritation | 2 | 2 | 2 | 2 | | |
| Tunnel vision | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 3 | 1 | 2 | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 1 | 2 | 1 | 1 | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 17 | 20 | 15 | 18 | 2 | 2 |
| Vaccination site pruritus | | 2 | | 2 | | |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vertigo | 2 | 2 | 2 | 2 | | |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Vomiting | 4 | 5 | 3 | 4 | 1 | 1 |
| | 217 | 252 | 174 | 198 | 43 | 54 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 4 | 4 | 3 | 3 | 1 | 1 |
| Asthenia | 2 | 2 | 2 | 2 | | |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | | 1 | | 1 | | |
| Body temperature increased | 8 | 10 | 8 | 10 | | |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Chills | 5 | 5 | 5 | 5 | | |
| Coordination abnormal | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 3 | | 2 | | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Drug ineffective | | 1 | | | | 1 |
| Epistaxis | 1 | 1 | | | 1 | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fatigue | 3 | 4 | 3 | 4 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 4 | 3 | 3 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypertensive crisis | 2 | 2 | | | 2 | 2 |
| Hypoacusis | 1 | 1 | 1 | 1 | | |
| Illness | | 2 | | 2 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Lymphadenitis | | 1 | | 1 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 2 | 1 | 2 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 5 | 5 | 5 | 5 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nausea | 3 | 3 | 3 | 3 | | |
| Night sweats | | 1 | | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 6 | 7 | 6 | 7 | | |
| Rash | 1 | 1 | | | 1 | 1 |
| Skin tightness | 1 | 1 | | | 1 | 1 |
| Sleep disorder due to general medical condition, insomnia type | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Thirst | 1 | 1 | 1 | 1 | | |
| Vaccination site discolouration | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 3 | 3 | 3 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| | 80 | 94 | 64 | 76 | 16 | 18 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | | 1 | | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | | | 1 | 1 |
| Headache | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | | | 1 | 1 |
| Myalgia | 2 | 3 | 2 | 3 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | | 1 | | 1 | | |
| Pyrexia | 3 | 3 | 2 | 2 | 1 | 1 |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| | 20 | 25 | 13 | 18 | 7 | 7 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bradyphrenia | 1 | 1 | 1 | 1 | | |
| Depression | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Eye pain | | 1 | | 1 | | |
| Headache | 1 | 2 | 1 | 1 | | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Pyrexia | 1 | 2 | 1 | 1 | | 1 |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Upper respiratory tract congestion | 1 | 1 | 1 | 1 | | |
| | 11 | 16 | 11 | 13 | | 3 |

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Country Where Event Occurred

LEBANON

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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Country Where Event Occurred
LITHUANIA

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Chills | | 1 | | 1 | | |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Pain in extremity | | 1 | | 1 | | |
| Peripheral swelling | | 1 | | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Tachycardia | | 1 | | 1 | | |
| Tendon pain | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 5 | 11 | 3 | 9 | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Arthralgia | | 2 | | 2 | | |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure increased | | 1 | | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Dizziness | 1 | 3 | | 2 | 1 | 1 |
| Feeling drunk | | 1 | | 1 | | |
| Headache | 2 | 6 | 1 | 5 | 1 | 1 |
| Hyperhidrosis | | 1 | | 1 | | |
| Hypoesthesia | 2 | 2 | 2 | 2 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | | 3 | | 3 | | |
| Myositis | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 2 | | 1 | 1 | 1 |
| Overdose | | 1 | | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Polymyositis | 1 | 1 | | | 1 | 1 |
| Pyrexia | | 4 | | 4 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sensitive skin | | 1 | | 1 | | |
| Skin mass | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 2 | 3 | 1 | 2 | 1 | 1 |
| Underdose | | 1 | | 1 | | |
| Vaccination complication | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | | 2 | | 2 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 32 | 63 | 17 | 48 | 15 | 15 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accidental overdose | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 4 | 4 | | | 4 | 4 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 2 | | | 2 | 2 |
| Heart rate increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 3 | 4 | 2 | 3 | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | 1 | 1 | | |
| Local reaction | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | | | 1 | 1 |
| Neck pain | | 1 | | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Product preparation issue | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Stress | 1 | 1 | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Taste disorder | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vomiting | 2 | 2 | | | 2 | 2 |
| | 52 | 56 | 19 | 23 | 33 | 33 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Death | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 2 | 2 | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea | | 1 | | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 2 | 1 | 2 |
| Pyrexia | 1 | 2 | 1 | 2 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 4 | 7 | 4 | 7 |

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Country Where Event Occurred
LUXEMBOURG

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Chillblains | 1 | 1 | 1 | 1 | | |
| Chills | 3 | 3 | | | 3 | 3 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dry skin | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Fatigue | 5 | 5 | | | 5 | 5 |
| Headache | 4 | 4 | | | 4 | 4 |
| Herpes zoster | | 1 | | 1 | | |
| Influenza | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 3 | 3 | | | 3 | 3 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Oral herpes | | 1 | | 1 | | |
| Pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 2 | 2 | | | 2 | 2 |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | | | 1 | 1 |
| Pyrexia | 3 | 3 | | | 3 | 3 |
| Rash | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | | | 1 | 1 |
| Skin haemorrhage | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Tongue ulceration | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 2 | | | 2 | 2 |
| | 50 | 52 | 4 | 6 | 46 | 46 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Diarrhoea | 1 | 1 | 1 | 1 |
| Dyspnoea exertional | 1 | 1 | 1 | 1 |
| Epilepsy | 1 | 1 | 1 | 1 |
| Face oedema | 1 | 1 | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 |
| Feeding disorder | 1 | 1 | 1 | 1 |
| Feeling hot | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| Hypotension | 1 | 1 | 1 | 1 |
| Loss of consciousness | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Pallor | 1 | 1 | 1 | 1 |
| Presyncope | 1 | 1 | 1 | 1 |
| Pulse abnormal | 1 | 1 | 1 | 1 |
| Swelling | 1 | 1 | 1 | 1 |
| Vaccination complication | 1 | 1 | 1 | 1 |
| Vaccination site reaction | 1 | 1 | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 |
| | 22 | 22 | 22 | 22 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Acute kidney injury | 1 | 1 | 1 | 1 |
| Altered state of consciousness | 1 | 1 | 1 | 1 |
| Hypernatraemia | 1 | 1 | 1 | 1 |
| Hyperthermia | 1 | 1 | 1 | 1 |
| Lung disorder | 1 | 1 | 1 | 1 |
| Sepsis | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

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Country Where Event Occurred

MALTA

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Fear of injection | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 2 | 2 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 2 | 1 | 1 | 1 | 1 |
| Pyrexia | 2 | 2 | 2 | 2 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Swelling | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 3 | 3 | 3 | 3 | | |
| | 26 | 26 | 21 | 21 | 5 | 5 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 3 | 4 | | | 3 | 4 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Asthma | 1 | 2 | | | 1 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 2 | 1 | 2 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Defaecation urgency | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 2 | | 1 | 1 | 1 |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Erythema | 1 | 2 | | 1 | 1 | 1 |
| Facial paralysis | 2 | 3 | | | 2 | 3 |
| Fatigue | 5 | 7 | 4 | 6 | 1 | 1 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| Hot flush | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | | 1 | | | | 1 |
| Hypertension | | 1 | | | | 1 |
| Hypoaesthesia | 1 | 2 | 1 | 2 | | |
| Injection site pain | | 1 | | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Lethargy | 1 | 4 | 1 | 4 | | |
| Limb discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 2 | 1 | 2 | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 3 | 5 | 2 | 4 | 1 | 1 |
| Nausea | 2 | 3 | 1 | 2 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Off label use | | 1 | | 1 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Pain | 3 | 4 | 3 | 4 | | |
| Pain in extremity | 4 | 4 | 3 | 3 | 1 | 1 |
| Palpitations | 1 | 2 | | 1 | 1 | 1 |
| Paraesthesia | 1 | 3 | 1 | 3 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product use issue | | 1 | | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 4 | 5 | 3 | 4 | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash erythematous | 2 | 3 | | 1 | 2 | 2 |
| Rash pruritic | | 1 | | | | 1 |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Somnolence | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 2 | | | 1 | 2 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 3 | 2 | 3 | | |
| Vaccination site urticaria | 1 | 2 | | 1 | 1 | 1 |
| Vomiting | 2 | 3 | 1 | 2 | 1 | 1 |
| Wheezing | 1 | 2 | | | 1 | 2 |
| | 78 | 116 | 43 | 72 | 35 | 44 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fatigue | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 2 | 2 | 2 | 2 | | |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Administration site movement impairment | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Nausea | | 1 | | 1 | | |
| | 2 | 3 | | 1 | 2 | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| COVID-19 | | 1 | | 1 |
| Drug ineffective | | 1 | | 1 |
| | | 2 | | 2 |

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Country Where Event Occurred

MEXICO

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 11 | 13 | 9 | 11 | 2 | 2 |
| Allergy to vaccine | 1 | 1 | 1 | 1 | | |
| Allodynia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anaphylactic shock | 5 | 5 | | | 5 | 5 |
| Anosmia | 3 | 3 | 3 | 3 | | |
| Anxiety | 5 | 5 | 2 | 2 | 3 | 3 |
| Arthralgia | 63 | 72 | 56 | 65 | 7 | 7 |
| Asthenia | 70 | 76 | 61 | 67 | 9 | 9 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Axillary mass | 1 | 1 | 1 | 1 | | |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Back pain | 3 | 3 | 3 | 3 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 15 | 17 | 12 | 14 | 3 | 3 |
| Bowel movement irregularity | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 7 | 7 | 3 | 3 | 4 | 4 |
| Cellulitis | 3 | 3 | | | 3 | 3 |
| Chest pain | 12 | 12 | 9 | 9 | 3 | 3 |
| Chills | 56 | 59 | 47 | 50 | 9 | 9 |
| Conjunctival hyperaemia | 1 | 1 | 1 | 1 | | |
| Cough | 32 | 34 | 26 | 28 | 6 | 6 |
| COVID-19 | 3 | 3 | 1 | 1 | 2 | 2 |
| Crying | 2 | 2 | 1 | 1 | 1 | 1 |
| Cyanosis | 1 | 1 | 1 | 1 | | |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 9 | 10 | 8 | 9 | 1 | 1 |
| Diarrhoea | 22 | 23 | 18 | 19 | 4 | 4 |
| Discomfort | 3 | 4 | 3 | 4 | | |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Disseminated Bacillus Calmette-Guerin infection | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dizziness | 68 | 72 |
| Drug ineffective | 2 | 2 |
| Dry mouth | 3 | 3 |
| Dysgeusia | 4 | 5 |
| Dysphagia | 2 | 2 |
| Dyspnoea | 85 | 86 |
| Dyspnoea exertional | 3 | 3 |
| Dysstasia | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear disorder | 1 | 1 |
| Ear pain | 1 | 2 |
| Erythema | 15 | 16 |
| Eye disorder | 1 | 1 |
| Eye injury | 2 | 2 |
| Eye irritation | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eye pain | 2 | 2 |
| Face oedema | 1 | 1 |
| Facial paralysis | 1 | 1 |
| Fatigue | 61 | 62 |
| Febrile convulsion | 2 | 2 |
| Feeling abnormal | 1 | 1 |
| Feeling hot | 2 | 2 |
| Flushing | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| General physical condition abnormal | 1 | 1 |
| General physical health deterioration | 3 | 3 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematochezia | 1 | 1 |
| Headache | 109 | 123 |
| Head discomfort | 2 | 2 |
| Heart rate increased | 2 | 2 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 53 | 57 | 15 | 15 |
| | | 2 | 2 |
| 1 | 1 | 2 | 2 |
| 3 | 4 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 52 | 53 | 33 | 33 |
| 3 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 12 | 13 | 3 | 3 |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 51 | 52 | 10 | 10 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 96 | 110 | 13 | 13 |
| 2 | 2 | | |
| 2 | 2 | | |

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

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Hemiparaesthesia | 1 | 1 |
| Hemiplegia | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 6 | 6 |
| Hyperpyrexia | 1 | 1 |
| Hypersensitivity | 7 | 7 |
| Hypertension | 10 | 10 |
| Hypertensive crisis | 3 | 3 |
| Hypoaesthesia | 8 | 8 |
| Hypoaesthesia oral | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hyposmia | 1 | 1 |
| Hypotension | 2 | 2 |
| Hypothermia | 1 | 1 |
| Hypoventilation | 1 | 1 |
| Hypovolaemic shock | 1 | 1 |
| Induration | 10 | 10 |
| Inflammation | 18 | 19 |
| Irritability | 8 | 8 |
| Irritability postvaccinal | 1 | 1 |
| Local reaction | 12 | 13 |
| Loss of consciousness | 3 | 3 |
| Lymphadenopathy | 11 | 13 |
| Malaise | 10 | 10 |
| Mass | 1 | 1 |
| Maternal exposure during pregnancy | 3 | 3 |
| Metrorrhagia | 1 | 1 |
| Mobility decreased | 2 | 3 |
| Muscle contractions involuntary | 1 | 1 |
| Muscular weakness | 4 | 4 |
| Myalgia | 69 | 79 |
| Nasal congestion | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 5 | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 3 | 3 |
| 7 | 7 | 3 | 3 |
| | | 3 | 3 |
| 3 | 3 | 5 | 5 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 9 | 9 | 1 | 1 |
| 13 | 14 | 5 | 5 |
| 6 | 6 | 2 | 2 |
| 1 | 1 | | |
| 10 | 11 | 2 | 2 |
| | | 3 | 3 |
| 10 | 12 | 1 | 1 |
| 8 | 8 | 2 | 2 |
| 1 | 1 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| 2 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 62 | 72 | 7 | 7 |
| 3 | 3 | | |

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

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Nasopharyngitis | 2 | 2 |
| Nausea | 58 | 60 |
| Nodule | 12 | 12 |
| Occupational exposure to SARS-CoV-2 | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Odynophagia | 9 | 9 |
| Oedema | 26 | 29 |
| Oedema peripheral | 2 | 2 |
| Off label use | 4 | 4 |
| Oropharyngeal discomfort | 2 | 2 |
| Oropharyngeal pain | 38 | 38 |
| Otitis media acute | 1 | 1 |
| Oxygen saturation decreased | 7 | 7 |
| Pain | 67 | 70 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 5 | 6 |
| Pallor | 1 | 1 |
| Paraesthesia | 11 | 13 |
| Paraesthesia oral | 1 | 1 |
| Paralysis | 4 | 4 |
| Peripheral coldness | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal hypoaesthesia | 1 | 1 |
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Photopsia | 1 | 1 |
| Pneumonia | 1 | 1 |
| Product use issue | 4 | 4 |
| Prurigo | 1 | 1 |
| Pruritus | 22 | 22 |
| Pyrexia | 53 | 62 |
| Rash | 17 | 18 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 49 | 51 | 9 | 9 |
| 11 | 11 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 5 | 5 | 4 | 4 |
| 17 | 20 | 9 | 9 |
| 2 | 2 | | |
| 4 | 4 | | |
| | | 2 | 2 |
| 34 | 34 | 4 | 4 |
| 1 | 1 | | |
| 2 | 2 | 5 | 5 |
| 59 | 62 | 8 | 8 |
| 1 | 1 | | |
| 3 | 4 | 2 | 2 |
| 1 | 1 | | |
| 5 | 7 | 6 | 6 |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 4 | | |
| 1 | 1 | | |
| 16 | 16 | 6 | 6 |
| 49 | 58 | 4 | 4 |
| 9 | 10 | 8 | 8 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Respiratory distress | 84 | 84 |
| Rhinorrhoea | 24 | 24 |
| Seizure | 6 | 6 |
| Sensitive skin | 38 | 38 |
| Sensory loss | | 1 |
| Shock | 2 | 2 |
| Sinus tachycardia | 1 | 1 |
| Somnolence | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Suspected COVID-19 | 1 | 1 |
| Swelling | 1 | 2 |
| Syncope | 8 | 8 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 59 | 61 |
| Tachypnoea | 2 | 2 |
| Tenderness | 2 | 2 |
| Thirst | 2 | 2 |
| Throat irritation | 2 | 2 |
| Tinnitus | 1 | 1 |
| Tremor | 4 | 4 |
| Vaccination site erythema | 1 | 2 |
| Vaccination site hypersensitivity | 5 | 5 |
| Vaccination site hypoaesthesia | 1 | 1 |
| Vaccination site induration | 3 | 5 |
| Vaccination site inflammation | 3 | 3 |
| Vaccination site movement impairment | 2 | 2 |
| Vaccination site nodule | 2 | 4 |
| Vaccination site oedema | 1 | 1 |
| Vaccination site pain | 31 | 41 |
| Vaccination site paraesthesia | 2 | 2 |
| Vaccination site pruritus | 1 | 1 |
| Vaccination site reaction | 4 | 4 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 84 | 84 |
| 22 | 22 | 2 | 2 |
| | | 6 | 6 |
| 34 | 34 | 4 | 4 |
| | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| | | 8 | 8 |
| 1 | 1 | | |
| 48 | 50 | 11 | 11 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 4 | 4 | | |
| 1 | 2 | | |
| 5 | 5 | | |
| 1 | 1 | | |
| 3 | 5 | | |
| 3 | 3 | | |
| 2 | 2 | | |
| 2 | 4 | | |
| 1 | 1 | | |
| 31 | 41 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 4 | 4 | | |

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 * AE=Adverse Event
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Age Range

18 - 30 years

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|------|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 19 | 20 | 5 | 5 |
| 1 | 1 | | |
| 1194 | 1300 | 413 | 413 |

Vaccination site warmth
Vertigo
Vision blurred
Vomiting
Wheezing

1
2
2
24
1
1,607

1
2
2
25
1
1,713

1
1
1
19
1
1194

1
1
1
20
1
1300

413

413

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 39 | 41 | 36 | 38 | 3 | 3 |
| Abdominal pain upper | 1 | 3 | | 2 | 1 | 1 |
| Abnormal faeces | 1 | 1 | | | 1 | 1 |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Affect lability | 1 | 1 | 1 | 1 | | |
| Ageusia | 3 | 4 | 2 | 3 | 1 | 1 |
| Akathisia | | 1 | | 1 | | |
| Allergy to vaccine | 3 | 3 | 2 | 2 | 1 | 1 |
| Allodynia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Anaphylactic shock | 8 | 9 | | | 8 | 9 |
| Angina pectoris | | 1 | | | | 1 |
| Angioedema | | 2 | | | | 2 |
| Anosmia | 6 | 7 | 4 | 5 | 2 | 2 |
| Anxiety | 8 | 8 | 7 | 7 | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 120 | 144 | 109 | 132 | 11 | 12 |
| Asthenia | 165 | 182 | 146 | 161 | 19 | 21 |
| Asthma | | 1 | | 1 | | |
| Atypical pneumonia | 1 | 1 | | | 1 | 1 |
| Auricular swelling | 1 | 1 | 1 | 1 | | |
| Axonal neuropathy | | 1 | | | | 1 |
| Back pain | 7 | 8 | 7 | 8 | | |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blindness | 1 | 1 | | | 1 | 1 |
| Blood glucose decreased | | 1 | | | | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure diastolic increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 12 | 13 | 7 | 7 | 5 | 6 |
| Body temperature decreased | 1 | 1 | 1 | 1 | | |
| Body temperature fluctuation | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 23 | 25 | 20 | 22 | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Bradycardia | 1 | 1 |
| Bronchial disorder | 1 | 1 |
| Bronchospasm | 16 | 16 |
| Burning sensation | | 2 |
| Cellulitis | 5 | 5 |
| Chest discomfort | 4 | 5 |
| Chest pain | 20 | 21 |
| Chills | 124 | 135 |
| Choluria | 1 | 1 |
| Coagulation time prolonged | | 1 |
| Colitis | 1 | 1 |
| Conjunctivitis | 3 | 3 |
| Cough | 76 | 83 |
| COVID-19 | 5 | 6 |
| COVID-19 pneumonia | | 2 |
| Crying | 8 | 8 |
| Cyanosis | 1 | 2 |
| Deafness | 1 | 1 |
| Decreased appetite | 13 | 14 |
| Decreased immune responsiveness | 1 | 1 |
| Deficiency of bile secretion | 1 | 1 |
| Dehydration | 1 | 2 |
| Demyelination | | 2 |
| Depressed level of consciousness | 1 | 1 |
| Diarrhoea | 40 | 45 |
| Discharge | 1 | 1 |
| Discomfort | 7 | 13 |
| Disease recurrence | 2 | 2 |
| Disorientation | 3 | 3 |
| Dizziness | 138 | 150 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 3 | 7 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| 7 | 7 | 9 | 9 |
| | | | 2 |
| | | 5 | 5 |
| 3 | 4 | 1 | 1 |
| 19 | 20 | 1 | 1 |
| 112 | 123 | 12 | 12 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| 68 | 75 | 8 | 8 |
| 1 | 1 | 4 | 5 |
| | | | 2 |
| 8 | 8 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 10 | 11 | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 2 |
| | | 1 | 1 |
| 36 | 40 | 4 | 5 |
| 1 | 1 | | |
| 6 | 12 | 1 | 1 |
| 2 | 2 | | |
| 3 | 3 | | |
| 122 | 134 | 16 | 16 |
| | | 1 | 1 |
| | | 3 | 7 |

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 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Dry mouth | 3 | 3 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 5 | 5 |
| Dysphagia | 3 | 3 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 172 | 178 |
| Dyspnoea exertional | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear infection | 2 | 2 |
| Ear pain | 2 | 2 |
| Electrolyte imbalance | 1 | 1 |
| Encephalitis post immunisation | | 1 |
| Epigastric discomfort | | 1 |
| Epistaxis | 1 | 1 |
| Erythema | 32 | 33 |
| Expired product administered | 1 | 1 |
| External ear inflammation | 1 | 1 |
| Eye inflammation | | 1 |
| Eye injury | 7 | 7 |
| Eye irritation | 3 | 3 |
| Eyelid oedema | 1 | 1 |
| Eyelid rash | 1 | 1 |
| Eye pain | 6 | 7 |
| Eye pruritus | 1 | 1 |
| Eye swelling | | 2 |
| Face oedema | 1 | 2 |
| Facial paralysis | 3 | 3 |
| Fatigue | 131 | 135 |
| Febrile convulsion | 3 | 3 |
| Feeling cold | 2 | 3 |
| Feeling hot | 3 | 5 |
| Feeling of despair | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | | |
| 1 | 1 | | |
| 3 | 3 | 2 | 2 |
| 3 | 3 | | |
| 1 | 1 | | |
| 130 | 133 | 42 | 45 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 29 | 30 | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 7 | 7 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 6 | 7 | | |
| 1 | 1 | | |
| | 1 | | 1 |
| 1 | 2 | | |
| | | 3 | 3 |
| 119 | 123 | 12 | 12 |
| 1 | 1 | 2 | 2 |
| 2 | 3 | | |
| 1 | 3 | 2 | 2 |
| 1 | 1 | | |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # | Cumulative Total # |
|--|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Flushing | 1 | 1 |
| Foreign body sensation in eyes | 1 | 1 |
| Gastrointestinal disorder | | 1 |
| Gastrointestinal motility disorder | | 1 |
| General physical health deterioration | 2 | 2 |
| Haematochezia | 1 | 1 |
| Haemoptysis | 1 | 1 |
| Haemorrhage | 1 | 1 |
| Headache | 217 | 254 |
| Heart rate increased | 2 | 2 |
| Hemiparesis | 1 | 1 |
| Hemiplegia | 1 | 1 |
| Hepatic pain | 1 | 1 |
| Hot flush | 1 | 1 |
| Hunger | 1 | 1 |
| Hyperaesthesia | 2 | 2 |
| Hyperbilirubinaemia | 1 | 1 |
| Hyperhidrosis | 5 | 6 |
| Hypernatraemia | | 1 |
| Hypersensitivity | 10 | 13 |
| Hypersomnia | 1 | 1 |
| Hypertension | 18 | 20 |
| Hypertensive crisis | 9 | 10 |
| Hyperthermia | 2 | 2 |
| Hypoaesthesia | 7 | 8 |
| Hypoaesthesia oral | 4 | 4 |
| Hypotension | 3 | 3 |
| Hypothermia | 1 | 1 |
| Hypovolaemic shock | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 2 |
| Induration | 26 | 26 |
| Inflammation | 20 | 21 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 192 | 226 | 25 | 28 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 5 | 6 | | |
| | | | 1 |
| 9 | 12 | 1 | 1 |
| 1 | 1 | | |
| 10 | 11 | 8 | 9 |
| | | 9 | 10 |
| 2 | 2 | | |
| 5 | 5 | 2 | 3 |
| 3 | 3 | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 23 | 23 | 3 | 3 |
| 18 | 18 | 2 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Influenza | 2 | 2 |
| Injection site pain | 1 | 1 |
| Intussusception | 2 | 2 |
| Irritability | 12 | 12 |
| Irritability postvaccinal | 1 | 1 |
| Jaundice | 1 | 1 |
| Lacrimation increased | 3 | 3 |
| Laryngeal oedema | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Lip oedema | 1 | 2 |
| Localised oedema | 1 | 1 |
| Local reaction | 14 | 15 |
| Loss of consciousness | 1 | 2 |
| Loss of personal independence in daily activities | | 1 |
| Lymphadenopathy | 17 | 18 |
| Lymphangitis | 1 | 1 |
| Lymphopenia | | 1 |
| Malaise | 13 | 13 |
| Maternal exposure during pregnancy | 2 | 2 |
| Mechanical urticaria | | 1 |
| Mobility decreased | 1 | 3 |
| Mononeuropathy | | 1 |
| Mouth haemorrhage | 1 | 1 |
| Muscle contractions involuntary | 1 | 2 |
| Muscle contracture | | 1 |
| Muscle spasms | 1 | 3 |
| Muscle spasticity | | 1 |
| Muscular weakness | 3 | 4 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 142 | 164 |
| Myelitis | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 11 | 11 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 3 | 3 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| 13 | 14 | 1 | 1 |
| | | 1 | 2 |
| | | | 1 |
| 14 | 15 | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |
| 13 | 13 | | |
| 2 | 2 | | |
| | 1 | | |
| 1 | 3 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 2 | | 1 |
| | | | 1 |
| 3 | 4 | | |
| 1 | 1 | | |
| 129 | 150 | 13 | 14 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Myelitis transverse | | 1 |
| Nasal congestion | 3 | 4 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 93 | 108 |
| Neck pain | 2 | 3 |
| Nerve degeneration | | 1 |
| Nervousness | 2 | 2 |
| Neuritis | | 2 |
| Nodule | 31 | 32 |
| Ocular hyperaemia | 1 | 1 |
| Odynophagia | 13 | 13 |
| Oedema | 42 | 45 |
| Oedema peripheral | 1 | 1 |
| Oral dysaesthesia | 1 | 1 |
| Oropharyngeal discomfort | 4 | 4 |
| Oropharyngeal pain | 78 | 80 |
| Otitis externa | 1 | 1 |
| Oxygen saturation abnormal | 3 | 3 |
| Oxygen saturation decreased | 11 | 11 |
| Pain | 152 | 162 |
| Pain in extremity | 10 | 12 |
| Pain in jaw | 1 | 1 |
| Pain of skin | 1 | 1 |
| Pallor | 1 | 1 |
| Palpitations | 4 | 5 |
| Papule | 1 | 1 |
| Paraesthesia | 23 | 27 |
| Paraesthesia oral | 5 | 7 |
| Paralysis | 4 | 5 |
| Pelvic pain | | 1 |
| Peripheral coldness | 1 | 1 |
| Peripheral motor neuropathy | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 3 | 4 | | |
| | | 1 | 1 |
| 81 | 93 | 12 | 15 |
| 2 | 3 | | |
| | | | 1 |
| 2 | 2 | | |
| | | | 2 |
| 27 | 28 | 4 | 4 |
| 1 | 1 | | |
| 12 | 12 | 1 | 1 |
| 35 | 38 | 7 | 7 |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | 1 | 1 |
| 72 | 74 | 6 | 6 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| 8 | 8 | 3 | 3 |
| 138 | 147 | 14 | 15 |
| 10 | 12 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 5 | | |
| 1 | 1 | | |
| 21 | 22 | 2 | 5 |
| 5 | 6 | | 1 |
| | | 4 | 5 |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Peripheral swelling | 1 | 1 |
| Peroneal nerve injury | | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal disorder | 1 | 1 |
| Pharyngeal inflammation | 2 | 2 |
| Pharyngitis | 1 | 1 |
| Photophobia | 1 | 1 |
| Pneumonia | 5 | 5 |
| Presyncope | 1 | 1 |
| Productive cough | 1 | 1 |
| Pruritus | 29 | 34 |
| Purpura | 2 | 2 |
| Pyrexia | 94 | 112 |
| Radiculopathy | | 2 |
| Rales | 1 | 1 |
| Rash | 32 | 43 |
| Rash erythematous | 1 | 1 |
| Rash maculo-papular | 2 | 3 |
| Raynaud's phenomenon | 1 | 1 |
| Respiratory distress | 171 | 172 |
| Rhinitis | 1 | 1 |
| Rhinorrhoea | 65 | 71 |
| Sacroiliitis | | 1 |
| SARS-CoV-2 ant body test negative | 3 | 3 |
| SARS-CoV-2 test positive | 1 | 2 |
| Sciatica | | 1 |
| Sciatic nerve neuropathy | | 1 |
| Secretion discharge | 1 | 1 |
| Seizure | 7 | 11 |
| Sensation of foreign body | 2 | 2 |
| Sensitisation | 1 | 1 |
| Sensitive skin | 90 | 90 |

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 5 | 5 |
| 1 | 1 | | |
| 1 | 1 | | |
| 26 | 30 | 3 | 4 |
| 1 | 1 | 1 | 1 |
| 84 | 101 | 10 | 11 |
| | | | 2 |
| 1 | 1 | | |
| 26 | 34 | 6 | 9 |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 1 | | |
| | | 171 | 172 |
| 1 | 1 | | |
| 58 | 64 | 7 | 7 |
| | | | 1 |
| 3 | 3 | | |
| 1 | 1 | | 1 |
| | | | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 7 | 11 |
| 2 | 2 | | |
| 1 | 1 | | |
| 79 | 79 | 11 | 11 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Sensory disturbance | 1 | 1 |
| Sensory loss | | 1 |
| Sinus tachycardia | 1 | 1 |
| Skin haemorrhage | 1 | 1 |
| Skin lesion | 1 | 1 |
| Skin swelling | 1 | 1 |
| Slow response to stimuli | | 1 |
| Sneezing | | 1 |
| Somnolence | 5 | 6 |
| Speech disorder | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Suspected COVID-19 | 2 | 2 |
| Sweating fever | 1 | 1 |
| Swelling | 2 | 2 |
| Swelling face | 1 | 1 |
| Syncope | 15 | 17 |
| Systemic lupus erythematosus | 1 | 1 |
| Tachycardia | 101 | 109 |
| Tachypnoea | 2 | 2 |
| Tenderness | 2 | 2 |
| Throat irritation | 3 | 5 |
| Throat tightness | 1 | 1 |
| Thrombocytopenic purpura | 1 | 1 |
| Tinnitus | 2 | 2 |
| Tongue oedema | 2 | 2 |
| Transaminases increased | 1 | 1 |
| Traumatic lung injury | 2 | 2 |
| Tremor | 3 | 3 |
| Tympanic membrane disorder | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urticaria | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 5 | 6 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 15 | 17 |
| | | 1 | 1 |
| 83 | 91 | 18 | 18 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | | |
| 2 | 4 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site cellulitis | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 3 | 3 | 3 | 3 | | |
| Vaccination site hyperaesthesia | 1 | 2 | 1 | 2 | | |
| Vaccination site hypersensitivity | 12 | 13 | 12 | 13 | | |
| Vaccination site induration | 9 | 9 | 7 | 7 | 2 | 2 |
| Vaccination site inflammation | 3 | 4 | 3 | 4 | | |
| Vaccination site joint pain | | 1 | | 1 | | |
| Vaccination site nodule | 5 | 6 | 4 | 5 | 1 | 1 |
| Vaccination site oedema | 4 | 5 | 4 | 5 | | |
| Vaccination site pain | 49 | 75 | 44 | 69 | 5 | 6 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 3 | 4 | 3 | 4 | | |
| Vaccination site warmth | 6 | 7 | 6 | 7 | | |
| Vertigo | 5 | 6 | 4 | 5 | 1 | 1 |
| Vision blurred | 9 | 9 | 8 | 8 | 1 | 1 |
| Vomiting | 32 | 35 | 30 | 32 | 2 | 3 |
| White blood cell count increased | | 1 | | | | 1 |
| | 3,158 | 3,540 | 2529 | 2829 | 629 | 711 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 9 | 9 | 8 | 8 | 1 | 1 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anaphylactic shock | 6 | 6 | | | 6 | 6 |
| Anxiety | 2 | 2 | 1 | 1 | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 16 | 18 | 14 | 16 | 2 | 2 |
| Asthenia | 19 | 19 | 18 | 18 | 1 | 1 |
| Aura | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Body temperature increased | 4 | 4 | 4 | 4 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Brain oedema | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 4 | 4 | 2 | 2 | 2 | 2 |
| Cellulitis | 2 | 2 | | | 2 | 2 |
| Chest discomfort | 3 | 3 | 3 | 3 | | |
| Chest pain | 3 | 3 | 3 | 3 | | |
| Chills | 21 | 22 | 15 | 16 | 6 | 6 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | 13 | 13 | 10 | 10 | 3 | 3 |
| COVID-19 | 5 | 5 | | | 5 | 5 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Decreased activity | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 10 | 10 | 8 | 8 | 2 | 2 |
| Dermatosis | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 4 | 4 | 2 | 2 | 2 | 2 |
| Diplegia | 1 | 1 | | | 1 | 1 |
| Discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Dizziness | 31 | 33 | 24 | 25 | 7 | 8 |
| Drug ineffective | 4 | 4 | | | 4 | 4 |
| Dry mouth | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dry throat | 1 | 1 |
| Dysgeusia | | 1 |
| Dysphagia | 1 | 1 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 38 | 38 |
| Ear discomfort | 1 | 1 |
| Epistaxis | 1 | 1 |
| Erythema | 7 | 7 |
| Eye injury | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eye movement disorder | 1 | 1 |
| Fatigue | 15 | 15 |
| Feeling abnormal | 1 | 1 |
| Generalised tonic-clonic seizure | 2 | 2 |
| General physical health deterioration | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematochezia | 1 | 1 |
| Haemorrhage | 2 | 2 |
| Headache | 37 | 40 |
| Heart rate increased | 1 | 1 |
| Hot flush | | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 3 | 3 |
| Hypertension | 7 | 7 |
| Hypertensive crisis | 4 | 5 |
| Hyperthermia | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 |
| Hypothermia | 1 | 1 |
| Induration | 6 | 6 |
| Inflammation | 7 | 7 |
| Laryngeal oedema | 2 | 2 |
| Laryngospasm | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 28 | 28 | 10 | 10 |
| 1 | 1 | | |
| 1 | 1 | | |
| 7 | 7 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 13 | 13 | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 29 | 32 | 8 | 8 |
| 1 | 1 | | |
| | 1 | | |
| | | 2 | 2 |
| 1 | 1 | 2 | 2 |
| 3 | 3 | 4 | 4 |
| | | 4 | 5 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 6 | 6 | | |
| 7 | 7 | | |
| | | 2 | 2 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Lateropulsion | 1 | 1 |
| Lethargy | 1 | 1 |
| Lip oedema | 1 | 1 |
| Local reaction | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 2 | 2 |
| Malaise | 5 | 5 |
| Masticatory pain | | 1 |
| Metamorphopsia | 1 | 1 |
| Muscular weakness | 2 | 2 |
| Myalgia | 19 | 20 |
| Nausea | 23 | 23 |
| Neuropathy peripheral | 1 | 1 |
| Nodule | 7 | 7 |
| Obstructive airways disorder | 1 | 1 |
| Odynophagia | 2 | 2 |
| Oedema | 10 | 11 |
| Oropharyngeal pain | 14 | 14 |
| Oxygen saturation abnormal | 1 | 1 |
| Oxygen saturation decreased | 3 | 3 |
| Pain | 26 | 27 |
| Pain in extremity | 1 | 1 |
| Pain in jaw | 1 | 1 |
| Paraesthesia | 5 | 6 |
| Parotid gland enlargement | | 1 |
| Parotitis | | 1 |
| Pharyngeal oedema | 1 | 1 |
| Pneumonia | 1 | 1 |
| Pruritus | 8 | 8 |
| Pyrexia | 14 | 16 |
| Rash | 10 | 10 |
| Rash erythematous | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 2 | 2 | 3 | 3 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 15 | 16 | 4 | 4 |
| 21 | 21 | 2 | 2 |
| | | 1 | 1 |
| 6 | 6 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 10 | 11 | | |
| 13 | 13 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 21 | 22 | 5 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| 3 | 4 | 2 | 2 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 7 | 1 | 1 |
| 10 | 12 | 4 | 4 |
| 7 | 7 | 3 | 3 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Respiratory disorder | 1 | 1 |
| Respiratory distress | 35 | 35 |
| Respiratory failure | 1 | 1 |
| Rhinorrhoea | 10 | 10 |
| Salivary hypersecretion | 1 | 1 |
| Seizure | 3 | 3 |
| Sensation of foreign body | 1 | 1 |
| Sensitisation | 1 | 1 |
| Sensitive skin | 11 | 11 |
| Skin disorder | 1 | 1 |
| Sleep inertia | 1 | 1 |
| Somnolence | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 1 |
| Syncope | 4 | 4 |
| Tachycardia | 22 | 23 |
| Tachypnoea | 1 | 1 |
| Tension headache | 1 | 1 |
| Throat irritation | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue oedema | 1 | 1 |
| Toothache | 1 | 1 |
| Upper airway obstruction | 1 | 1 |
| Urticaria | 1 | 1 |
| Vaccination site discomfort | 1 | 1 |
| Vaccination site erythema | 1 | 2 |
| Vaccination site hypersensitivity | 1 | 1 |
| Vaccination site induration | 2 | 2 |
| Vaccination site nodule | 1 | 1 |
| Vaccination site oedema | 2 | 2 |
| Vaccination site pain | 10 | 13 |
| Vaccination site pruritus | 1 | 1 |
| Vaccination site reaction | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 35 | 35 |
| | | 1 | 1 |
| 8 | 8 | 2 | 2 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| 10 | 10 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 4 | 4 |
| 18 | 18 | 4 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 10 | 13 | | |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vertigo | 2 | 2 | 1 | 1 | 1 | 1 |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 7 | 7 | 4 | 4 | 3 | 3 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 622 | 647 | 416 | 438 | 206 | 209 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Myalgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| | 16 | 16 | 7 | 7 | 9 | 9 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | | 3 | | 3 | | |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 2 | 2 | 2 | 2 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| COVID-19 | 1 | 6 | 1 | 2 | | 4 |
| COVID-19 pneumonia | | 1 | | | | 1 |
| Demyelination | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 7 | | | 1 | 7 |
| Dyspnoea | 1 | 2 | | 1 | 1 | 1 |
| Epilepsy | | 1 | | | | 1 |
| Fatigue | 2 | 3 | 2 | 3 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 2 | 1 | 2 | | |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 2 | 2 | 2 | 2 | | |
| Hypoaesthesia | 1 | 3 | 1 | 3 | | |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Incomplete course of vaccination | 1 | 1 | 1 | 1 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Laryngospasm | | 1 | | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Mononeuropathy | 1 | 1 | | | 1 | 1 |
| Muscle rigidity | 1 | 1 | 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|----|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Muscle spasms | | 1 | | 1 | | | |
| Myalgia | 1 | 1 | 1 | 1 | | | |
| Nausea | 3 | 3 | 3 | 3 | | | |
| Nervousness | 1 | 1 | 1 | 1 | | | |
| Off label use | | 2 | | 2 | | | |
| Oropharyngeal pain | | 1 | | 1 | | | |
| Oxygen saturation decreased | | 1 | | | | | 1 |
| Pain | 1 | 1 | 1 | 1 | | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | | |
| Paraesthesia | 2 | 4 | 2 | 4 | | | |
| Pneumonia | | 3 | | | | | 3 |
| Product use issue | | 2 | | 2 | | | |
| Pyelonephritis | 1 | 1 | | | 1 | | 1 |
| Pyrexia | | 2 | | 2 | | | |
| Rash | | 2 | | 2 | | | |
| Respiratory distress | | 1 | | | | | 1 |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | | 1 |
| Seizure | | 2 | | | | | 2 |
| Suspected COVID-19 | | 1 | | | | | 1 |
| Tachycardia | 2 | 2 | 1 | 1 | 1 | | 1 |
| Transaminases increased | 1 | 1 | | | 1 | | 1 |
| Urticaria | 1 | 1 | 1 | 1 | | | |
| Vaccination site pain | 2 | 4 | 2 | 4 | | | |
| Vaccination site rash | | 1 | | 1 | | | |
| Vomiting | 1 | 1 | 1 | 1 | | | |
| | 47 | 95 | 34 | 61 | 13 | | 34 |

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Country Where Event Occurred

NETHERLANDS

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | | 1 | | | | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Arthralgia | 6 | 6 | 6 | 6 | | |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 2 | 1 | 1 | | 1 |
| Chills | 12 | 13 | 11 | 11 | 1 | 2 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Diplopia | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 6 | 7 | 4 | 4 | 2 | 3 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysarthria | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 4 | 4 | 3 | 3 | 1 | 1 |
| Epilepsy | 3 | 3 | | | 3 | 3 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Faeces discoloured | 1 | 1 | 1 | 1 | | |
| Fatigue | 10 | 10 | 9 | 9 | 1 | 1 |
| Flushing | 1 | 1 | 1 | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 14 | 14 | 12 | 12 | 2 | 2 |
| Head discomfort | | 1 | | | | 1 |
| Hemianaesthesia | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperpyrexia | 5 | 5 | | | 5 | 5 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------|------------------------------------|--------------------------------------|
| Hypersensitivity | 3 | 3 |
| Hypertension | 2 | 2 |
| Hyperventilation | 2 | 3 |
| Hyponatraemia | 1 | 1 |
| Hypotension | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Malaise | 17 | 17 |
| Migraine | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 12 | 12 |
| Nausea | 14 | 14 |
| Nystagmus | 1 | 1 |
| Pain in extremity | 1 | 1 |
| Pain of skin | 1 | 1 |
| Pallor | 1 | 1 |
| Palpitations | 1 | 2 |
| Paraesthesia oral | 1 | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | 2 | 2 |
| Presyncope | 1 | 1 |
| Pruritus | 1 | 1 |
| Pupillary disorder | 1 | 1 |
| Pyrexia | 6 | 6 |
| Rash | 1 | 2 |
| Seizure | 1 | 1 |
| Speech disorder | 1 | 1 |
| Status epilepticus | 1 | 1 |
| Syncope | 5 | 5 |
| Tachycardia | 1 | 1 |
| Throat tightness | 1 | 1 |
| Torticollis | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 3 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 13 | 13 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 12 | 12 | | |
| 11 | 11 | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 5 | 5 | 1 | 1 |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 1 | 1 | 1 | 1 | | |
| Urticaria | 5 | 6 | 2 | 2 | 3 | 4 |
| Vaccination site bruising | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site haematoma | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 4 | 4 | 4 | 4 | | |
| Vaccination site pain | 8 | 8 | 8 | 8 | | |
| Vaccination site swelling | 5 | 5 | 5 | 5 | | |
| Vaccination site warmth | 2 | 2 | 2 | 2 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 204 | 213 | 144 | 144 | 60 | 69 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 1 | | 1 | | |
| Accommodation disorder | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 3 | 4 | | | 3 | 4 |
| Arthralgia | 5 | 5 | 5 | 5 | | |
| Axillary pain | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Bundle branch block right | 1 | 1 | 1 | 1 | | |
| Chills | 10 | 10 | 10 | 10 | | |
| Choking sensation | | 1 | | | | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 3 | | 1 | 2 | 2 |
| Deafness neurosensory | 1 | 1 | | | 1 | 1 |
| Derealisation | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 4 | 4 | 1 | 1 | 3 | 3 |
| Dyspnoea exertional | 1 | 1 | 1 | 1 | | |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Erythema | | 1 | | 1 | | |
| Extensive swelling of vaccinated limb | 3 | 3 | 3 | 3 | | |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 8 | 9 | 8 | 9 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling drunk | 1 | 1 | 1 | 1 | | |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Fluid retention | 1 | 1 | 1 | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hallucination | 1 | 1 | 1 | 1 | | |
| Headache | 14 | 15 | 14 | 15 | | |
| Hyperpyrexia | 5 | 5 | | | 5 | 5 |
| Hypotension | 2 | 2 | 1 | 1 | 1 | 1 |
| Incorrect route of product administration | | 1 | | 1 | | |
| Injection site erythema | 2 | 2 | 2 | 2 | | |
| Injection site inflammation | 1 | 1 | 1 | 1 | | |
| Injection site pain | 2 | 2 | 2 | 2 | | |
| Injection site pruritus | 1 | 1 | 1 | 1 | | |
| Injection site swelling | 2 | 2 | 2 | 2 | | |
| Injection site warmth | 2 | 2 | 2 | 2 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 3 | 3 | 3 | 3 | | |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 14 | 15 | 12 | 13 | 2 | 2 |
| Myalgia | 12 | 14 | 12 | 14 | | |
| Nausea | 11 | 12 | 11 | 12 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 2 | 2 | 2 | | |
| Paraesthesia oral | | 1 | | 1 | | |
| Pharyngeal oedema | | 1 | | | | 1 |
| Pharyngeal swelling | 2 | 2 | | | 2 | 2 |
| Pituitary apoplexy | 1 | 1 | | | 1 | 1 |
| Polyuria | 1 | 1 | 1 | 1 | | |
| Psychotic symptom | 1 | 1 | | | 1 | 1 |
| Pyrexia | 2 | 2 | | | 2 | 2 |
| Rash | 1 | 1 | 1 | 1 | | |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Sinus tachycardia | 1 | 1 | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sneezing | | 1 | | 1 | | |
| Sudden hearing loss | 2 | 2 | | | 2 | 2 |
| Swelling face | 1 | 2 | | 1 | 1 | 1 |
| Swollen tongue | 2 | 2 | | | 2 | 2 |
| Syncope | 4 | 4 | | | 4 | 4 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tongue oedema | | 1 | | | | 1 |
| Tremor | 2 | 2 | 2 | 2 | | |
| Urticaria | 1 | 2 | 1 | 2 | | |
| Vaccination site bruising | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 3 | 4 | 3 | 4 | | |
| Vaccination site inflammation | 3 | 4 | 3 | 4 | | |
| Vaccination site pain | 6 | 7 | 6 | 7 | | |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site swelling | 4 | 5 | 4 | 5 | | |
| Vaccination site warmth | 4 | 5 | 4 | 5 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vestibular neuronitis | 1 | 1 | | | 1 | 1 |
| Vision blurred | 2 | 2 | 2 | 2 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 188 | 215 | 139 | 161 | 49 | 54 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 2 | | | 1 | 2 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anxiety | | 1 | | | | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Atrial f brillation | 2 | 2 | | | 2 | 2 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 6 | 7 | 4 | 5 | 2 | 2 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Disorganised speech | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 2 | | 1 | 1 | 1 |
| Dysphagia | 1 | 2 | | | 1 | 2 |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Electrocardiogram ST segment abnormal | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Erythema | | 1 | | | | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 3 | 3 | 1 | 1 | 2 | 2 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Headache | 6 | 8 | 4 | 6 | 2 | 2 |
| Herpes ophthalmic | 1 | 1 | | | 1 | 1 |
| Hyperacusis | 1 | 1 | 1 | 1 | | |
| Hyperpyrexia | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 2 | 2 | | | 2 | 2 |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Influenza l ke illness | | 1 | | 1 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Malaise | 6 | 7 |
| Mood altered | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 |
| Myalgia | 3 | 4 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 4 | 5 |
| Oral pruritus | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain in extremity | 1 | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | | 1 |
| Paraesthesia oral | 1 | 1 |
| Peripheral coldness | | 1 |
| Pharyngeal swelling | 1 | 2 |
| Pneumonia | 1 | 1 |
| Postmenopausal haemorrhage | 1 | 1 |
| Pruritus | | 1 |
| Pyrexia | 1 | 1 |
| Rash erythematous | 1 | 1 |
| Rash maculo-papular | | 1 |
| Rhinitis | 1 | 1 |
| Sialoadenitis | 2 | 2 |
| Sudden hearing loss | 2 | 2 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling face | 2 | 2 |
| Swollen tongue | 1 | 1 |
| Syncope | 3 | 3 |
| Tachycardia | 2 | 2 |
| Throat tightness | 1 | 1 |
| Thrombosis | 1 | 1 |
| Tinnitus | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 4 | 2 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 3 | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

51 - 64 years

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| 1 | 1 | | |
| 2 | 2 | | |
| 4 | 5 | 1 | 1 |
| 2 | 2 | | |
| | 1 | | |
| 45 | 57 | 55 | 63 |

100

120

45

57

55

63

Unresponsive to stimuli

2

2

Vaccination site erythema

1

1

Vaccination site inflammation

2

2

Vaccination site pain

5

6

Vaccination site warmth

2

2

Vomiting

2

1

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Conjunctival oedema | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Death | 3 | 3 | | | 3 | 3 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Ischaemic cerebral infarction | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Malaise | 4 | 4 | 1 | 1 | 3 | 3 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Postictal state | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site haematoma | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| | 43 | 43 | 13 | 13 | 30 | 30 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Apallic syndrome | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 4 | 4 | 3 | 3 | 1 | 1 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac disorder | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 4 | 4 | | | 4 | 4 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebral infarction | 2 | 2 | | | 2 | 2 |
| Cerebral ischaemia | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 3 | 3 | | | 3 | 3 |
| Chills | 2 | 2 | | | 2 | 2 |
| Choking | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 2 | 2 | | | 2 | 2 |
| Confusional state | 2 | 2 | 1 | 1 | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Cystitis | 1 | 1 | | | 1 | 1 |
| Death | 5 | 5 | | | 5 | 5 |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Dehydration | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 8 | 8 | 1 | 1 | 7 | 7 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Epilepsy | 2 | 2 |
| Erythema | 1 | 1 |
| Fatigue | 10 | 10 |
| Feeding disorder | 1 | 1 |
| Gastrointestinal haemorrhage | 2 | 2 |
| Gaze palsy | 1 | 1 |
| Headache | 2 | 2 |
| Hemiparesis | 2 | 2 |
| Hemiplegia | 1 | 1 |
| Hepatic failure | 1 | 1 |
| Hyperpyrexia | 1 | 1 |
| Hypertensive crisis | 1 | 1 |
| Hypovolaemic shock | 1 | 1 |
| Ischaemic cerebral infarction | 1 | 1 |
| Lung disorder | 1 | 1 |
| Malaise | 15 | 15 |
| Melaena | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscle twitching | 1 | 1 |
| Myalgia | 3 | 3 |
| Myocardial infarction | 2 | 2 |
| Nausea | 7 | 7 |
| Ocular hyperaemia | 1 | 1 |
| Off label use | 1 | 1 |
| Oxygen saturation decreased | 4 | 4 |
| Pallor | 2 | 2 |
| Peripheral coldness | 1 | 1 |
| Pneumonia | 1 | 1 |
| Pneumonia aspiration | 1 | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 1 | 1 |
| Pulmonary oedema | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 1 | 1 |
| 4 | 4 | 6 | 6 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 5 | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | 6 | 6 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pyrexia | 10 | 10 | 1 | 1 | 9 | 9 |
| Rash | 1 | 1 | | | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Retching | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | 1 | 1 | 1 | 1 |
| Status epilepticus | 1 | 1 | | | 1 | 1 |
| Sudden cardiac death | 1 | 1 | | | 1 | 1 |
| Sudden death | 4 | 4 | | | 4 | 4 |
| Swelling of eyelid | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Vomiting | 2 | 2 | 1 | 1 | 1 | 1 |
| Weight decreased | 1 | 1 | | | 1 | 1 |
| | 165 | 165 | 33 | 33 | 132 | 132 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Basilar artery thrombosis | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Exposure to SARS-CoV-2 | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | | 1 | | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 5 | 4 | 5 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 3 | 3 | 3 | 3 | | |
| Malaise | 3 | 3 | 3 | 3 | | |
| Myalgia | 2 | 2 | 2 | 2 | | |
| Nausea | 2 | 2 | 2 | 2 | | |
| Occupational exposure to product | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | 1 | 1 | | |
| Product label confusion | | 1 | | 1 | | |
| Product preparation error | | 1 | | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vaccination site haematoma | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| | 33 | 38 | 31 | 36 | 2 | 2 |

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Country Where Event Occurred
NORTHERN MARIANA ISLANDS

Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | | 1 | | 1 |
| Chest discomfort | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Disorientation | | 1 | | 1 |
| Dizziness | | 1 | | 1 |
| Fatigue | | 1 | | 1 |
| Headache | | 1 | | 1 |
| Pain in extremity | | 1 | | 1 |
| Poor quality sleep | | 1 | | 1 |
| | | 9 | | 9 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

NORWAY

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Chills | 2 | 2 | 1 | 1 | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 2 | | 1 | 1 | 1 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Fatigue | 6 | 6 | 5 | 5 | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling drunk | 1 | 1 | 1 | 1 | | |
| General physical health deterioration | 1 | 1 | 1 | 1 | | |
| Headache | 9 | 10 | 7 | 8 | 2 | 2 |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Malaise | 4 | 4 | 4 | 4 | | |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Nausea | 3 | 4 | 3 | 4 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Photophobia | 2 | 2 | 2 | 2 | | |
| Pyrexia | 3 | 4 | 3 | 4 | | |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 3 | 2 | 2 | 1 | 1 |
| | 53 | 57 | 46 | 50 | 7 | 7 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 2 | 2 | 2 | 2 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blepharospasm | | 1 | | 1 | | |
| Breast enlargement | 1 | 1 | 1 | 1 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Burning sensation | | 1 | | | | 1 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Chest discomfort | | 1 | | | | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 5 | 6 | 5 | 6 | | |
| Cold sweat | 3 | 4 | 2 | 2 | 1 | 2 |
| Concussion | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| Decreased activity | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Diarrhoea | 3 | 3 | 3 | 3 | | |
| Diverticulitis | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 3 | 2 | 2 | | 1 |
| Dry mouth | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 2 | 2 | | | 2 | 2 |
| Dyspnoea | 1 | 2 | 1 | 1 | | 1 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Ear swelling | 1 | 1 | 1 | 1 | | |
| Erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Faeces discoloured | 1 | 1 | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fatigue | 8 | 9 | 8 | 9 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | 2 | 2 | 2 | 2 | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Frostbite | 1 | 1 | | | 1 | 1 |
| Hallucination | 1 | 1 | | | 1 | 1 |
| Headache | 11 | 12 | 11 | 12 | | |
| Heart rate increased | 2 | 2 | | | 2 | 2 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | 2 | 3 | 1 | 1 | 1 | 2 |
| Hyperventilation | | 1 | | | | 1 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 | | |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Influenza | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Intranasal hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Intranasal paraesthesia | 1 | 1 | 1 | 1 | | |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 2 | 2 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 2 | 2 | 2 | 2 | | |
| Myalgia | 2 | 2 | 2 | 2 | | |
| Nausea | 5 | 5 | 5 | 5 | | |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pain in extremity | 3 | 4 | 3 | 4 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Paranasal sinus discomfort | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pharyngeal swelling | 1 | 1 | 1 | 1 | | |
| Pruritus | 2 | 2 | 1 | 1 | 1 | 1 |
| Pyrexia | 5 | 6 | 5 | 6 | | |
| Rash | 3 | 3 | 1 | 1 | 2 | 2 |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Respiratory a kalosis | | 1 | | | | 1 |
| Respiratory rate decreased | 1 | 1 | 1 | 1 | | |
| Restlessness | 1 | 1 | | | 1 | 1 |
| Skin laceration | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tendon pain | 1 | 1 | 1 | 1 | | |
| Thirst | 1 | 1 | 1 | 1 | | |
| Throat clearing | 1 | 1 | 1 | 1 | | |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 9 | 9 | 9 | 9 | | |
| Vaccination site paraesthesia | 2 | 2 | 2 | 2 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 2 | 2 | 2 | 2 | | |

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Age Range

31 - 50 years

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 127 | 133 | 27 | 35 |

154

168

127

133

27

35

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Abdominal wall haemorrhage | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | | 1 | | 1 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cerebral infarction | 1 | 1 | | | 1 | 1 |
| Chills | 3 | 3 | 3 | 3 | | |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| C-reactive protein increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 4 | 4 | 2 | 2 | 2 | 2 |
| Fatigue | 4 | 5 | 3 | 4 | 1 | 1 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Flushing | 1 | 1 | 1 | 1 | | |
| Gastritis | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 4 | 3 | 3 | 1 | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Influenza | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Injection site muscle weakness | | 1 | | 1 | | |
| International normalised ratio increased | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Listless | 1 | 1 | 1 | 1 | | |
| Livedo reticularis | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Malaise | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 6 | 5 | 5 | 1 | 1 |
| Nausea | 2 | 2 | 2 | 2 | | |
| Oropharyngeal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Psychomotor hyperactivity | 1 | 1 | 1 | 1 | | |
| Pyrexia | 4 | 4 | 2 | 2 | 2 | 2 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Somnolence | 2 | 2 | 1 | 1 | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | | | 1 | 1 |
| | 76 | 80 | 51 | 55 | 25 | 25 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Adverse reaction | 1 | 1 | 1 | 1 | | |
| Altered state of consciousness | 2 | 2 | | | 2 | 2 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Aspiration | 1 | 1 | | | 1 | 1 |
| Bacterial test positive | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | | 2 | | | | 2 |
| Body temperature increased | | 1 | | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | | 1 | | | | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Confusional state | 2 | 2 | | | 2 | 2 |
| Cough | 1 | 2 | | | 1 | 2 |
| C-reactive protein increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 3 | 4 | 2 | 2 | 1 | 2 |
| Disease recurrence | | 1 | | | | 1 |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 4 | 5 | 1 | 1 | 3 | 4 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 3 | 4 | 2 | 3 | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling hot | 1 | 2 | 1 | 2 | | |
| Flushing | | 1 | | 1 | | |
| Gastroenteritis | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 2 | 4 | | | 2 | 4 |
| General symptom | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Heart rate irregular | | 1 | | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Infective exacerbation of chronic obstructive airways disease | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 4 | 2 | 3 | | 1 |
| Malignant hypertension | | 1 | | | | 1 |
| Nausea | 6 | 7 | 5 | 5 | 1 | 2 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Obstructive airways disorder | 1 | 1 | | | 1 | 1 |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | | 1 | | | | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Pneumonia | 2 | 3 | | | 2 | 3 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pyrexia | 5 | 6 | 4 | 4 | 1 | 2 |
| Rales | | 1 | | | | 1 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory rate increased | | 1 | | | | 1 |
| Retching | | 1 | | 1 | | |
| Somnolence | 1 | 2 | | | 1 | 2 |
| Sputum increased | 1 | 1 | 1 | 1 | | |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Vomiting | 4 | 4 | 2 | 2 | 2 | 2 |
| | 79 | 104 | 32 | 39 | 47 | 65 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 3 | 3 | 1 | 1 | 2 | 2 |
| Acute coronary syndrome | | 1 | | | | 1 |
| Acute kidney injury | | 1 | | | | 1 |
| Acute myocardial infarction | 2 | 3 | | | 2 | 3 |
| Altered state of consciousness | 4 | 4 | | | 4 | 4 |
| Anal incontinence | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 2 | | 1 | 1 | 1 |
| Apathy | | 1 | | | | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Apnoea | 2 | 2 | | | 2 | 2 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bacterial sepsis | 1 | 1 | | | 1 | 1 |
| Bedridden | 4 | 4 | | | 4 | 4 |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature decreased | | 1 | | 1 | | |
| Bradycardia | 2 | 2 | | | 2 | 2 |
| Cardiac failure | 2 | 3 | | | 2 | 3 |
| Cerebral haemorrhage | 1 | 2 | | | 1 | 2 |
| Cerebrovascular accident | 6 | 8 | | | 6 | 8 |
| Cerebrovascular disorder | 1 | 1 | | | 1 | 1 |
| Chest pain | 3 | 3 | | | 3 | 3 |
| Chills | 3 | 3 | 1 | 1 | 2 | 2 |
| Chronic kidney disease | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 3 | | | 1 | 3 |
| Communication disorder | 1 | 1 | 1 | 1 | | |
| Concomitant disease aggravated | | 1 | | | | 1 |
| Condition aggravated | 2 | 3 | 1 | 1 | 1 | 2 |
| Confusional state | 9 | 12 | 5 | 5 | 4 | 7 |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Constipation | 1 | 1 | 1 | 1 | | |
| Coordination abnormal | | 1 | | | | 1 |
| Coronary artery occlusion | 1 | 1 | | | 1 | 1 |
| Cough | 5 | 5 | 3 | 3 | 2 | 2 |
| C-reactive protein increased | 11 | 11 | 2 | 2 | 9 | 9 |
| Death | 16 | 24 | | | 16 | 24 |
| Decreased appetite | 7 | 9 | 2 | 2 | 5 | 7 |
| Dehydration | 1 | 1 | | | 1 | 1 |
| Delirium | 1 | 2 | | | 1 | 2 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 3 | 5 | | | 3 | 5 |
| Diarrhoea | 8 | 9 | 6 | 6 | 2 | 3 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dizziness | 4 | 4 | 2 | 2 | 2 | 2 |
| Drooling | 1 | 1 | 1 | 1 | | |
| Dry skin | 1 | 1 | 1 | 1 | | |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysphagia | 3 | 4 | | | 3 | 4 |
| Dysphonia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 17 | 19 | 4 | 4 | 13 | 15 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Eye haemorrhage | 2 | 2 | | | 2 | 2 |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Facial paresis | 2 | 2 | | | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 3 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | 1 | 2 |
| 5 | 5 | 4 | 7 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 3 | 3 | 2 | 2 |
| 2 | 2 | 9 | 9 |
| | | 16 | 24 |
| 2 | 2 | 5 | 7 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 3 | 5 |
| 6 | 6 | 2 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 3 | 4 |
| 2 | 2 | | |
| 4 | 4 | 13 | 15 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 2 | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Faeces discoloured | 1 | 1 |
| Fall | 6 | 6 |
| Fatigue | 23 | 26 |
| Feeling abnormal | 2 | 2 |
| Feeling hot | | 1 |
| Femoral neck fracture | 1 | 1 |
| Food refusal | 1 | 1 |
| Fracture | 1 | 1 |
| Gastrointestinal haemorrhage | | 1 |
| General physical health deterioration | 25 | 31 |
| Haematemesis | 1 | 1 |
| Haemoglobin decreased | 1 | 1 |
| Hallucination | 1 | 2 |
| Headache | 8 | 8 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 4 | 6 |
| Heart rate irregular | 1 | 1 |
| Hemiparesis | 2 | 2 |
| Hyperglycaemia | 1 | 1 |
| Hyperkalaemia | 1 | 1 |
| Hypernatraemia | 1 | 1 |
| Hypertension | 2 | 2 |
| Hyperventilation | 2 | 3 |
| Hypophagia | 1 | 2 |
| Hypotension | 3 | 5 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Increased bronchial secretion | 2 | 2 |
| Infection | 6 | 7 |
| Influenza like illness | 1 | 2 |
| Intracardiac thrombus | | 1 |
| Ischaemic stroke | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 2 | 2 | 4 | 4 |
| 18 | 18 | 5 | 8 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 2 | 2 | 23 | 29 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 7 | 7 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 2 | 4 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 2 | 3 | | |
| | | 1 | 2 |
| | | 3 | 5 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 5 | 6 |
| | | 1 | 2 |
| | | | 1 |
| | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytosis | 1 | 1 | 1 | 1 | | |
| Local reaction | | 1 | | | | 1 |
| Loss of consciousness | 2 | 3 | | | 2 | 3 |
| Lower respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Malaise | 3 | 4 | 2 | 2 | 1 | 2 |
| Malignant hypertension | 1 | 1 | | | 1 | 1 |
| Malnutrition | 1 | 1 | | | 1 | 1 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Metastases to peritoneum | 1 | 1 | | | 1 | 1 |
| Motor dysfunction | 1 | 1 | 1 | 1 | | |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Nasal congestion | 3 | 3 | 3 | 3 | | |
| Nasopharyngitis | 1 | 1 | | | 1 | 1 |
| Nausea | 13 | 14 | 8 | 8 | 5 | 6 |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Nitrite urine present | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | 3 | 3 | 2 | 2 | 1 | 1 |
| Oropharyngeal pain | 4 | 4 | 3 | 3 | 1 | 1 |
| Oxygen saturation decreased | 7 | 9 | 1 | 1 | 6 | 8 |
| Pain | 5 | 5 | 3 | 3 | 2 | 2 |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 3 | | | 1 | 3 |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 8 | 10 | | | 8 | 10 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Presyncope | 2 | 2 | | | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| 2 | 2 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 3 | 3 | | |
| | | 1 | 1 |
| 8 | 8 | 5 | 6 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| 3 | 3 | 1 | 1 |
| 1 | 1 | 6 | 8 |
| 3 | 3 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 3 |
| | | 1 | 1 |
| | | 8 | 10 |
| | | 1 | 1 |
| | | 2 | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Productive cough | 4 | 4 | | | 4 | 4 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pupil fixed | | 2 | | | | 2 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 26 | 29 | 8 | 8 | 18 | 21 |
| Rales | 2 | 2 | 2 | 2 | | |
| Rash | 2 | 2 | 2 | 2 | | |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | 2 | 3 | | | 2 | 3 |
| Respiratory failure | 3 | 3 | | | 3 | 3 |
| Respiratory rate increased | 2 | 4 | 2 | 2 | | 2 |
| Restlessness | 4 | 5 | 1 | 2 | 3 | 3 |
| Rhinorrhoea | 3 | 3 | 3 | 3 | | |
| Secretion discharge | 1 | 1 | | | 1 | 1 |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Somnolence | 3 | 4 | 3 | 3 | | 1 |
| Speech disorder | 3 | 3 | 2 | 2 | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Sudden death | 2 | 4 | | | 2 | 4 |
| Syncope | 5 | 7 | | | 5 | 7 |
| Tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Terminal state | 2 | 2 | | | 2 | 2 |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | 1 | 2 | | | 1 | 2 |
| Unresponsive to stimuli | 3 | 3 | | | 3 | 3 |
| Urinary incontinence | 1 | 1 | | | 1 | 1 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 2 | 3 | 2 | 3 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 3 | 2 | 2 | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 2 | 4 | 2 | 3 | | 1 |
| Vaccination site swelling | | 2 | | 1 | | 1 |
| Vomiting | 12 | 17 | 5 | 6 | 7 | 11 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 435 | 528 | 147 | 156 | 288 | 372 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Incorrect dose administered | | 1 | | 1 |
| Intercepted product preparation error | 1 | 1 | 1 | 1 |
| Poor quality product administered | | 6 | | 6 |
| Product administered at inappropriate site | | 1 | | 1 |
| Product preparation error | | 2 | | 2 |
| Product temperature excursion issue | | 6 | | 6 |
| Wrong technique in product usage process | | 1 | | 1 |
| | 1 | 18 | 1 | 18 |

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Country Where Event Occurred

OMAN

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea | | 1 | | 1 |
| Fatigue | | 1 | | 1 |
| Gastritis | | 1 | | 1 |
| Headache | | 1 | | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| Pain | | 1 | | 1 |
| Product supply issue | 1 | 1 | 1 | 1 |
| Pyrexia | | 1 | | 1 |
| | 2 | 8 | 2 | 8 |

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Country Where Event Occurred

PANAMA

Age Range

Unknown

Preferred Term

Flatulence

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous

Nonserious

I

C

1

1

1

1

1

1

1

1

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Country Where Event Occurred

POLAND

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Anxiety | | 1 | | 1 |
| Diarrhoea | | 1 | | 1 |
| Exposure via breast milk | | 2 | | 2 |
| Pyrexia | | 1 | | 1 |
| | | 5 | | 5 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Abdominal pain upper | | 1 | | | | 1 | |
| Ageusia | | 1 | | 1 | | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 | |
| Arthralgia | 1 | 3 | | 1 | 1 | 2 | |
| Asthenia | 5 | 6 | 3 | 4 | 2 | 2 | |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 | |
| Axillary pain | 2 | 2 | 2 | 2 | | | |
| Blood pressure decreased | 2 | 2 | 1 | 1 | 1 | 1 | |
| Bone pain | 1 | 2 | | | 1 | 2 | |
| Bradycardia | 1 | 1 | | | 1 | 1 | |
| Chest pain | 1 | 1 | | | 1 | 1 | |
| Chills | 1 | 3 | 1 | 2 | | 1 | |
| COVID-19 | 1 | 1 | | | 1 | 1 | |
| Decreased appetite | 1 | 1 | 1 | 1 | | | |
| Dizziness | 2 | 2 | | | 2 | 2 | |
| Drug ineffective | 1 | 1 | | | 1 | 1 | |
| Dysgeusia | | 1 | | 1 | | | |
| Epistaxis | | 1 | | 1 | | | |
| Erythema | 1 | 1 | | | 1 | 1 | |
| Eye pain | 3 | 3 | | | 3 | 3 | |
| Fatigue | 2 | 3 | 2 | 3 | | | |
| Feeling hot | 1 | 1 | | | 1 | 1 | |
| Formication | 1 | 1 | | | 1 | 1 | |
| Headache | 6 | 8 | 3 | 5 | 3 | 3 | |
| Hyperhidrosis | 2 | 2 | 2 | 2 | | | |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 | |
| Hypotonic-hyporesponsive episode | 1 | 1 | 1 | 1 | | | |
| Infection | 1 | 1 | | | 1 | 1 | |
| Laryngospasm | 1 | 1 | | | 1 | 1 | |
| Lymphadenopathy | 3 | 3 | 1 | 1 | 2 | 2 | |
| Lymph node pain | 3 | 3 | 1 | 1 | 2 | 2 | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myalgia | 3 | 5 | 1 | 2 | 2 | 3 |
| Nausea | 2 | 3 | 1 | 2 | 1 | 1 |
| Neck pain | 2 | 4 | 1 | 2 | 1 | 2 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 3 | 6 | 1 | 3 | 2 | 3 |
| Pancreatitis acute | | 1 | | | | 1 |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pyrexia | 8 | 11 | 3 | 5 | 5 | 6 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Spinal pain | | 1 | | | | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Taste disorder | | 1 | | 1 | | |
| Tremor | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | | 2 | | 2 | | |
| Vaccination site pain | 5 | 10 | 5 | 9 | | 1 |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 1 | 2 | 1 | 2 | | |
| Vertigo | 2 | 2 | | | 2 | 2 |
| Visual field defect | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 86 | 122 | 35 | 60 | 51 | 62 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 2 | | 1 | 1 | 1 |
| Ageusia | 2 | 2 | 2 | 2 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anaphylactic shock | 5 | 5 | | | 5 | 5 |
| Angioedema | 3 | 3 | | | 3 | 3 |
| Anosmia | 2 | 2 | 2 | 2 | | |
| Antibody test abnormal | 1 | 1 | 1 | 1 | | |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 2 | 3 | | | 2 | 3 |
| Arthralgia | 9 | 16 | 6 | 13 | 3 | 3 |
| Arthritis | | 1 | | 1 | | |
| Asthenia | 14 | 22 | 7 | 14 | 7 | 8 |
| Asthma | 3 | 3 | | | 3 | 3 |
| Asymptomatic COVID-19 | | 1 | | | | 1 |
| Back pain | 4 | 4 | 4 | 4 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 4 | 4 | | | 4 | 4 |
| Blood pressure increased | 1 | 2 | | | 1 | 2 |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Brachial plexus injury | 1 | 1 | | | 1 | 1 |
| Bronchial oedema | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Chest discomfort | | 1 | | 1 | | |
| Chills | 12 | 18 | 8 | 13 | 4 | 5 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Contusion | 1 | 1 | | | 1 | 1 |
| Cough | | 2 | | 2 | | |
| COVID-19 | 8 | 9 | 2 | 2 | 6 | 7 |
| Decreased appetite | 2 | 2 | 1 | 1 | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 3 | 3 | 1 | 1 | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Disease recurrence | | 1 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 5 | 5 |
| Drug ineffective | 6 | 9 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 1 | 1 |
| Dysphagia | 1 | 1 |
| Dyspnoea | 7 | 8 |
| Dysstasia | | 1 |
| Ear pain | | 1 |
| Ecchymosis | 1 | 1 |
| Erythema | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eye pain | 1 | 2 |
| Face oedema | 1 | 1 |
| Facial paralysis | 1 | 1 |
| Fatigue | 1 | 1 |
| Febrile convulsion | 3 | 3 |
| Feeling abnormal | 1 | 2 |
| Feeling cold | 1 | 2 |
| Feeling hot | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Haematoma | | 1 |
| Headache | 16 | 25 |
| Heart rate increased | 1 | 3 |
| Hot flush | | 1 |
| Hydronephrosis | 1 | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 4 | 6 |
| Hypertension | 1 | 2 |
| Hypoaesthesia | 3 | 5 |
| Hypoaesthesia oral | 2 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 4 | 4 |
| | | 6 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 6 | 6 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 2 | | |
| | | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 10 | 18 | 6 | 7 |
| | 1 | 1 | 2 |
| | | | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 2 | 4 | 4 |
| | 1 | 1 | 1 |
| | 1 | 3 | 4 |
| | | 2 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypopnoea | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Hypotonic-hyporesponsive episode | 8 | 8 | 2 | 2 | 6 | 6 |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Influenza | | 1 | | 1 | | |
| Initial insomnia | | 1 | | 1 | | |
| Insomnia | | 1 | | 1 | | |
| Joint range of motion decreased | | 1 | | 1 | | |
| Lacrimation increased | 1 | 1 | | | 1 | 1 |
| Laryngospasm | 2 | 2 | | | 2 | 2 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 7 | 7 | | | 7 | 7 |
| Lymphadenopathy | 13 | 16 | 5 | 8 | 8 | 8 |
| Lymph node pain | 10 | 10 | 4 | 4 | 6 | 6 |
| Malaise | 5 | 5 | 4 | 4 | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 2 | 1 | 2 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 15 | 22 | 8 | 15 | 7 | 7 |
| Myocardial hypoxia | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nausea | 7 | 12 | 4 | 9 | 3 | 3 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Oedema | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 3 | | 2 | 1 | 1 |
| Oxygen saturation decreased | 3 | 4 | | 1 | 3 | 3 |
| Pain | 1 | 2 | | 1 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Painful respiration | | 1 |
| Pain in extremity | 8 | 13 |
| Pain of skin | | 1 |
| Pallor | 2 | 3 |
| Palpitations | 1 | 1 |
| Paraparesis | | 1 |
| Parosmia | 2 | 2 |
| Peripheral swelling | | 1 |
| Petechiae | 2 | 2 |
| Pharyngeal swelling | 1 | 1 |
| Presyncope | | 1 |
| Product administered at inappropriate site | | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 2 | 2 |
| Pulpitis dental | | 1 |
| Pyrexia | 24 | 34 |
| Rash | 1 | 1 |
| Rash macular | | 1 |
| Respiratory arrest | 1 | 1 |
| Respiratory tract oedema | 1 | 1 |
| Rhinitis | 1 | 1 |
| Rhinorrhoea | | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| SARS-CoV-2 test negative | 1 | 1 |
| SARS-CoV-2 test positive | | 1 |
| Seizure | 5 | 5 |
| Shock symptom | 1 | 1 |
| Somnolence | 3 | 3 |
| Spinal pain | 1 | 1 |
| Suspected COVID-19 | 1 | 1 |
| Swollen tongue | 2 | 2 |
| Syncope | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 6 | 11 | 2 | 2 |
| | 1 | | |
| | | 2 | 3 |
| 1 | 1 | | |
| | | | 1 |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| 10 | 19 | 14 | 15 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 5 | 6 | | | 5 | 6 |
| Taste disorder | 1 | 2 | | 1 | 1 | 1 |
| Therapeutic response unexpected | | 1 | | 1 | | |
| Throat irritation | | 1 | | 1 | | |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Toothache | | 1 | | 1 | | |
| Tracheal oedema | 1 | 1 | | | 1 | 1 |
| Tremor | | 1 | | | | 1 |
| Urticaria | 1 | 2 | | 1 | 1 | 1 |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 3 | 5 | 1 | 3 | 2 | 2 |
| Vaccination site extravasation | | 1 | | 1 | | |
| Vaccination site induration | 1 | 2 | 1 | 2 | | |
| Vaccination site movement impairment | 1 | 2 | 1 | 2 | | |
| Vaccination site pain | 9 | 24 | 7 | 22 | 2 | 2 |
| Vaccination site pruritus | 1 | 3 | 1 | 3 | | |
| Vaccination site reaction | 8 | 10 | | 2 | 8 | 8 |
| Vaccination site swelling | 2 | 4 | 1 | 3 | 1 | 1 |
| Vaccination site warmth | | 1 | | 1 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Visual field defect | | 1 | | 1 | | |
| Vomiting | 1 | 3 | | 2 | 1 | 1 |
| | 347 | 494 | 125 | 250 | 222 | 244 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 2 | | 1 | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Ageusia | 3 | 3 | 2 | 2 | 1 | 1 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Anosmia | 3 | 3 | 2 | 2 | 1 | 1 |
| Anxiety | | 1 | | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Arthropathy | | 1 | | 1 | | |
| Asthenia | 13 | 18 | 6 | 11 | 7 | 7 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure increased | 4 | 5 | 1 | 1 | 3 | 4 |
| Body temperature increased | 2 | 4 | 2 | 4 | | |
| Bone pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Breast pain | 1 | 1 | | | 1 | 1 |
| Burning sensation | | 1 | | 1 | | |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 2 | 1 | 2 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 9 | 9 | 5 | 5 | 4 | 4 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Conjunctival hyperaemia | | 1 | | 1 | | |
| Contusion | 1 | 1 | | | 1 | 1 |
| Cough | 5 | 6 | 2 | 3 | 3 | 3 |
| COVID-19 | 2 | 5 | 1 | 1 | 1 | 4 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Decreased activity | | 1 | | 1 | | |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disease progression | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Disorientation | 1 | 1 |
| Dizziness | 4 | 6 |
| Drug ineffective | 2 | 4 |
| Dry mouth | | 1 |
| Dysgeusia | 1 | 1 |
| Dyspnoea | 3 | 3 |
| Encephalopathy | 1 | 1 |
| Erythema | 1 | 1 |
| Erythema multiforme | 2 | 2 |
| Fatigue | 2 | 3 |
| Febrile convulsion | 1 | 1 |
| Feeling abnormal | | 1 |
| Feeling cold | 2 | 2 |
| Feeling hot | | 1 |
| Gait disturbance | | 1 |
| Goitre | 1 | 1 |
| Headache | 11 | 15 |
| Head discomfort | 1 | 1 |
| Heart rate increased | | 1 |
| Herpes virus infection | | 1 |
| Hot flush | | 1 |
| Hyperaesthesia | 1 | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoaesthesia eye | 1 | 1 |
| Hypotonic-hyporesponsive episode | 1 | 1 |
| Inappropriate schedule of product administration | | 1 |
| Influenza like illness | 1 | 2 |
| Joint swelling | 1 | 1 |
| Lividity | 1 | 1 |
| Loss of consciousness | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 2 | 4 | 2 | 2 |
| | | 2 | 4 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 2 | 3 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 5 | 9 | 6 | 6 |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Lymphadenopathy | 5 | 5 |
| Lymph node pain | 2 | 2 |
| Malaise | 4 | 5 |
| Migraine | | 1 |
| Musculoskeletal stiffness | | 2 |
| Myalgia | 8 | 10 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 3 | 4 |
| Neck pain | 1 | 2 |
| Off label use | 1 | 1 |
| Oropharyngeal pain | 1 | 2 |
| Pain in extremity | 4 | 6 |
| Pallor | | 1 |
| Paraesthesia | 1 | 2 |
| Paraesthesia oral | 1 | 1 |
| Paresis | | 1 |
| Parosmia | 1 | 1 |
| Petechiae | 1 | 1 |
| Pneumonia | | 1 |
| Product use issue | 1 | 1 |
| Prostatitis | 1 | 1 |
| Pyrexia | 17 | 20 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Rash rubelliform | 1 | 1 |
| Rhinorrhoea | 1 | 1 |
| Seizure | 2 | 2 |
| Speech disorder | 1 | 1 |
| Spinal pain | | 1 |
| Suspected COVID-19 | 1 | 1 |
| Swelling | | 1 |
| Syncope | 4 | 4 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 2 | 3 | 2 | 2 |
| | 1 | | |
| | 2 | | |
| 4 | 6 | 4 | 4 |
| 1 | 1 | | |
| 1 | 2 | 2 | 2 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 5 | 8 | 12 | 12 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 4 | 4 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Thyroiditis | 1 | 1 | | | 1 | 1 |
| Thyroid pain | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 2 | 1 | 2 | | |
| Urinary tract inflammation | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 8 | 10 | 5 | 7 | 3 | 3 |
| Vaccination site reaction | 8 | 9 | 1 | 2 | 7 | 7 |
| Vaccination site swelling | | 1 | | 1 | | |
| Vertigo | 2 | 2 | | | 2 | 2 |
| Vision blurred | | 1 | | 1 | | |
| Vomiting | 3 | 3 | | | 3 | 3 |
| | 203 | 267 | 78 | 134 | 125 | 133 |

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 * AE=Adverse Event
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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | | | 1 | 1 |
| Decreased nasolabial fold | 1 | 1 | 1 | 1 | | |
| Erythema | | 1 | | | | 1 |
| Febrile convulsion | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Helplessness | | 1 | | | | 1 |
| Herpes virus infection | | 1 | | 1 | | |
| Hyperaesthesia | 1 | 2 | 1 | 1 | | 1 |
| Incorrect route of product administration | | 1 | | 1 | | |
| Muscle tightness | | 1 | | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Pain | | 1 | | | | 1 |
| Pain in extremity | | 1 | | | | 1 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 3 | 1 | 1 | 1 | 2 |
| Swelling | | 1 | | | | 1 |
| Temperature intolerance | 1 | 1 | 1 | 1 | | |
| Vaccination site infection | | 1 | | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vaccination site reaction | | 1 | | 1 | | |
| Vaccination site scab | | 1 | | 1 | | |
| Vaccination site vesicles | | 1 | | 1 | | |
| | 12 | 27 | 9 | 17 | 3 | 10 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Aortic aneurysm rupture | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 5 | 5 | 2 | 2 | 3 | 3 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Blood glucose increased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac death | 1 | 1 | | | 1 | 1 |
| Cerebral haematoma | 2 | 2 | | | 2 | 2 |
| Contusion | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | 2 | 2 | | | 2 | 2 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Ear swelling | 1 | 1 | | | 1 | 1 |
| Electrolyte imbalance | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gastrointestinal disorder | 1 | 1 | | | 1 | 1 |
| Gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Haemoptysis | 1 | 1 | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haemorrhagic stroke | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | | | 1 | 1 |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypoaesthesia | 3 | 3 | 1 | 1 | 2 | 2 |
| Insomnia | 2 | 2 | 2 | 2 | | |
| Lividity | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 3 | 3 | | | 3 | 3 |
| Malaise | 3 | 3 | 2 | 2 | 1 | 1 |
| Movement disorder | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal pain | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nausea | 3 | 3 | 2 | 2 | 1 | 1 |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pyrexia | 5 | 5 | 3 | 3 | 2 | 2 |
| Seizure | 2 | 2 | | | 2 | 2 |
| Speech disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vomiting | 4 | 4 | 1 | 1 | 3 | 3 |
| Walking disability | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Yellow skin | 1 | 1 | | | 1 | 1 |
| | 95 | 95 | 31 | 31 | 64 | 64 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 3 | 2 | 3 | | |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Adnexa uteri pain | 1 | 1 | 1 | 1 | | |
| Ageusia | 1 | 2 | 1 | 2 | | |
| Anosmia | 2 | 5 | 2 | 5 | | |
| Antibody test abnormal | 11 | 11 | 11 | 11 | | |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Arthralgia | 15 | 25 | 14 | 24 | 1 | 1 |
| Arthropathy | 1 | 1 | 1 | 1 | | |
| Asthenia | 14 | 27 | 13 | 26 | 1 | 1 |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Axillary pain | | 3 | | 3 | | |
| Back pain | 2 | 5 | 2 | 5 | | |
| Blood pressure decreased | 1 | 2 | | 1 | 1 | 1 |
| Blood urine present | | 1 | | 1 | | |
| Bone pain | 3 | 5 | 3 | 5 | | |
| Breast pain | | 1 | | 1 | | |
| Burning sensation | | 1 | | 1 | | |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 15 | 22 | 14 | 21 | 1 | 1 |
| Chorea | 1 | 1 | 1 | 1 | | |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Coagulopathy | 1 | 1 | 1 | 1 | | |
| Confusional state | 1 | 1 | 1 | 1 | | |
| COVID-19 | 16 | 23 | 2 | 3 | 14 | 20 |
| Crying | | 1 | | 1 | | |
| Cystitis | | 1 | | 1 | | |
| Deafness | 2 | 2 | | | 2 | 2 |
| Death | 5 | 5 | | | 5 | 5 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Decreased appetite | | 2 |
| Delirium | 1 | 1 |
| Diarrhoea | 1 | 6 |
| Disease recurrence | 1 | 1 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 3 | 7 |
| Drug ineffective | 14 | 20 |
| Dysgeusia | 1 | 2 |
| Dysphonia | 2 | 2 |
| Dyspnoea | 1 | 2 |
| Epistaxis | | 1 |
| Exercise tolerance decreased | 1 | 1 |
| Exposure during pregnancy | 1 | 2 |
| Exposure via breast milk | | 5 |
| Extensive swelling of vaccinated limb | 1 | 1 |
| Fatigue | 3 | 7 |
| Feeling abnormal | 3 | 5 |
| Feeling cold | 4 | 5 |
| Feeling hot | 3 | 3 |
| Flatulence | 1 | 1 |
| Flushing | 2 | 2 |
| Headache | 12 | 24 |
| Heart rate increased | 2 | 2 |
| Herpes virus infection | | 1 |
| Herpes zoster | | 1 |
| Hot flush | | 1 |
| Hyperacusis | 1 | 1 |
| Hyperaesthesia teeth | | 1 |
| Hyperhidrosis | 2 | 3 |
| Hypertension | 1 | 1 |
| Hypoaesthesia | 6 | 7 |
| Hypoaesthesia oral | 2 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| | | 1 | 1 |
| 1 | 6 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 3 | 7 | | |
| | | 14 | 20 |
| | 1 | 1 | 1 |
| 2 | 2 | | |
| 1 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | 5 | | |
| 1 | 1 | | |
| 2 | 6 | 1 | 1 |
| 3 | 5 | | |
| 4 | 5 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 12 | 24 | | |
| 2 | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 2 | 3 | | |
| | | 1 | 1 |
| 6 | 7 | | |
| 1 | 2 | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypoxia | 1 | 1 |
| Illness | 1 | 1 |
| Incorrect dose administered | | 1 |
| Incorrect route of product administration | | 1 |
| Increased upper airway secretion | 1 | 1 |
| Inflammation | | 2 |
| Influenza like illness | 2 | 4 |
| Insomnia | 5 | 6 |
| Iritis | | 1 |
| Joint effusion | 1 | 1 |
| Joint swelling | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lung disorder | 1 | 1 |
| Lymphadenopathy | 2 | 5 |
| Lymph node pain | | 1 |
| Malaise | 15 | 22 |
| Mental disorder | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal pain | 1 | 1 |
| Myalgia | 21 | 30 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 6 | 9 |
| Neck pain | 2 | 2 |
| Needle issue | | 1 |
| Night sweats | 1 | 1 |
| Nodule | 1 | 1 |
| Oedema | | 1 |
| Off label use | | 8 |
| Oxygen saturation decreased | | 1 |
| Pain | 3 | 4 |
| Pain in extremity | 10 | 17 |
| Palpitations | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| 2 | 4 | | |
| 5 | 6 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 4 | 1 | 1 |
| | 1 | | |
| 15 | 22 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 20 | 29 | 1 | 1 |
| 1 | 1 | | |
| 6 | 9 | | |
| 2 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 7 | | 1 |
| | | | 1 |
| 3 | 4 | | |
| 9 | 16 | 1 | 1 |
| 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Paraesthesia | 3 | 3 |
| Paralysis | | 1 |
| Paresis | | 1 |
| Parotitis | 1 | 1 |
| Peripheral coldness | 1 | 1 |
| Pharyngeal swelling | 1 | 1 |
| Photophobia | 1 | 1 |
| Poor quality product administered | 4 | 4 |
| Poor quality sleep | | 1 |
| Product label confusion | | 2 |
| Product preparation error | 1 | 1 |
| Product temperature excursion issue | 1 | 1 |
| Product use issue | | 7 |
| Pruritus | | 1 |
| Pyrexia | 23 | 40 |
| Rash | 1 | 3 |
| Respiratory failure | 1 | 1 |
| Retching | | 1 |
| Rhinorrhoea | 3 | 4 |
| SARS-CoV-2 ant body test negative | 2 | 2 |
| Sepsis | 1 | 1 |
| Sinus headache | 1 | 1 |
| Sinusitis | | 1 |
| Skin hypertrophy | 1 | 1 |
| Somnolence | 2 | 5 |
| Suppressed lactation | | 2 |
| Swelling | | 1 |
| Syncope | 4 | 4 |
| Tachycardia | 2 | 3 |
| Taste disorder | 1 | 1 |
| Tension headache | 1 | 1 |
| Therapeutic response unexpected | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | | |
| | | | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 4 | | |
| | 1 | | |
| | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 6 | | 1 |
| | 1 | | |
| 21 | 37 | 2 | 3 |
| 1 | 3 | | |
| | | 1 | 1 |
| | 1 | | |
| 3 | 4 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 2 | 5 | | |
| | 1 | | 1 |
| | 1 | | |
| | | 4 | 4 |
| 1 | 1 | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thirst | 1 | 1 | 1 | 1 | | |
| Tinnitus | 4 | 4 | 4 | 4 | | |
| Tonsillar hypertrophy | | 1 | | 1 | | |
| Ulnar nerve palsy | 1 | 1 | 1 | 1 | | |
| Urticaria | | 1 | | 1 | | |
| Vaccination site erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site macule | | 1 | | 1 | | |
| Vaccination site movement impairment | | 1 | | 1 | | |
| Vaccination site oedema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 11 | 26 | 10 | 25 | 1 | 1 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site reaction | 1 | 4 | 1 | 4 | | |
| Vaccination site swelling | 3 | 5 | 3 | 5 | | |
| Vaccination site warmth | 1 | 2 | 1 | 2 | | |
| Vein disorder | 1 | 1 | 1 | 1 | | |
| Viral infection | 1 | 1 | 1 | 1 | | |
| Visual impairment | 1 | 1 | 1 | 1 | | |
| Vomiting | 2 | 5 | 2 | 5 | | |
| | 340 | 571 | 275 | 486 | 65 | 85 |

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Country Where Event Occurred

PORTUGAL

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Eructation | | 1 | | 1 |
| Exposure via breast milk | 1 | 3 | 1 | 3 |
| | 1 | 4 | 1 | 4 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Aphthous ulcer | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 8 | 8 | | | 8 | 8 |
| Asthenia | 6 | 6 | | | 6 | 6 |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Axillary pain | 3 | 3 | | | 3 | 3 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Body temperature increased | | 1 | | 1 | | |
| Breast pain | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Chest discomfort | 2 | 2 | | | 2 | 2 |
| Chest pain | 2 | 2 | | | 2 | 2 |
| Chills | 19 | 20 | 1 | 1 | 18 | 19 |
| Cold sweat | 2 | 2 | | | 2 | 2 |
| Condition aggravated | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 2 | 3 | | | 2 | 3 |
| Decreased appetite | 2 | 3 | | 1 | 2 | 2 |
| Depressed mood | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | | 1 | | | | 1 |
| Diarrhoea | 5 | 5 | 1 | 1 | 4 | 4 |
| Dizziness | 8 | 8 | 1 | 1 | 7 | 7 |
| Drug ineffective | 3 | 5 | | | 3 | 5 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Dysphonia | 1 | 1 |
| Dyspnoea | 4 | 4 |
| Ear pain | 2 | 2 |
| Eczema | 1 | 1 |
| Erythema | 2 | 3 |
| Face oedema | | 1 |
| Fatigue | 9 | 10 |
| Feeling hot | 2 | 2 |
| Flatulence | 1 | 1 |
| Flushing | 1 | 1 |
| Headache | 42 | 43 |
| Hemiparaesthesia | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypertension | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoglycaemia | 1 | 1 |
| Hypotension | 1 | 1 |
| Illness | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect route of product administration | 2 | 2 |
| Injected limb mobility decreased | | 1 |
| Laryngeal oedema | 1 | 1 |
| Lip oedema | 1 | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 17 | 18 |
| Malaise | 4 | 4 |
| Migraine | 1 | 1 |
| Motor dysfunction | 2 | 2 |
| Myalgia | 52 | 53 |
| Nasal congestion | 3 | 3 |
| Nausea | 14 | 16 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | | 1 |
| | | 9 | 10 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 40 | 41 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 17 | 17 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 2 | 51 | 51 |
| | | 3 | 3 |
| | 1 | 14 | 15 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Odynophagia | 3 | 3 | | | 3 | 3 |
| Oedema | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Oral candidiasis | 1 | 1 | | | 1 | 1 |
| Overdose | | 2 | | 2 | | |
| Pain | 7 | 7 | | | 7 | 7 |
| Painful respiration | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 6 | 6 | 1 | 1 | 5 | 5 |
| Paraesthesia | 6 | 6 | | | 6 | 6 |
| Polydipsia | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 2 | | 1 | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 39 | 39 | | | 39 | 39 |
| Rash | 3 | 4 | | 1 | 3 | 3 |
| Rash pruritic | | 1 | | 1 | | |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 3 | 3 | | | 3 | 3 |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sinusitis | 1 | 1 | 1 | 1 | | |
| Somnolence | | 1 | | 1 | | |
| Swelling | 1 | 1 | | | 1 | 1 |
| Syncope | 3 | 3 | | | 3 | 3 |
| Tachycardia | 2 | 2 | | | 2 | 2 |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Throat tightness | 2 | 2 | | | 2 | 2 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 2 | 2 | | | 2 | 2 |
| Tremor | 1 | 2 | | 1 | 1 | 1 |
| Urticaria | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site erythema | 4 | 5 | | 1 | 4 | 4 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 2 | 3 | | | 2 | 3 |
| Vaccination site pain | 20 | 25 | 2 | 5 | 18 | 20 |
| Vaccination site paraesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vomiting | 8 | 8 | | | 8 | 8 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 384 | 417 | 17 | 36 | 367 | 381 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | | 1 | | | | 1 |
| Abdominal pain | 6 | 7 | | | 6 | 7 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 4 | 4 | 1 | 1 | 3 | 3 |
| Abnormal faeces | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 3 | | | 1 | 3 |
| Anaphylactic reaction | 4 | 5 | | | 4 | 5 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 5 | 5 | | | 5 | 5 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Aphthous ulcer | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arthralgia | 52 | 52 | 3 | 3 | 49 | 49 |
| Arthritis reactive | | 1 | | | | 1 |
| Asthenia | 39 | 39 | | | 39 | 39 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Autophony | 1 | 1 | | | 1 | 1 |
| Axillary pain | 6 | 6 | | | 6 | 6 |
| Back pain | 4 | 4 | | | 4 | 4 |
| Blood pressure increased | 1 | 2 | | | 1 | 2 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Bradycardia | 2 | 2 | | | 2 | 2 |
| Bradyphrenia | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Breast swelling | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cerebral venous sinus thrombosis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 4 | 4 | 1 | 1 | 3 | 3 |
| Chest pain | 8 | 10 | | | 8 | 10 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Chillblains | | 1 |
| Chills | 47 | 51 |
| Cold sweat | 1 | 1 |
| Condition aggravated | 1 | 1 |
| Confusional state | 1 | 1 |
| Cough | 10 | 12 |
| COVID-19 | 5 | 10 |
| Cutaneous vasculitis | 1 | 1 |
| Cyanosis | 1 | 1 |
| Deafness transitory | 1 | 1 |
| Decreased appetite | 2 | 2 |
| Depressed level of consciousness | 1 | 1 |
| Diarrhoea | 15 | 16 |
| Discomfort | 1 | 1 |
| Disease recurrence | 1 | 1 |
| Dizziness | 35 | 35 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 3 | 6 |
| Drug interaction | 1 | 1 |
| Dry eye | | 1 |
| Dry mouth | 2 | 2 |
| Dysarthria | 3 | 3 |
| Dysgeusia | 5 | 5 |
| Dyskinesia | 1 | 1 |
| Dysphagia | 6 | 7 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 11 | 11 |
| Dyspnoea at rest | 1 | 1 |
| Eczema | 1 | 1 |
| Eructation | | 1 |
| Erythema | 5 | 8 |
| Exophthalmos | | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 2 | 47 | 49 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 8 | 10 |
| 1 | 2 | 4 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | 15 | 15 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 32 | 32 |
| | | 1 | 1 |
| | | 3 | 6 |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | 3 | 3 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 6 | 7 |
| | | 1 | 1 |
| 1 | 1 | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | 5 | 7 |
| | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Eye disorder | 1 | 1 |
| Eye irritation | 1 | 1 |
| Eyelid myokymia | 1 | 1 |
| Eyelid oedema | 2 | 3 |
| Eye movement disorder | | 1 |
| Eye pain | | 1 |
| Eye paraesthesia | | 1 |
| Eye swelling | 1 | 1 |
| Face oedema | 5 | 5 |
| Facial paralysis | 3 | 4 |
| Faeces soft | 1 | 1 |
| Fatigue | 40 | 44 |
| Feeling abnormal | 1 | 2 |
| Feeling cold | 4 | 4 |
| Feeling hot | 9 | 10 |
| Flatulence | 1 | 1 |
| Flushing | 5 | 7 |
| Functional gastrointestinal disorder | | 1 |
| Gait disturbance | 1 | 1 |
| Gait inability | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 2 |
| Gonorrhoea | 1 | 1 |
| Groin pain | 1 | 1 |
| Haematoma | 1 | 1 |
| Headache | 147 | 157 |
| Head discomfort | 1 | 1 |
| Heart rate increased | 1 | 1 |
| Hemianaesthesia | 1 | 1 |
| Hemidysaesthesia | 1 | 1 |
| Hot flush | 2 | 2 |
| Hyperaemia | 1 | 1 |
| Hyperaesthesia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 3 |
| | | | 1 |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 3 | 4 |
| | | 1 | 1 |
| 2 | 5 | 38 | 39 |
| 1 | 2 | | |
| | | 4 | 4 |
| | | 9 | 10 |
| | | 1 | 1 |
| | | 5 | 7 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hyperglycaemia | 3 | 3 |
| Hyperhidrosis | 7 | 7 |
| Hypersensitivity | 3 | 4 |
| Hypertension | 10 | 10 |
| Hypertensive crisis | 1 | 1 |
| Hyperthermia | 4 | 4 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 3 | 3 |
| Hypoaesthesia oral | 4 | 6 |
| Hypoglycaemia | 2 | 2 |
| Hypoperfusion | 1 | 1 |
| Hypotension | 7 | 7 |
| Hypothyroidism | | 1 |
| Impaired work ability | 2 | 2 |
| Incorrect route of product administration | 10 | 12 |
| Inflammation | 1 | 1 |
| Influenza | 2 | 2 |
| Influenza like illness | 1 | 1 |
| Insomnia | 4 | 4 |
| Intercostal neuralgia | 1 | 2 |
| Joint range of motion decreased | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Laryngeal oedema | 6 | 6 |
| Lid retraction | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Lip oedema | 6 | 7 |
| Lip pruritus | | 1 |
| Lip swelling | 2 | 2 |
| Localised oedema | 3 | 3 |
| Loss of personal independence in daily activities | 2 | 2 |
| Lymphadenitis | 2 | 2 |
| Lymphadenopathy | 45 | 49 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 2 | 2 |
| | | 7 | 7 |
| | | 3 | 4 |
| | | 10 | 10 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 4 | 6 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 7 | 7 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| 10 | 12 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 4 | 4 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 6 | 7 |
| | | | 1 |
| | | 2 | 2 |
| | | 3 | 3 |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| 1 | 3 | 44 | 46 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Lymph node pain | 1 | 1 |
| Macule | 1 | 1 |
| Malaise | 17 | 19 |
| Mastitis | 1 | 1 |
| Metrorrhagia | 1 | 1 |
| Migraine | 1 | 3 |
| Motor dysfunction | 1 | 1 |
| Muscle fatigue | 2 | 2 |
| Muscle spasms | 2 | 2 |
| Muscular weakness | 2 | 2 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 166 | 178 |
| Myelitis | 1 | 1 |
| Myelosuppression | 1 | 1 |
| Myocarditis | 2 | 2 |
| Nasal congestion | 1 | 1 |
| Nasal discomfort | 1 | 1 |
| Nasal dryness | 1 | 1 |
| Nausea | 49 | 52 |
| Neck pain | 2 | 2 |
| Nystagmus | 2 | 3 |
| Occupational exposure to SARS-CoV-2 | 1 | 1 |
| Ocular discomfort | | 1 |
| Ocular hyperaemia | 1 | 1 |
| Odynophagia | 6 | 9 |
| Oedema | 1 | 1 |
| Oedema mouth | 1 | 1 |
| Oedema peripheral | 3 | 3 |
| Oesophageal stenosis | 1 | 1 |
| Off label use | 6 | 7 |
| Ophthalmic herpes simplex | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 17 | 18 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 6 | 12 | 160 | 166 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 3 | 47 | 49 |
| | | 2 | 2 |
| | | 2 | 3 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 2 | 5 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 6 | 7 | | |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Oral pain | 1 | 1 |
| Oropharyngeal discomfort | 4 | 4 |
| Oropharyngeal oedema | | 1 |
| Oropharyngeal pain | 1 | 2 |
| Overdose | 1 | 3 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 8 | 9 |
| Pain in extremity | 8 | 9 |
| Pain in jaw | | 1 |
| Pallor | 3 | 5 |
| Palpitations | 3 | 3 |
| Paraesthesia | 22 | 25 |
| Paraesthesia oral | 5 | 7 |
| Paralysis | 1 | 1 |
| Perineal pain | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal erythema | 1 | 1 |
| Pharyngeal inflammation | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 3 |
| Phlebitis | 1 | 1 |
| Phonophobia | 1 | 1 |
| Photophobia | 2 | 3 |
| Piloerection | 3 | 3 |
| Pleuritic pain | 2 | 2 |
| Polydipsia | 2 | 2 |
| Poor quality sleep | 1 | 1 |
| Postural orthostatic tachycardia syndrome | 1 | 1 |
| Presyncope | 15 | 17 |
| Procedural haemorrhage | 1 | 1 |
| Productive cough | | 1 |
| Product use issue | 6 | 7 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | | 1 |
| | | 1 | 2 |
| 1 | 3 | | |
| | | 1 | 1 |
| | 1 | 8 | 8 |
| 1 | 1 | 7 | 8 |
| | | | 1 |
| | 1 | 3 | 4 |
| | | 3 | 3 |
| 3 | 5 | 19 | 20 |
| | | 5 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | | 3 | 3 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 15 | 16 |
| | | 1 | 1 |
| | | | 1 |
| 6 | 7 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Pruritus | 11 | 14 |
| Pyrexia | 116 | 121 |
| Rash | 15 | 19 |
| Rash erythematous | 2 | 2 |
| Rash macular | 1 | 1 |
| Rash maculo-papular | | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Renal disorder | 1 | 1 |
| Respiratory distress | 1 | 1 |
| Rhinorrhoea | 8 | 9 |
| SARS-CoV-2 test positive | 2 | 3 |
| Scar | | 1 |
| Seizure | 1 | 1 |
| Sensation of foreign body | 1 | 1 |
| Sensory disturbance | 1 | 1 |
| Sensory loss | 3 | 4 |
| Sinus tachycardia | 1 | 1 |
| Skin lesion | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Somnolence | 8 | 11 |
| Stomatitis | 1 | 2 |
| Swelling | 1 | 1 |
| Syncope | 5 | 5 |
| Synovial cyst | 2 | 2 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 20 | 23 |
| Tachypnoea | 1 | 2 |
| Taste disorder | 3 | 4 |
| Tenosynovitis | | 1 |
| Terminal ileitis | 1 | 1 |
| Throat irritation | 4 | 6 |

| Spontaneous | | | |
|-------------|---|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | 11 | 12 |
| 2 | 5 | 114 | 116 |
| | 1 | 15 | 18 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 7 | 8 |
| | | 2 | 3 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 8 | 10 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | 20 | 22 |
| | | 1 | 2 |
| | 1 | 3 | 3 |
| | 1 | | |
| | | 1 | 1 |
| | 2 | 4 | 4 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Throat tightness | | 1 |
| Thrombophlebitis | 1 | 1 |
| Thyroid function test abnormal | | 1 |
| Tinnitus | 1 | 1 |
| Tongue eruption | | 1 |
| Tongue oedema | 5 | 7 |
| Tongue pruritus | | 1 |
| Tonsillar hypertrophy | 1 | 1 |
| Tremor | 16 | 16 |
| Trichoglossia | 1 | 1 |
| Trismus | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urticaria | 3 | 4 |
| Urticaria papular | 1 | 1 |
| Vaccination failure | 1 | 1 |
| Vaccination site discomfort | 1 | 2 |
| Vaccination site erythema | 10 | 11 |
| Vaccination site induration | 1 | 1 |
| Vaccination site inflammation | 4 | 4 |
| Vaccination site oedema | 6 | 7 |
| Vaccination site pain | 69 | 83 |
| Vaccination site paraesthesia | 1 | 1 |
| Vaccination site pruritus | 6 | 6 |
| Vaccination site rash | 1 | 1 |
| Vaccination site swelling | 6 | 6 |
| Vaccination site warmth | 3 | 3 |
| Ventricular extrasystoles | 1 | 1 |
| Vertigo | 4 | 4 |
| Vertigo positional | | 1 |
| Vision blurred | 2 | 3 |
| Visual impairment | 1 | 1 |
| Vomiting | 12 | 13 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 5 | 7 |
| | | | 1 |
| | | 1 | 1 |
| | | 16 | 16 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | 10 | 10 |
| | | 1 | 1 |
| | | 4 | 4 |
| | 1 | 6 | 6 |
| 9 | 19 | 60 | 64 |
| 1 | 1 | | |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 6 | 6 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | | 1 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 11 | 12 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vulvovaginal burning sensation | 1 | 1 | | | 1 | 1 |
| Vulvovaginal swelling | 1 | 1 | | | 1 | 1 |
| Weight decreased | | 1 | | 1 | | |
| | 1,448 | 1,620 | 84 | 160 | 1364 | 1460 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 2 | | 1 | 1 | 1 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Amylase increased | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Anxiety | 2 | 3 | | 1 | 2 | 2 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 9 | 9 | | | 9 | 9 |
| Asthenia | 9 | 9 | | | 9 | 9 |
| Asymptomatic COVID-19 | 1 | 1 | 1 | 1 | | |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | 3 | 3 | | | 3 | 3 |
| Balance disorder | 2 | 3 | | | 2 | 3 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Bone pain | | 1 | | 1 | | |
| Breast pain | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 3 | | | 2 | 3 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 16 | 17 | 1 | 1 | 15 | 16 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Circumoral oedema | | 1 | | | | 1 |
| Conjunctival irritation | 1 | 1 | | | 1 | 1 |
| Cough | 3 | 3 | | | 3 | 3 |
| COVID-19 | 4 | 6 | 1 | 1 | 3 | 5 |
| Crohn's disease | 1 | 1 | | | 1 | 1 |
| Crying | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 5 | 5 | | | 5 | 5 |
| Dizziness | 9 | 10 | | | 9 | 10 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Drug ineffective | 2 | 4 |
| Dry throat | 1 | 1 |
| Dysgeusia | | 1 |
| Dyspepsia | 1 | 1 |
| Dysphagia | 1 | 1 |
| Dyspnoea | 2 | 2 |
| Dyspnoea at rest | 1 | 1 |
| Dysstasia | 1 | 1 |
| Ear pain | 1 | 1 |
| Erythema | 3 | 4 |
| Exposure to SARS-CoV-2 | 1 | 1 |
| Eye irritation | 1 | 2 |
| Eyelid oedema | 1 | 1 |
| Eye pruritus | 1 | 1 |
| Face oedema | 5 | 5 |
| Facial paralysis | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 11 | 13 |
| Feeling hot | 1 | 1 |
| Feeling of body temperature change | 1 | 1 |
| General symptom | 1 | 1 |
| Haemoptysis | 1 | 1 |
| Headache | 34 | 36 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 4 | 5 |
| Hypersensitivity | | 1 |
| Hypertension | 3 | 3 |
| Hypertensive crisis | 1 | 1 |
| Hyperthermia | 2 | 2 |
| Hypoaesthesia | 1 | 1 |
| Hypoaesthesia oral | | 2 |
| Hypokalaemia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 4 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 4 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | 11 | 12 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 3 | 33 | 33 |
| | | 1 | 1 |
| | | 4 | 5 |
| | | | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | | 2 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Inappropriate schedule of product administration | 2 | 2 | 2 | 2 | | |
| Incorrect route of product administration | 2 | 2 | 2 | 2 | | |
| Insomnia | 4 | 4 | 1 | 1 | 3 | 3 |
| Laryngeal oedema | 1 | 3 | | | 1 | 3 |
| Leukocyturia | 1 | 1 | 1 | 1 | | |
| Lipase increased | 1 | 1 | | | 1 | 1 |
| Lip oedema | | 2 | | | | 2 |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 12 | 13 | | | 12 | 13 |
| Malaise | 8 | 9 | | | 8 | 9 |
| Migraine | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscle tightness | 1 | 1 | | | 1 | 1 |
| Muscular weakness | | 1 | | | | 1 |
| Myalgia | 37 | 40 | 1 | 3 | 36 | 37 |
| Myalgia intercostal | 1 | 1 | | | 1 | 1 |
| Myoclonus | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nasal obstruction | | 1 | | | | 1 |
| Nausea | 16 | 18 | 1 | 1 | 15 | 17 |
| Neck mass | 1 | 1 | 1 | 1 | | |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Odynophagia | 1 | 1 | 1 | 1 | | |
| Oedema mouth | 1 | 1 | | | 1 | 1 |
| Oedema mucosal | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 1 | 1 | 1 | 1 | | |
| Oesophageal pain | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oral herpes | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 2 | 3 | | | 2 | 3 |
| Oropharyngeal pain | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 5 | 5 | | | 5 | 5 |

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* I=Interval, C=Cumulative
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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pallor | 1 | 1 |
| Palmar-plantar erythrodysesthesia syndrome | | 1 |
| Palpitations | 2 | 3 |
| Paraesthesia | 5 | 6 |
| Paraesthesia oral | 4 | 4 |
| Peripheral coldness | 1 | 2 |
| Pharyngeal hypoaesthesia | | 1 |
| Presyncope | 1 | 1 |
| Product administered at inappropriate site | 1 | 1 |
| Proteinuria | 1 | 1 |
| Pruritus | 6 | 9 |
| Pyrexia | 32 | 35 |
| Rash | 8 | 10 |
| Rash maculo-papular | 1 | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Respiratory tract congestion | | 1 |
| Rhinitis | 1 | 1 |
| Rhinorrhoea | 1 | 2 |
| Seizure | 1 | 1 |
| Sinus tachycardia | | 1 |
| Skin reaction | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Stiff tongue | 1 | 1 |
| Syncope | 1 | 1 |
| Synovial cyst | 2 | 2 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 4 | 4 |
| Takayasu's arteritis | 1 | 1 |
| Taste disorder | 2 | 2 |
| Tongue coated | 1 | 1 |
| Tongue discomfort | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | | 1 |
| | 1 | 2 | 2 |
| | | 5 | 6 |
| | | 4 | 4 |
| | | 1 | 2 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 6 | 9 |
| 1 | 2 | 31 | 33 |
| 1 | 1 | 7 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tongue dry | 1 | 2 | | | 1 | 2 |
| Tongue eruption | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 2 | 2 | | | 2 | 2 |
| Tremor | 2 | 2 | | | 2 | 2 |
| Upper-airway cough syndrome | | 1 | | | | 1 |
| Urticaria | 2 | 2 | | | 2 | 2 |
| Vaccination complication | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 2 | | | 2 | 2 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 3 | 3 | | | 3 | 3 |
| Vaccination site pain | 10 | 12 | | 2 | 10 | 10 |
| Vaccination site pruritus | 1 | 2 | | | 1 | 2 |
| Vaccination site swelling | 2 | 2 | | | 2 | 2 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 2 | 2 | | | 2 | 2 |
| Vasculitis | 1 | 1 | | | 1 | 1 |
| Vertigo | 3 | 3 | | | 3 | 3 |
| Vomiting | 3 | 3 | | | 3 | 3 |
| Wound | 1 | 1 | 1 | 1 | | |
| | 405 | 463 | 27 | 40 | 378 | 423 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | | 1 | | | | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Rhabdomyolysis | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | | | 1 | 1 |
| Varicella | 1 | 1 | | | 1 | 1 |
| | 19 | 20 | 7 | 7 | 12 | 13 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 1 | 1 | 1 | 1 |
| COVID-19 | 5 | 5 | 3 | 3 | 2 | 2 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | | 2 | | | | 2 |
| Decreased appetite | 2 | 2 | 1 | 1 | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dyslexia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Fatigue | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hypertension | 2 | 2 | | | 2 | 2 |
| Hypotension | 5 | 5 | | | 5 | 5 |
| Leukaemoid reaction | 1 | 1 | | | 1 | 1 |
| Nausea | 2 | 2 | | | 2 | 2 |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Rash | 2 | 2 | | | 2 | 2 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 45 | 47 | 8 | 8 | 37 | 39 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Abdominal discomfort | | 1 | | 1 | | | |
| Abdominal pain | 1 | 1 | | | 1 | 1 | |
| Abdominal pain upper | | 1 | | 1 | | | |
| Amnesia | | 1 | | 1 | | | |
| Arthralgia | 1 | 1 | | | 1 | 1 | |
| Asthenia | 5 | 6 | 1 | 2 | 4 | 4 | |
| Back pain | 3 | 3 | 1 | 1 | 2 | 2 | |
| Chest pain | 2 | 3 | | 1 | 2 | 2 | |
| Chills | 7 | 8 | 1 | 2 | 6 | 6 | |
| Choroiditis | 1 | 1 | | | 1 | 1 | |
| Cough | 1 | 1 | 1 | 1 | | | |
| COVID-19 | 6 | 14 | 1 | 1 | 5 | 13 | |
| Decreased appetite | 2 | 3 | | 1 | 2 | 2 | |
| Diarrhoea | 2 | 3 | 1 | 2 | 1 | 1 | |
| Dizziness | 2 | 4 | | 2 | 2 | 2 | |
| Drug ineffective | 5 | 14 | | | 5 | 14 | |
| Dysarthria | | 1 | | 1 | | | |
| Dysgeusia | | 1 | | 1 | | | |
| Dysphonia | 1 | 1 | 1 | 1 | | | |
| Dyspnoea | 3 | 3 | 1 | 1 | 2 | 2 | |
| Embolism | | 1 | | | | 1 | |
| Erythema | | 3 | | 2 | | 1 | |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | | |
| Exposure via breast milk | | 2 | | 2 | | | |
| Face oedema | 1 | 4 | | 1 | 1 | 3 | |
| Facial paralysis | 1 | 1 | | | 1 | 1 | |
| Fatigue | 3 | 4 | | 1 | 3 | 3 | |
| Feeling cold | 2 | 2 | | | 2 | 2 | |
| Headache | 14 | 22 | 4 | 11 | 10 | 11 | |
| Hyperglycaemia | | 1 | | | | 1 | |
| Hyperhidrosis | 3 | 3 | 1 | 1 | 2 | 2 | |
| Hypersensitivity | | 5 | | 4 | | 1 | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypoaesthesia | 1 | 3 |
| Hypoaesthesia oral | | 2 |
| Hypokalaemia | 2 | 2 |
| Inappropriate schedule of product administration | | 1 |
| Insomnia | 1 | 1 |
| Inspiratory capacity decreased | 1 | 1 |
| Laryngeal oedema | | 2 |
| Lip oedema | | 1 |
| Localised oedema | | 1 |
| Lymphadenitis | | 1 |
| Lymphadenopathy | 1 | 3 |
| Malaise | 4 | 8 |
| Maternal exposure during pregnancy | 1 | 2 |
| Migraine | | 2 |
| Muscle contractions involuntary | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 15 | 20 |
| Nausea | 3 | 8 |
| Odynophagia | | 1 |
| Off label use | 1 | 3 |
| Oral disorder | | 1 |
| Oropharyngeal oedema | | 1 |
| Oropharyngeal pain | 2 | 2 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 2 | 2 |
| Pain in extremity | | 1 |
| Pallor | | 1 |
| Paraesthesia | | 2 |
| Paraesthesia oral | | 2 |
| Peripheral coldness | 1 | 1 |
| Pharyngeal inflammation | 1 | 1 |
| Pneumonia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | 1 | 1 |
| | 1 | | 1 |
| | | 2 | 2 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 2 |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 3 | | |
| 1 | 5 | 3 | 3 |
| 1 | 2 | | |
| | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 9 | 11 | 11 |
| 1 | 6 | 2 | 2 |
| | | | 1 |
| 1 | 3 | | |
| | | | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | |
| | | 1 | 1 |
| | | | |
| | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Presyncope | | 1 |
| Productive cough | | 1 |
| Product use issue | 1 | 2 |
| Pruritus | 2 | 3 |
| Pyrexia | 8 | 12 |
| Rash | | 6 |
| Rash maculo-papular | | 1 |
| Rash pruritic | | 1 |
| Renal colic | 1 | 1 |
| Rhinorrhoea | 2 | 3 |
| SARS-CoV-2 test positive | 1 | 3 |
| Sensory loss | 1 | 1 |
| Skin exfoliation | 1 | 1 |
| Somnolence | | 2 |
| Stomatitis | | 1 |
| Tachycardia | 2 | 4 |
| Taste disorder | | 1 |
| Throat irritation | 1 | 2 |
| Tongue discomfort | 1 | 1 |
| Tongue disorder | | 1 |
| Tongue oedema | | 1 |
| Tremor | 2 | 3 |
| Urticaria | | 1 |
| Urticaria cholinergic | | 1 |
| Vaccination site erythema | 1 | 2 |
| Vaccination site haemorrhage | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 |
| Vaccination site oedema | 1 | 2 |
| Vaccination site pain | 6 | 23 |
| Vaccination site pruritus | 1 | 1 |
| Vaccination site swelling | 1 | 2 |
| Vomiting | 1 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | | 1 |
| 1 | 2 | | |
| | | 2 | 3 |
| | 4 | 8 | 8 |
| | 5 | | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 2 |
| | | 1 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | 1 |
| | 1 | | |
| 1 | 3 | 1 | 1 |
| | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | 2 | 2 |
| | | | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 17 | 5 | 6 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | 1 | 2 |

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Age Range

Unknown

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 31 | 132 | 112 | 157 |

143

289

31

132

112

157

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Country Where Event Occurred
PUERTO RICO

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 |
| Axillary pain | | 1 | | 1 |
| Bone disorder | | 1 | | 1 |
| Bone neoplasm | | 1 | | 1 |
| Bone pain | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Fatigue | | 2 | | 2 |
| Headache | 1 | 2 | 1 | 2 |
| Inappropriate schedule of product administration | | 1 | | 1 |
| Inflammation | | 1 | | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Nodule | | 1 | | 1 |
| Off label use | | 1 | | 1 |
| Pain in extremity | | 1 | | 1 |
| Palpitations | | 1 | | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| Tachycardia | 1 | 1 | 1 | 1 |
| Vaccination site erythema | | 1 | | 1 |
| Vaccination site inflammation | | 1 | | 1 |
| Vaccination site pain | 1 | 3 | 1 | 3 |
| Vaccination site swelling | | 1 | | 1 |
| | 6 | 25 | 6 | 25 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 2 | 1 | 2 | | |
| Antibody test abnormal | 1 | 1 | 1 | 1 | | |
| Antinuclear antibody positive | 1 | 1 | 1 | 1 | | |
| Arthralgia | 3 | 4 | 3 | 4 | | |
| Asthenia | | 1 | | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood test abnormal | 1 | 1 | 1 | 1 | | |
| Burning sensation | | 1 | | 1 | | |
| Chills | | 2 | | 2 | | |
| Decreased appetite | | 1 | | 1 | | |
| Diarrhoea | | 2 | | 2 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dry mouth | | 1 | | 1 | | |
| Dyskinesia | | 1 | | | | 1 |
| Dyspepsia | | 1 | | 1 | | |
| Dysphonia | | 1 | | 1 | | |
| Erythema | | 1 | | 1 | | |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 2 | | | 1 | 2 |
| Fatigue | 2 | 7 | 2 | 7 | | |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Gait disturbance | | 1 | | 1 | | |
| Gingival bleeding | | 1 | | 1 | | |
| Haematoma | | 1 | | 1 | | |
| Headache | 5 | 12 | 5 | 12 | | |
| Heart rate decreased | | 1 | | | | 1 |
| Hypertension | | 1 | | 1 | | |
| Hypoaesthesia | 1 | 3 | 1 | 3 | | |
| Inappropriate schedule of product administration | 2 | 2 | 2 | 2 | | |
| Limb discomfort | | 1 | | 1 | | |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 3 | 1 | 3 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Malaise | | 1 | | 1 | | |
| Migraine | | 1 | | | | 1 |
| Movement disorder | | 1 | | 1 | | |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | 3 | 5 | 3 | 5 | | |
| Nausea | 2 | 4 | 2 | 4 | | |
| Neck pain | | 1 | | 1 | | |
| Neuralgia | | 1 | | 1 | | |
| Night sweats | | 1 | | | | 1 |
| Off label use | | 1 | | 1 | | |
| Pain | 3 | 5 | 3 | 5 | | |
| Pain in extremity | 1 | 3 | 1 | 3 | | |
| Paraesthesia | 1 | 2 | 1 | 2 | | |
| Photophobia | | 1 | | 1 | | |
| Pruritus | | 1 | | 1 | | |
| Puncture site swelling | | 1 | | 1 | | |
| Pyrexia | 2 | 8 | 2 | 8 | | |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| Sinus arrhythmia | | 1 | | | | 1 |
| Speech disorder | | 1 | | 1 | | |
| Stress | 1 | 1 | 1 | 1 | | |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swelling face | | 1 | | 1 | | |
| Tachycardia | | 1 | | 1 | | |
| Taste disorder | | 2 | | 2 | | |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site pain | 1 | 3 | 1 | 3 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| | 41 | 116 | 40 | 109 | 1 | 7 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Abdominal pain | | 1 | | 1 |
| Arthralgia | | 1 | | 1 |
| Depression | | 1 | | 1 |
| Diarrhoea | | 1 | | 1 |
| Discomfort | 1 | 1 | 1 | 1 |
| Dyspnoea | | 1 | | 1 |
| Fatigue | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Head discomfort | | 1 | | 1 |
| Hypoaesthesia | | 1 | | 1 |
| Joint range of motion decreased | | 1 | | 1 |
| Muscle spasms | | 1 | | 1 |
| Nausea | | 1 | | 1 |
| Pain in extremity | | 1 | | 1 |
| Paraesthesia | | 1 | | 1 |
| | 3 | 15 | 3 | 15 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Abdominal discomfort | | 1 | | 1 |
| Arthralgia | | 1 | | 1 |
| Burning sensation | | 1 | | 1 |
| Headache | | 2 | | 2 |
| Hypoaesthesia | | 1 | | 1 |
| Rash | | 1 | | 1 |
| | | 7 | | 7 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Chills | | 1 | | 1 |
| Dehydration | 1 | 1 | 1 | 1 |
| Fatigue | | 1 | | 1 |
| Lymphadenitis | 1 | 1 | 1 | 1 |
| Maternal exposure during pregnancy | | 1 | | 1 |
| Pain | | 1 | | 1 |
| Pain in extremity | | 1 | | 1 |
| Poor quality product administered | 10 | 10 | 10 | 10 |
| Pyrexia | | 2 | | 2 |
| Thirst | 1 | 1 | 1 | 1 |
| | 13 | 20 | 13 | 20 |

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Country Where Event Occurred
QATAR

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | | 1 | | | | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspepsia | 1 | 1 | 1 | 1 | | |
| Erythema | | 1 | | | | 1 |
| Mood altered | 1 | 1 | 1 | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Nausea | | 1 | | | | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| | 6 | 10 | 4 | 5 | 2 | 5 |

Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Overdose | | 1 | | 1 |
| Product preparation error | | 1 | | 1 |
| | | 2 | | 2 |

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* I=Interval, C=Cumulative
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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 3 | 3 | 4 | 4 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Dyspepsia | 1 | 1 | 1 | 1 |
| Feeling cold | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

ROMANIA

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Angina pectoris | | 1 | | | | 1 |
| Arthralgia | 4 | 5 | 2 | 3 | 2 | 2 |
| Asthenia | 2 | 3 | 1 | 2 | 1 | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Breast pain | | 1 | | 1 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 6 | 9 | 3 | 6 | 3 | 3 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | | | 2 | 2 |
| COVID-19 | | 1 | | | | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | | | 2 | 2 |
| Drug ineffective | | 1 | | | | 1 |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 5 | 1 | 4 | 1 | 1 |
| Headache | 6 | 8 | 2 | 4 | 4 | 4 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Inflammation | 1 | 1 | 1 | 1 | | |
| Lip oedema | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 2 | 3 | | 1 | 2 | 2 |
| Malaise | 1 | 1 | | | 1 | 1 |
| Migraine | | 1 | | 1 | | |
| Musculoskeletal chest pain | 1 | 1 | | | 1 | 1 |
| Myalgia | 7 | 9 | 2 | 4 | 5 | 5 |
| Nasal discomfort | 1 | 1 | 1 | 1 | | |
| Nausea | 3 | 6 | 1 | 4 | 2 | 2 |
| Off label use | | 1 | | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pain in extremity | | 2 | | 2 | | |
| Panic attack | | 1 | | 1 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Paraplegia | 1 | 1 | | | 1 | 1 |
| Parosmia | 1 | 1 | 1 | 1 | | |
| Product use issue | | 1 | | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 7 | 10 | 2 | 5 | 5 | 5 |
| Rash | | 1 | | 1 | | |
| SARS-CoV-2 ant body test negative | 2 | 2 | 2 | 2 | | |
| Scar pain | | 1 | | 1 | | |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Suppressed lactation | | 1 | | 1 | | |
| Tachycardia | 3 | 3 | 2 | 2 | 1 | 1 |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 9 | 17 | 4 | 12 | 5 | 5 |
| Vaccination site swelling | | 1 | | 1 | | |
| Vertigo | 2 | 2 | | | 2 | 2 |
| Vomiting | 2 | 2 | | | 2 | 2 |
| | 85 | 126 | 29 | 67 | 56 | 59 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Ageusia | | 1 | | 1 | | |
| Agitation | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | | 1 | | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Anxiety | | 2 | | 1 | | 1 |
| Arthralgia | 4 | 11 | 1 | 6 | 3 | 5 |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthenia | 6 | 10 | 2 | 5 | 4 | 5 |
| Axillary pain | | 1 | | 1 | | |
| Back pain | | 1 | | 1 | | |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 2 | | 1 | 1 | 1 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 2 | | 1 | 1 | 1 |
| Chest pain | 1 | 2 | | | 1 | 2 |
| Chills | 9 | 19 | 2 | 11 | 7 | 8 |
| Circumoral oedema | 1 | 1 | | | 1 | 1 |
| Cough | | 1 | | | | 1 |
| COVID-19 | 1 | 2 | | | 1 | 2 |
| Decreased appetite | 1 | 2 | | 1 | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Dizziness | 5 | 5 | 1 | 1 | 4 | 4 |
| Drug eruption | 2 | 2 | | | 2 | 2 |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Dysphagia | | 1 | | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Dysphonia | | 1 |
| Dyspnoea | 2 | 2 |
| Ear pain | | 1 |
| Erythema | 2 | 2 |
| Erythema nodosum | 1 | 1 |
| Exposure during pregnancy | | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eyelid ptosis | 1 | 1 |
| Face oedema | 2 | 2 |
| Facial pain | | 1 |
| Facial paralysis | 2 | 3 |
| Faeces soft | 1 | 1 |
| Fatigue | 1 | 9 |
| Foaming at mouth | 1 | 1 |
| General physical health deterioration | 1 | 2 |
| Headache | 13 | 29 |
| Heart rate increased | 3 | 3 |
| Hyperaemia | 1 | 1 |
| Hyperhidrosis | 2 | 3 |
| Hyperpyrexia | 1 | 1 |
| Hypersensitivity | 2 | 3 |
| Hypertension | 1 | 5 |
| Hypertensive crisis | | 1 |
| Hyperthermia | | 1 |
| Hypoaesthesia | 2 | 3 |
| Hypotension | 4 | 4 |
| Incorrect route of product administration | 2 | 2 |
| Influenza like illness | | 1 |
| Injected limb mobility decreased | 1 | 2 |
| Insomnia | 1 | 1 |
| Intracranial pressure increased | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | 2 | 2 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | | |
| | | 2 | 3 |
| | | 1 | 1 |
| | 7 | 1 | 2 |
| | | 1 | 1 |
| 1 | 2 | | |
| 4 | 18 | 9 | 11 |
| | | 3 | 3 |
| | | 1 | 1 |
| 2 | 3 | | |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | | 1 | 5 |
| | | | 1 |
| | 1 | | |
| 1 | 2 | 1 | 1 |
| | | 4 | 4 |
| | | 2 | 2 |
| | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Lipase increased | 1 | 1 |
| Lip oedema | 2 | 3 |
| Localised oedema | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 2 | 3 |
| Lymph node pain | | 1 |
| Malaise | | 3 |
| Maternal exposure during pregnancy | | 1 |
| Memory impairment | 1 | 1 |
| Migraine | | 1 |
| Muscle contractions involuntary | | 1 |
| Myalgia | 7 | 22 |
| Myoclonus | 1 | 1 |
| Nausea | 9 | 15 |
| Nephropathy | 1 | 1 |
| Nervous system disorder | 3 | 3 |
| Nystagmus | | 1 |
| Oedematous pancreatitis | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Overdose | 1 | 1 |
| Oxygen saturation decreased | 2 | 2 |
| Pain | 1 | 4 |
| Pain in extremity | 1 | 5 |
| Palpitations | | 2 |
| Paraesthesia | 6 | 10 |
| Paraesthesia ear | | 1 |
| Paralysis | 1 | 1 |
| Pericarditis | 1 | 1 |
| Peripheral coldness | | 1 |
| Polyuria | 1 | 1 |
| Presyncope | | 2 |
| Pruritus | 3 | 5 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | 1 | | |
| | 3 | | |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | 13 | 7 | 9 |
| | | 1 | 1 |
| 3 | 8 | 6 | 7 |
| | | 1 | 1 |
| 3 | 3 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 4 | | |
| 1 | 5 | | |
| | | | 2 |
| 3 | 6 | 3 | 4 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| | 2 | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pulse abnormal | 1 | 1 |
| Pyrexia | 11 | 20 |
| Rash | 1 | 4 |
| Rash erythematous | 2 | 4 |
| Rash pruritic | 2 | 2 |
| Raynaud's phenomenon | 1 | 1 |
| Renal pain | 2 | 2 |
| Sinus tachycardia | 2 | 2 |
| Skin irritation | 1 | 1 |
| Skin plaque | 1 | 1 |
| Somnolence | 1 | 3 |
| Speech disorder | 1 | 1 |
| Spinal pain | | 1 |
| Suffocation feeling | 1 | 1 |
| Syncope | 3 | 3 |
| Syringe issue | | 1 |
| Tachycardia | 3 | 5 |
| Tinnitus | 1 | 1 |
| Tongue disorder | | 1 |
| Tongue spasm | 1 | 1 |
| Tremor | 1 | 1 |
| Urticaria | 1 | 1 |
| Vaccination site erythema | 2 | 4 |
| Vaccination site induration | | 2 |
| Vaccination site inflammation | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 |
| Vaccination site movement impairment | | 1 |
| Vaccination site pain | 9 | 24 |
| Vaccination site paraesthesia | 1 | 1 |
| Vaccination site pruritus | 1 | 2 |
| Vaccination site reaction | 4 | 5 |
| Vaccination site swelling | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 4 | 13 | 7 | 7 |
| | 3 | 1 | 1 |
| | | 2 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 3 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 3 | 3 |
| | 1 | | |
| | | 3 | 5 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 3 | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 6 | 21 | 3 | 3 |
| 1 | 1 | | |
| 1 | 2 | | |
| 4 | 5 | | |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ventricular extrasystoles | | 1 | | 1 | | |
| Vertigo | 4 | 5 | | 1 | 4 | 4 |
| Vestibular disorder | | 1 | | 1 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 4 | | 2 | 1 | 2 |
| Wrong technique in product usage process | | 2 | | 2 | | |
| | 208 | 385 | 51 | 197 | 157 | 188 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Administration site pain | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 2 | | | 1 | 2 |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anxiety | | 1 | | | | 1 |
| Arthralgia | 1 | 2 | | 1 | 1 | 1 |
| Asthenia | | 1 | | 1 | | |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Balance disorder | | 1 | | | | 1 |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Body temperature abnormal | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 5 | 7 | 3 | 4 | 2 | 3 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dry mouth | | 1 | | | | 1 |
| Dysgeusia | | 1 | | | | 1 |
| Dyspnoea | 2 | 3 | | | 2 | 3 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Erythema | 3 | 5 | 1 | 2 | 2 | 3 |
| Facial neuralgia | 1 | 1 | | | 1 | 1 |
| Facial paralysis | | 1 | | | | 1 |
| Fatigue | 3 | 5 | 1 | 2 | 2 | 3 |
| Feeling cold | | 1 | | | | 1 |
| Feeling hot | | 1 | | | | 1 |
| Headache | 7 | 9 | 2 | 3 | 5 | 6 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Heart rate increased | 2 | 2 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 1 | 2 |
| Hypertension | 3 | 4 |
| Hypoaesthesia | 2 | 3 |
| Hypocalcaemia | | 1 |
| Hypokinesia | 1 | 1 |
| Incorrect route of product administration | | 1 |
| Insomnia | | 1 |
| Joint ankylosis | | 1 |
| Laryngeal oedema | | 1 |
| Lip oedema | | 1 |
| Lymphadenopathy | 1 | 2 |
| Malaise | 2 | 2 |
| Monoplegia | 1 | 1 |
| Myalgia | 5 | 7 |
| Nasal dryness | 1 | 1 |
| Nausea | 2 | 3 |
| Pain in extremity | | 1 |
| Pallor | 1 | 1 |
| Paraesthesia | 2 | 2 |
| Presyncope | 1 | 1 |
| Pruritus | | 1 |
| Pulse abnormal | 1 | 1 |
| Pyrexia | 4 | 6 |
| Rash | 2 | 3 |
| Respiration abnormal | 1 | 1 |
| Rhinalgia | 1 | 1 |
| Seizure | | 1 |
| Sensory loss | 1 | 1 |
| Somnolence | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 3 | 4 |
| 1 | 1 | 1 | 2 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 3 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | 1 | 2 |
| | | | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 3 | 3 | 3 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | | 1 | | | | 1 |
| Thirst | | 1 | | | | 1 |
| Tongue oedema | | 1 | | | | 1 |
| Tremor | | 1 | | | | 1 |
| Urticaria | 2 | 3 | | 1 | 2 | 2 |
| Vaccination site erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 3 | 5 | 2 | 4 | 1 | 1 |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vertigo | | 1 | | | | 1 |
| Vomiting | 2 | 2 | 1 | 1 | 1 | 1 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 89 | 138 | 31 | 51 | 58 | 87 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrioventricular block | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Cardiac fibrillation | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | | | 1 | 1 |
| Hypertension | 2 | 2 | 1 | 1 | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 2 | | | 2 | 2 |
| | 19 | 19 | 5 | 5 | 14 | 14 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 2 | | 1 | | 1 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angle closure glaucoma | | 1 | | | | 1 |
| Anosmia | | 2 | | 1 | | 1 |
| Anxiety | | 3 | | 3 | | |
| Arthralgia | | 5 | | 5 | | |
| Asthenia | | 4 | | 4 | | |
| Asthma | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure abnormal | | 1 | | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature abnormal | | 1 | | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| Chest discomfort | | 1 | | 1 | | |
| Chills | 1 | 7 | | 6 | 1 | 1 |
| Circumstance or information capable of leading to medication error | | 3 | | 3 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| Cough | | 2 | | 1 | | 1 |
| COVID-19 | 25 | 34 | 1 | 1 | 24 | 33 |
| Crying | | 1 | | 1 | | |
| Diarrhoea | | 1 | | 1 | | |
| Disturbance in attention | | 1 | | 1 | | |
| Dizziness | 1 | 8 | 1 | 8 | | |
| Drug ineffective | 28 | 45 | 1 | 1 | 27 | 44 |
| Dyspnoea | 1 | 2 | 1 | 1 | | 1 |
| Emotional distress | | 1 | | 1 | | |
| Epiglottic oedema | | 1 | | | | 1 |
| Erythema | | 8 | | 8 | | |
| Erythema nodosum | | 1 | | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Exposure via breast milk | 1 | 1 |
| Eyelid oedema | | 1 |
| Eyelid ptosis | 1 | 1 |
| Facial paralysis | | 1 |
| Fatigue | 1 | 6 |
| Fear | | 1 |
| Feeling abnormal | 1 | 2 |
| Feeling cold | | 1 |
| Feeling hot | | 1 |
| Flushing | | 1 |
| Headache | 1 | 14 |
| Heart rate increased | 1 | 2 |
| Horner's syndrome | | 1 |
| Hyperhidrosis | | 3 |
| Hypertension | 1 | 1 |
| Illness | 1 | 1 |
| Incorrect route of product administration | | 1 |
| Inflammation | | 1 |
| Injected limb mobility decreased | | 2 |
| Intercepted medication error | | 1 |
| Limb injury | | 1 |
| Lip oedema | | 1 |
| Lip swelling | | 1 |
| Lymphadenopathy | | 6 |
| Malaise | 1 | 3 |
| Medication error | | 3 |
| Muscle swelling | | 1 |
| Muscular weakness | | 2 |
| Myalgia | | 7 |
| Nasal discomfort | | 1 |
| Nasal oedema | | 1 |
| Nausea | | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 6 | | |
| | 1 | | |
| | 1 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 14 | | |
| | 1 | 1 | 1 |
| | | | 1 |
| | 2 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| 1 | 3 | | |
| | 3 | | |
| | 1 | | |
| | 2 | | |
| | 7 | | |
| | 1 | | |
| | | | 1 |
| | 3 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| No adverse event | 1 | 1 |
| Odynophagia | | 1 |
| Oedema | | 1 |
| Oedema peripheral | | 1 |
| Off label use | | 2 |
| Oropharyngeal discomfort | | 1 |
| Pain | | 4 |
| Pain in extremity | | 20 |
| Panic attack | | 1 |
| Paraesthesia | 1 | 5 |
| Paraesthesia oral | | 1 |
| Presyncope | | 1 |
| Product preparation error | | 11 |
| Product preparation issue | | 6 |
| Product quality issue | | 1 |
| Product use issue | | 1 |
| Pruritus | | 2 |
| Pyrexia | | 18 |
| Rash | | 2 |
| Rash pruritic | | 1 |
| SARS-CoV-2 ant body test | 1 | 1 |
| SARS-CoV-2 ant body test negative | 3 | 3 |
| SARS-CoV-2 ant body test positive | 1 | 1 |
| SARS-CoV-2 test negative | | 1 |
| SARS-CoV-2 test positive | 3 | 10 |
| Skin discolouration | | 1 |
| Somnolence | | 2 |
| Suspected COVID-19 | 2 | 3 |
| Syncope | 3 | 4 |
| Systolic hypertension | | 1 |
| Tachycardia | 1 | 3 |
| Transaminases increased | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | 2 | | |
| | | | 1 |
| | 4 | | |
| | 20 | | |
| | 1 | | |
| 1 | 5 | | |
| | 1 | | |
| | 1 | | |
| | 11 | | |
| | 6 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 18 | | |
| | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | 2 | 9 |
| | 1 | | |
| | 2 | | |
| 1 | 1 | 1 | 2 |
| | | 3 | 4 |
| | | | 1 |
| 1 | 3 | | |
| | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | | 1 | | 1 | | |
| Underdose | | 1 | | 1 | | |
| Urticaria | | 2 | | 2 | | |
| Urticaria papular | | 1 | | 1 | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Vaccination site discomfort | | 3 | | 3 | | |
| Vaccination site erythema | | 13 | | 13 | | |
| Vaccination site inflammation | | 1 | | 1 | | |
| Vaccination site lymphadenopathy | | 2 | | 2 | | |
| Vaccination site movement impairment | | 2 | | 2 | | |
| Vaccination site nodule | | 1 | | 1 | | |
| Vaccination site pain | | 26 | | 26 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Vertigo | | 1 | | 1 | | |
| Wrong technique in product usage process | 1 | 11 | 1 | 11 | | |
| | 88 | 395 | 20 | 276 | 68 | 119 |

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Country Where Event Occurred

SAUDI ARABIA

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Arthralgia | 1 | 2 | 1 | 2 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Dizziness | | 1 | | 1 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 3 | 1 | 3 | | |
| Headache | 1 | 2 | 1 | 2 | | |
| Hyperhidrosis | 1 | 3 | 1 | 3 | | |
| Hypotension | | 1 | | | | 1 |
| Injection site pain | | 1 | | 1 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Malaise | | 1 | | 1 | | |
| Mastication disorder | 1 | 1 | 1 | 1 | | |
| Mouth ulceration | | 1 | | 1 | | |
| Myalgia | 1 | 3 | 1 | 3 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Pain of skin | | 1 | | 1 | | |
| Peripheral coldness | | 1 | | 1 | | |
| Pollakiuria | | 1 | | 1 | | |
| Pyrexia | 1 | 4 | 1 | 4 | | |
| Syncope | | 1 | | | | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaginal infection | | 1 | | 1 | | |
| | 16 | 41 | 14 | 37 | 2 | 4 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | 1 | 1 | | |
| Fatigue | | 1 | | 1 | | |
| Headache | | 1 | | 1 | | |
| Herpes zoster | | 1 | | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Pain | | 1 | | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| | 10 | 17 | 9 | 16 | 1 | 1 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Movement disorder | | 1 | | 1 |
| Musculoskeletal stiffness | | 1 | | 1 |
| | | 2 | | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 1 | 1 | 1 |
| Gait disturbance | 1 | 1 | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Fatigue | | 1 | | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 4 | 4 | 4 | 4 | | |
| Pain | 3 | 3 | 3 | 3 | | |
| Pain in extremity | 2 | 3 | | 1 | 2 | 2 |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Sciatica | 2 | 2 | 2 | 2 | | |
| | 15 | 17 | 13 | 15 | 2 | 2 |

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Country Where Event Occurred

SERBIA

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 1 | | 1 | | |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Anosmia | | 1 | | 1 | | |
| Arthralgia | 3 | 6 | 3 | 6 | | |
| Asphyxia | | 1 | | | | 1 |
| Asthenia | | 4 | | 4 | | |
| Axillary pain | | 1 | | 1 | | |
| Back pain | | 1 | | 1 | | |
| Body temperature increased | | 4 | | 3 | | 1 |
| Bone pain | | 1 | | 1 | | |
| Bronchospasm | 1 | 2 | 1 | 1 | | 1 |
| Chills | 1 | 3 | 1 | 3 | | |
| Confusional state | | 1 | | 1 | | |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 2 | 1 | 1 | | 1 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Decreased appetite | | 1 | | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Erythema | | 1 | | 1 | | |
| Eyelid ptosis | 1 | 1 | 1 | 1 | | |
| Fatigue | | 4 | | 4 | | |
| Feeling cold | | 1 | | 1 | | |
| Headache | 4 | 7 | 3 | 6 | 1 | 1 |
| Hyperhidrosis | 1 | 3 | 1 | 3 | | |
| Hypertension | | 1 | | | | 1 |
| Inflammatory marker increased | | 1 | | 1 | | |
| Influenza like illness | | 1 | | 1 | | |
| Insomnia | | 1 | | 1 | | |
| Loss of consciousness | | 1 | | | | 1 |
| Lymphadenopathy | | 1 | | 1 | | |
| Malaise | 3 | 7 | 3 | 7 | | |
| Monocyte count increased | | 1 | | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Muscular weakness | | 2 | | 2 | | |
| Myalgia | 4 | 10 | 3 | 9 | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 6 | | 5 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Oedema mucosal | | 1 | | | | 1 |
| Pain in extremity | | 3 | | 3 | | |
| Peripheral swelling | | 1 | | | | 1 |
| Pyrexia | 5 | 15 | 4 | 14 | 1 | 1 |
| Rash | | 1 | | 1 | | |
| Rash macular | | 1 | | | | 1 |
| Skin reaction | | 1 | | | | 1 |
| Tachycardia | 1 | 2 | 1 | 1 | | 1 |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site oedema | | 1 | | 1 | | |
| Vaccination site pain | 2 | 8 | 2 | 8 | | |
| Vomiting | | 1 | | 1 | | |
| | 34 | 122 | 28 | 104 | 6 | 18 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abscess | | 1 | | | | 1 |
| Axillary pain | | 1 | | | | 1 |
| Bone pain | | 1 | | 1 | | |
| Burning sensation | | 1 | | 1 | | |
| Chest discomfort | | 1 | | 1 | | |
| Chills | | 2 | | 1 | | 1 |
| Disease recurrence | | 1 | | 1 | | |
| Dizziness | | 1 | | 1 | | |
| Dry mouth | | 1 | | 1 | | |
| Erythema | 1 | 2 | 1 | 2 | | |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Fatigue | | 1 | | 1 | | |
| Headache | 1 | 3 | 1 | 3 | | |
| Hypertension | 1 | 2 | 1 | 2 | | |
| Lymphadenitis | | 1 | | | | 1 |
| Lymphadenopathy | | 1 | | | | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Nausea | | 1 | | 1 | | |
| Oedema peripheral | | 1 | | 1 | | |
| Pain | | 1 | | | | 1 |
| Pain in extremity | | 1 | | 1 | | |
| Pain in jaw | | 1 | | 1 | | |
| Pallor | 1 | 1 | 1 | 1 | | |
| Palpitations | | 1 | | 1 | | |
| Phlebitis | | 1 | | | | 1 |
| Pruritus | | 1 | | 1 | | |
| Pyrexia | 1 | 4 | 1 | 3 | | 1 |
| Rash | | 1 | | 1 | | |
| Superficial vein prominence | | 1 | | 1 | | |
| Swelling | 1 | 2 | 1 | 1 | | 1 |
| Vaccination complication | 1 | 1 | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | | 1 | | 1 | | |
| | 9 | 42 | 9 | 33 | | 9 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety | | 1 | | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Fall | | 1 | | 1 | | |
| Fear of death | | 1 | | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Huntington's disease | | 1 | | | | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 2 | 1 | 2 | | |
| | 4 | 9 | 4 | 8 | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | | 1 | | 1 | | |
| Pancreatitis acute | 1 | 1 | | | 1 | 1 |
| Pyrexia | 2 | 2 | 1 | 1 | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site haematoma | | 1 | | | | 1 |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| | 14 | 16 | 7 | 8 | 7 | 8 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 2 | 1 | 2 | | |
| Asthenia | | 1 | | 1 | | |
| Blood pressure increased | | 1 | | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chest pain | | 1 | | 1 | | |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| Diarrhoea | | 1 | | 1 | | |
| Erythema | | 1 | | 1 | | |
| Headache | 1 | 2 | 1 | 2 | | |
| Herpes zoster | | 1 | | 1 | | |
| Hypersensitivity | | 2 | | 1 | | 1 |
| Intraocular pressure increased | | 1 | | | | 1 |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 2 | 1 | 2 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| Pain in extremity | | 2 | | 2 | | |
| Paraesthesia | | 1 | | 1 | | |
| Pyrexia | 1 | 5 | 1 | 5 | | |
| Rash | | 1 | | | | 1 |
| Rash macular | | 1 | | | | 1 |
| SARS-CoV-2 test positive | | 1 | | 1 | | |
| Sleep disorder | | 1 | | 1 | | |
| Swelling of eyelid | | 1 | | 1 | | |
| Tinnitus | | 1 | | 1 | | |
| Urticaria | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 6 | 2 | 6 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 1 | 1 | 1 | 1 | | |
| | 12 | 45 | 12 | 41 | | 4 |

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Country Where Event Occurred
SINGAPORE

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Abdominal pain | | 1 | | 1 |
| Anaphylactic reaction | | 1 | | 1 |
| Anaphylactic shock | | 2 | | 2 |
| Angioedema | | 2 | | 2 |
| Chest discomfort | | 1 | | 1 |
| Cough | | 1 | | 1 |
| Diarrhoea | | 1 | | 1 |
| Dizziness | | 1 | | 1 |
| Dysphonia | | 1 | | 1 |
| Dyspnoea | | 1 | | 1 |
| Enlarged uvula | | 1 | | 1 |
| Lip swelling | | 2 | | 2 |
| Nausea | | 1 | | 1 |
| Palpitations | | 1 | | 1 |
| Periorbital swelling | | 1 | | 1 |
| Pruritus | | 1 | | 1 |
| Rash macular | | 2 | | 2 |
| Throat tightness | | 1 | | 1 |
| Urticaria | | 1 | | 1 |
| | | 23 | | 23 |

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* I=Interval, C=Cumulative
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | | 2 | | | | 2 |
| Chills | | 1 | | 1 | | |
| Cough | | 1 | | 1 | | |
| Diarrhoea | | 1 | | 1 | | |
| Dysphonia | | 1 | | 1 | | |
| Dyspnoea | | 1 | | 1 | | |
| Enlarged uvula | | 1 | | 1 | | |
| Head discomfort | | 1 | | 1 | | |
| Heart rate increased | | 1 | | 1 | | |
| Hypertension | | 1 | | 1 | | |
| Malaise | | 1 | | 1 | | |
| Palpitations | | 1 | | 1 | | |
| Urticaria | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | 1 | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 2 | 18 | 2 | 15 | | 3 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Anaphylactic shock | | 1 | | | | 1 |
| Chills | | 1 | | 1 | | |
| Eye swelling | | 1 | | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Urticaria | | 1 | | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 3 | 8 | 3 | 7 | | 1 |

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Country Where Event Occurred

SLOVAKIA

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal dreams | 1 | 1 | 1 | 1 | | |
| Asthenia | 3 | 3 | 3 | 3 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | | 2 | | 1 | | 1 |
| Chills | | 2 | | 1 | | 1 |
| COVID-19 | | 1 | | | | 1 |
| Dizziness | 3 | 4 | 3 | 4 | | |
| Drug ineffective | | 1 | | | | 1 |
| Erythema | | 1 | | | | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 4 | 2 | 3 | | 1 |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 2 | 3 | 1 | 2 | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Mydriasis | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Paraesthesia | | 1 | | | | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pruritus | | 1 | | | | 1 |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Rhinitis | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Throat tightness | | 1 | | 1 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 4 | 7 | 4 | 6 | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Vaccination site swelling | | 1 | | | | 1 | |
| Vertigo | 1 | 1 | 1 | 1 | | | |
| | 33 | 54 | 27 | 38 | 6 | 16 | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 5 | 5 | 5 | 5 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 2 | 1 | 2 | | |
| Chest discomfort | 2 | 2 | 2 | 2 | | |
| Chills | 7 | 10 | 6 | 9 | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 2 | 3 | | 1 | 2 | 2 |
| Cutaneous vasculitis | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Diplopia | | 1 | | 1 | | |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 3 | 1 | 2 | 1 | 1 |
| Erythema | 3 | 3 | 3 | 3 | | |
| Eye allergy | 1 | 1 | 1 | 1 | | |
| Eye irritation | 1 | 1 | 1 | 1 | | |
| Eye oedema | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Fatigue | 3 | 4 | 3 | 4 | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 3 | 5 | 3 | 5 | | |
| Hot flush | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypertension | 2 | 3 | 1 | 2 | 1 | 1 |
| Hypoaesthesia | | 1 | | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Insulin resistance | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Lymphadenopathy | | 1 |
| Malaise | 1 | 1 |
| Movement disorder | 1 | 1 |
| Myalgia | 3 | 3 |
| Nausea | 3 | 3 |
| Ocular hyperaemia | 1 | 1 |
| Oedema | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Oral discomfort | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 3 | 5 |
| Palpitations | 1 | 2 |
| Paraesthesia | 2 | 2 |
| Peripheral coldness | 1 | 1 |
| Petechiae | 1 | 1 |
| Presyncope | 3 | 3 |
| Product administered at inappropriate site | 1 | 2 |
| Pruritus | 1 | 1 |
| Pyrexia | 5 | 6 |
| Rash | 1 | 1 |
| SARS-CoV-2 test positive | | 1 |
| Sinus tachycardia | 1 | 1 |
| Syncope | 1 | 1 |
| Synovitis | 1 | 1 |
| Tachycardia | | 1 |
| Tachypnoea | 1 | 1 |
| Throat irritation | 1 | 2 |
| Tryptase decreased | 1 | 1 |
| Vaccination site joint movement impairment | | 1 |
| Vaccination site pain | 7 | 9 |
| Vertigo | 1 | 1 |
| Vomiting | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 5 | | |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 1 | 2 | | |
| 1 | 1 | | |
| 5 | 6 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 7 | 9 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

31 - 50 years

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 78 | 103 | 20 | 20 |

98

123

78

103

20

20

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* I=Interval, C=Cumulative
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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 3 | 3 | 2 | 2 | 1 | 1 |
| Axillary vein thrombosis | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Body temperature increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Chills | 7 | 8 | 5 | 6 | 2 | 2 |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Headache | 5 | 5 | 5 | 5 | | |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hypertension | | 1 | | 1 | | |
| Incorrect dose administered | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 2 | 2 | | |
| Medication error | 1 | 1 | 1 | 1 | | |
| Micturition urgency | 1 | 1 | | | 1 | 1 |
| Myalgia | 2 | 2 | 2 | 2 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 2 | 2 | 2 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 4 | 5 | 3 | 4 | 1 | 1 |
| Rash | 1 | 1 | 1 | 1 | | |
| Subclavian vein thrombosis | 1 | 1 | | | 1 | 1 |
| Syncope | | 1 | | | | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Venous thrombosis limb | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 53 | 57 | 37 | 40 | 16 | 17 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Anaphylactic reaction | 1 | 1 | 1 | 1 |
| Asthenia | 2 | 2 | 2 | 2 |
| COVID-19 | | 1 | | 1 |
| Dizziness | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 |
| Loss of consciousness | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 |
| | 10 | 11 | 10 | 11 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Myocardial ischaemia | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 5 | 5 | 3 | 3 | 2 | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Asthenia | | 1 | | 1 | | |
| Axillary pain | | 1 | | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Cough | | 2 | | 2 | | |
| COVID-19 | 1 | 2 | | 1 | 1 | 1 |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 2 | 1 | 2 | | |
| Limb discomfort | | 1 | | 1 | | |
| Lip oedema | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Myalgia | 1 | 2 | 1 | 2 | | |
| Pain in extremity | | 2 | | 2 | | |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | | 2 | | 2 | | |
| Rash | | 1 | | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| SARS-CoV-2 ant body test positive | | 1 | | | | 1 |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | | 1 | | 1 | | |
| Vaccination site urticaria | | 1 | | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 14 | 37 | 10 | 30 | 4 | 7 |

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Country Where Event Occurred

SLOVENIA

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Fatigue | 3 | 3 | 3 | 3 | | |
| Headache | 5 | 5 | 5 | 5 | | |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Neurological symptom | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 2 | 2 | 2 | 2 | | |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 2 | 2 | 2 | | |
| Sensory disturbance | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Thinking abnormal | 1 | 1 | 1 | 1 | | |
| Throat tightness | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 8 | 8 | 8 | 8 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| | 44 | 44 | 43 | 43 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrial tachycardia | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Dizziness | 2 | 2 | | | 2 | 2 |
| Dysgeusia | 2 | 2 | 2 | 2 | | |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Fatigue | 5 | 5 | 4 | 4 | 1 | 1 |
| Headache | 3 | 3 | 3 | 3 | | |
| Hyposmia | 2 | 2 | 2 | 2 | | |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 3 | 3 | 3 | 3 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | 2 | 2 | 2 | 2 | | |
| Nausea | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 2 | 2 | 2 | 2 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | 2 | 2 | | |
| Syncope | 2 | 2 | | | 2 | 2 |
| Tongue biting | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 5 | 5 | 4 | 4 | 1 | 1 |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 34 | 34 | 19 | 19 |

53

53

34

34

19

19

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Aura | 1 | 1 | 1 | 1 | | |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| B-cell lymphoma | 1 | 1 | | | 1 | 1 |
| B-cell type acute leukaemia | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Cerebral thrombosis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | 2 | 2 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 2 | 2 | 1 | 1 | 1 | 1 |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Headache | 5 | 5 | 3 | 3 | 2 | 2 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Oral herpes | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 5 | 5 | 3 | 3 | 2 | 2 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 48 | 48 | 25 | 25 | 23 | 23 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiopulmonary failure | | 1 | | | | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Sudden death | | 1 | | | | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 5 | 6 | 5 | 6 | | |
| | 7 | 10 | 7 | 8 | | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Asthenia | | 2 | | 2 | | |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Disease recurrence | | 1 | | | | 1 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Fatigue | 1 | 2 | 1 | 2 | | |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Hypertension | | 1 | | | | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 2 | 1 | 1 | 1 | 1 |
| Miosis | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Nausea | | 1 | | | | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Skin disorder | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | | | 2 | 2 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| Vaccination site erythema | 6 | 7 | 6 | 7 | | |
| Vaccination site oedema | 2 | 3 | 2 | 3 | | |
| Vaccination site pain | 12 | 12 | 12 | 12 | | |
| Vertigo | | 1 | | | | 1 |
| Vomiting | 1 | 2 | 1 | 1 | | 1 |
| White blood cell count increased | | 1 | | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 48 | 60 | 27 | 33 | 21 | 27 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autoimmune thyroiditis | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nightmare | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 11 | 12 | 10 | 11 | 1 | 1 |

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Country Where Event Occurred

SPAIN

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Exposure via breast milk | | 1 | | 1 |
| | | 1 | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 8 | 8 | | | 8 | 8 |
| Anaphylactic shock | 1 | 3 | | | 1 | 3 |
| Angioedema | 2 | 3 | | | 2 | 3 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 2 | 1 | 2 | | |
| Aphasia | 2 | 2 | | | 2 | 2 |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Appendicitis | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Asthenia | | 1 | | 1 | | |
| Asthma | 2 | 2 | | | 2 | 2 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Autoimmune demyelinating disease | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Bradykinesia | 1 | 1 | 1 | 1 | | |
| Bradyphrenia | 1 | 1 | 1 | 1 | | |
| Bronchial hyperreactivity | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Butterfly rash | 1 | 1 | | | 1 | 1 |
| Cellulitis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chills | 5 | 6 | | 1 | 5 | 5 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Circumoral swelling | | 1 | | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Cold sweat | 2 | 2 |
| Condition aggravated | 2 | 2 |
| Confusional state | 1 | 1 |
| Cough | 2 | 2 |
| COVID-19 | 5 | 5 |
| Decreased appetite | 1 | 1 |
| Diarrhoea | 3 | 4 |
| Dizziness | 8 | 9 |
| Drug ineffective | 3 | 3 |
| Dry throat | | 1 |
| Dyspnoea | 7 | 7 |
| Epigastric discomfort | 1 | 1 |
| Erythema | 4 | 6 |
| Eye pain | 1 | 1 |
| Eye pruritus | 1 | 1 |
| Face oedema | 2 | 2 |
| Facial paralysis | 4 | 4 |
| Fatigue | 6 | 7 |
| Feeling cold | 1 | 1 |
| Feeling hot | 2 | 2 |
| Gait disturbance | 1 | 1 |
| Gait inability | 1 | 1 |
| Gastroesophageal reflux disease | 1 | 1 |
| Groin pain | 1 | 1 |
| Haemophagocytic lymphohistiocytosis | 1 | 1 |
| Headache | 11 | 13 |
| Head injury | 1 | 1 |
| Hepatic failure | 1 | 1 |
| Hepatitis acute | 1 | 1 |
| Herpes virus infection | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Hyperhidrosis | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 5 | 5 |
| | | 1 | 1 |
| 1 | 2 | 2 | 2 |
| 1 | 2 | 7 | 7 |
| | | 3 | 3 |
| | 1 | | |
| | | 7 | 7 |
| | | 1 | 1 |
| | 2 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 4 | 4 |
| 2 | 3 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypersensitivity | 1 | 1 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 2 | 2 |
| Hypoglycaemia | 1 | 1 |
| Hypotension | 4 | 5 |
| Hypoxia | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Ischaemic stroke | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Laryngeal oedema | 1 | 2 |
| Lip oedema | 2 | 2 |
| Lip pruritus | 1 | 2 |
| Lip swelling | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 8 | 9 |
| Malaise | 7 | 8 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Musculoskeletal pain | 1 | 1 |
| Myalgia | 7 | 9 |
| Nausea | 7 | 11 |
| Night sweats | 1 | 1 |
| Odynophagia | 1 | 1 |
| Off label use | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Pain | 2 | 2 |
| Pain in extremity | 2 | 4 |
| Palatal oedema | 2 | 3 |
| Pallor | 1 | 1 |
| Palpitations | | 1 |
| Paraesthesia | 1 | 1 |
| Peripheral swelling | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 4 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 2 | 2 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 2 | 7 | 7 |
| 2 | 3 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 3 | 6 | 6 |
| 1 | 4 | 6 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 3 | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Petit mal epilepsy | 1 | 1 |
| Pharyngotonsillitis | 1 | 1 |
| Presyncope | 1 | 1 |
| Pruritus | 6 | 8 |
| Pyrexia | 18 | 24 |
| Rash | 1 | 2 |
| Rash erythematous | 1 | 1 |
| Rash papular | 1 | 1 |
| Respiratory distress | 1 | 2 |
| Respiratory failure | 1 | 1 |
| Sensation of foreign body | 1 | 1 |
| Shock | 1 | 1 |
| Sinus bradycardia | 1 | 1 |
| Somnolence | 2 | 2 |
| Speech disorder | 1 | 1 |
| Spinal cord injury | 1 | 1 |
| Swelling | 1 | 1 |
| Swelling face | 1 | 1 |
| Syncope | 6 | 6 |
| Tachycardia | 3 | 4 |
| Temperature regulation disorder | | 1 |
| Throat irritation | | 1 |
| Throat tightness | 1 | 1 |
| Tongue oedema | | 1 |
| Tonsillitis | 1 | 1 |
| Transaminases increased | 1 | 1 |
| Transient ischaemic attack | 1 | 1 |
| Tremor | 1 | 1 |
| Urticaria | 3 | 4 |
| Uterine haemorrhage | 1 | 1 |
| Vaccination complication | 1 | 1 |
| Vaccination site erythema | 4 | 5 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | 6 | 7 |
| 7 | 13 | 11 | 11 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 6 | 6 |
| | | 3 | 4 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 3 | 3 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 6 | 10 | | 4 | 6 | 6 |
| Vaccination site paraesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site pruritus | 3 | 4 | 1 | 2 | 2 | 2 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 2 | 2 | | | 2 | 2 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vision blurred | 2 | 2 | | | 2 | 2 |
| Vomiting | 7 | 9 | | 1 | 7 | 8 |
| Wheezing | 2 | 2 | | | 2 | 2 |
| | 280 | 334 | 45 | 86 | 235 | 248 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 3 | 5 | | 1 | 3 | 4 |
| Abdominal pain upper | 2 | 3 | 1 | 2 | 1 | 1 |
| Ageusia | 2 | 2 | | | 2 | 2 |
| Allergic reaction to excipient | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 8 | 9 | | | 8 | 9 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 7 | 7 | | | 7 | 7 |
| Anosmia | 2 | 2 | | | 2 | 2 |
| Anxiety | 1 | 2 | 1 | 2 | | |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Aphthous ulcer | 1 | 2 | | 1 | 1 | 1 |
| Arthralgia | 9 | 11 | 1 | 3 | 8 | 8 |
| Asphyxia | 2 | 2 | | | 2 | 2 |
| Asthenia | 17 | 18 | 5 | 6 | 12 | 12 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atrophic glossitis | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | 4 | 4 | | | 4 | 4 |
| Balance disorder | 3 | 3 | | | 3 | 3 |
| Blood fibrinogen increased | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure systolic increased | 1 | 1 | 1 | 1 | | |
| Body temperature abnormal | 1 | 1 | | | 1 | 1 |
| Body temperature increased | | 1 | | 1 | | |
| Brachial plexus injury | 1 | 1 | | | 1 | 1 |
| Bradypnea | 2 | 2 | | | 2 | 2 |
| Breast oedema | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cardiac failure acute | 1 | 1 | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Cardio-respiratory arrest | 1 | 1 |
| Catarrh | 1 | 1 |
| Cellulitis | 2 | 2 |
| Cervicobrachial syndrome | 1 | 1 |
| Cheilitis | 1 | 1 |
| Chest discomfort | 6 | 6 |
| Chest pain | 6 | 8 |
| Chills | 15 | 19 |
| Citrobacter infection | 1 | 1 |
| Cold sweat | 1 | 1 |
| Condition aggravated | 1 | 1 |
| Confusional state | 1 | 1 |
| Contusion | 2 | 2 |
| Cough | 7 | 9 |
| COVID-19 | 12 | 13 |
| C-reactive protein increased | 1 | 1 |
| Deafness | 1 | 1 |
| Death | | 1 |
| Decreased appetite | 2 | 2 |
| Dehydration | 1 | 1 |
| Depressed level of consciousness | 5 | 5 |
| Depressed mood | | 1 |
| Dermatitis allergic | 1 | 1 |
| Dermatitis bullous | 1 | 1 |
| Diarrhoea | 16 | 20 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplopia | 1 | 1 |
| Discomfort | 3 | 5 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 28 | 36 |
| Drowning | 1 | 1 |
| Drug hypersensitivity | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 6 | 6 |
| 2 | 4 | 4 | 4 |
| 5 | 9 | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 2 | 4 | 5 | 5 |
| 2 | 2 | 10 | 11 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 5 | 5 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 7 | 11 | 13 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 3 | 2 | 2 |
| | | 2 | 2 |
| 6 | 14 | 22 | 22 |
| | | 1 | 1 |
| | | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Drug ineffective | 8 | 9 |
| Dry mouth | | 1 |
| Dry throat | 1 | 1 |
| Dysaesthesia | 2 | 2 |
| Dysgeusia | 2 | 3 |
| Dysphagia | 1 | 1 |
| Dyspnoea | 13 | 14 |
| Dystonia | 1 | 1 |
| Ear infection | 1 | 1 |
| Ear pain | 2 | 2 |
| Ecchymosis | 1 | 1 |
| Eczema | 1 | 1 |
| Epilepsy | 1 | 1 |
| Erythema | 12 | 13 |
| Essential tremor | 1 | 1 |
| Face oedema | 5 | 6 |
| Facial paralysis | 8 | 9 |
| Fatigue | 8 | 12 |
| Feeling abnormal | 3 | 3 |
| Feeling cold | 1 | 2 |
| Feeling drunk | | 1 |
| Feeling hot | 3 | 3 |
| Flatulence | | 1 |
| Flushing | 2 | 2 |
| Formication | 1 | 3 |
| Gastroenteritis | | 1 |
| Generalised oedema | 2 | 2 |
| General physical health deterioration | 1 | 1 |
| Genital ulceration | 1 | 1 |
| Glossitis | | 1 |
| Glossodynia | 1 | 1 |
| Haematochezia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 8 | 9 |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| | | 13 | 14 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 11 | 11 |
| | | 1 | 1 |
| | | 5 | 6 |
| | | 8 | 9 |
| 2 | 4 | 6 | 8 |
| | | 3 | 3 |
| | | 1 | 2 |
| | 1 | | |
| | | 3 | 3 |
| | | | 1 |
| | | 2 | 2 |
| | 2 | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Haematoma | 2 | 2 |
| Haemorrhage | 2 | 2 |
| Haemorrhagic diathesis | 1 | 1 |
| Headache | 44 | 63 |
| Hepatitis | 1 | 1 |
| Herpes zoster | 7 | 7 |
| Herpes zoster reactivation | 1 | 1 |
| Hyperdynamic left ventricle | 1 | 1 |
| Hyperglycaemia | | 1 |
| Hyperhidrosis | 3 | 4 |
| Hypersensitivity | 5 | 5 |
| Hypertension | 6 | 6 |
| Hypertensive crisis | 7 | 7 |
| Hypertransaminasaemia | 1 | 1 |
| Hypoacusis | 1 | 1 |
| Hypoesthesia | 7 | 7 |
| Hypoesthesia oral | 2 | 2 |
| Hypocalcaemia | 1 | 1 |
| Hypoglycaemia | 1 | 1 |
| Hypophosphataemia | 1 | 1 |
| Hypotension | 2 | 2 |
| Hypothermia | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Immunisation reaction | | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Induration | 1 | 1 |
| Inflammation | 2 | 2 |
| Influenza | 2 | 2 |
| Influenza like illness | 1 | 1 |
| Insomnia | 1 | 1 |
| Insulin resistance | | 1 |
| Interstitial lung disease | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 10 | 25 | 34 | 38 |
| | | 1 | 1 |
| | | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | 3 | 3 |
| 1 | 1 | 4 | 4 |
| 3 | 3 | 3 | 3 |
| | | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 5 | 5 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Iron deficiency | 1 | 1 |
| Joint contracture | | 1 |
| Joint swelling | 1 | 1 |
| Joint warmth | 1 | 1 |
| Laryngeal oedema | 2 | 2 |
| Leukopenia | 1 | 1 |
| Lichen planus | 1 | 1 |
| Limb immobilisation | 1 | 1 |
| Lip oedema | 2 | 3 |
| Lip pruritus | 1 | 1 |
| Lip swelling | 1 | 1 |
| Lividity | 1 | 1 |
| Local reaction | 1 | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 11 | 11 |
| Lymphopenia | 1 | 1 |
| Malaise | 23 | 29 |
| Mental impairment | 1 | 1 |
| Migraine | 2 | 4 |
| Migraine with aura | 1 | 1 |
| Mobility decreased | 1 | 2 |
| Mononeuropathy | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Movement disorder | | 1 |
| Mucosal dryness | 1 | 1 |
| Muscle contracture | 2 | 2 |
| Muscle rigidity | 1 | 1 |
| Muscular weakness | | 2 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal pain | 8 | 9 |
| Musculoskeletal stiffness | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 10 | 10 |
| 1 | 1 | | |
| 7 | 12 | 16 | 17 |
| | | 1 | 1 |
| | 1 | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 3 | 6 | 6 |
| | 1 | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Myalgia | 19 | 24 |
| Myelitis | 1 | 1 |
| Myoclonic dystonia | 1 | 1 |
| Nasal congestion | 3 | 4 |
| Nasopharyngitis | | 1 |
| Nausea | 18 | 25 |
| Neck pain | | 1 |
| Nervousness | | 1 |
| Neuralgia | 2 | 2 |
| Neuropathy peripheral | 1 | 1 |
| Neurosensory hypoacusis | 1 | 1 |
| Nuchal rigidity | | 1 |
| Ocular hyperaemia | 1 | 1 |
| Odynophagia | 4 | 4 |
| Oedema | 4 | 4 |
| Oedema peripheral | 3 | 3 |
| Off label use | 5 | 5 |
| Oral candidiasis | 1 | 1 |
| Oral dysaesthesia | 1 | 1 |
| Oral herpes | 2 | 2 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 4 | 6 |
| Pain in extremity | 5 | 7 |
| Palatal oedema | 6 | 6 |
| Palatal swelling | 1 | 1 |
| Pallor | 1 | 1 |
| Palpitations | 4 | 4 |
| Paraesthesia | 14 | 19 |
| Paraesthesia oral | 4 | 4 |
| Parotitis | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 6 | 11 | 13 | 13 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 3 | 3 |
| | 1 | | |
| 5 | 9 | 13 | 16 |
| | | | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 2 | 2 | 2 | 2 |
| | | 3 | 3 |
| 5 | 5 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 4 | 2 | 2 |
| 2 | 3 | 3 | 4 |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| 2 | 7 | 12 | 12 |
| | | 4 | 4 |
| | | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Pelvic pain | | 1 |
| Pericarditis | 1 | 1 |
| Periorbital oedema | | 1 |
| Peripheral swelling | 1 | 2 |
| Persistent depressive disorder | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal inflammation | 1 | 1 |
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal swelling | 1 | 1 |
| Photopsia | 1 | 1 |
| Pleuritic pain | 1 | 1 |
| Presyncope | 6 | 6 |
| Productive cough | 1 | 1 |
| Product use issue | 4 | 4 |
| Pruritus | 18 | 20 |
| Pulse abnormal | 1 | 1 |
| Purpura | 1 | 1 |
| Pyrexia | 38 | 47 |
| Rash | 11 | 13 |
| Rash erythematous | 1 | 1 |
| Rash maculo-papular | 2 | 2 |
| Rash papular | 1 | 1 |
| Rash pruritic | 2 | 3 |
| Red blood cell sedimentation rate increased | 1 | 1 |
| Respiratory distress | 2 | 2 |
| Rhinitis | | 1 |
| Rhinorrhoea | 1 | 3 |
| SARS-CoV-2 ant body test positive | 1 | 1 |
| Sensation of foreign body | 2 | 2 |
| Sensory loss | 1 | 2 |
| Skin exfoliation | 1 | 1 |
| Skin odour abnormal | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 5 | 5 |
| | | 1 | 1 |
| 4 | 4 | | |
| 1 | 3 | 17 | 17 |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 16 | 31 | 31 |
| | 2 | 11 | 11 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | | |
| | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Slow speech | 1 | 1 |
| Somnolence | 2 | 4 |
| Stomatitis | | 2 |
| Stridor | 1 | 1 |
| Subcutaneous abscess | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Swelling face | 2 | 2 |
| Swollen tongue | 2 | 2 |
| Syncope | 8 | 8 |
| Tachycardia | 17 | 17 |
| Tachycardia paroxysmal | 1 | 1 |
| Tachypnoea | 1 | 1 |
| Temperature regulation disorder | 6 | 7 |
| Throat irritation | 4 | 5 |
| Throat tightness | 1 | 1 |
| Thrombocytopenia | 1 | 1 |
| Thunderclap headache | 1 | 1 |
| Tic | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue erythema | 1 | 1 |
| Tongue oedema | 1 | 2 |
| Tongue pruritus | 1 | 2 |
| Tongue ulceration | | 1 |
| Tremor | 2 | 2 |
| Trigeminal neuralgia | 1 | 1 |
| Tunnel vision | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 |
| Urticaria | 13 | 14 |
| Uterine haemorrhage | 1 | 1 |
| Vaccination site erythema | 1 | 2 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 3 | 1 | 1 |
| | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 8 | 8 |
| 5 | 5 | 12 | 12 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | 4 | 4 |
| 1 | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 2 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 12 | 12 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site inflammation | 3 | 3 | | | 3 | 3 |
| Vaccination site joint erythema | 3 | 3 | | | 3 | 3 |
| Vaccination site joint inflammation | 2 | 2 | | | 2 | 2 |
| Vaccination site joint movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | | 1 | | 1 | | |
| Vaccination site oedema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 15 | 22 | 3 | 9 | 12 | 13 |
| Vaccination site paraesthesia | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site pruritus | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site warmth | 2 | 2 | | | 2 | 2 |
| Vaginal haemorrhage | | 1 | | 1 | | |
| Vasculitis | 1 | 1 | | | 1 | 1 |
| Venous thrombosis limb | 1 | 1 | 1 | 1 | | |
| Vertigo | 5 | 5 | 1 | 1 | 4 | 4 |
| Vision blurred | 3 | 3 | 1 | 1 | 2 | 2 |
| Vomiting | 13 | 17 | 3 | 5 | 10 | 12 |
| Wheezing | 3 | 3 | | | 3 | 3 |
| | 821 | 986 | 143 | 270 | 678 | 716 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 2 | 2 | | | 2 | 2 |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 12 | 13 | | | 12 | 13 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 8 | 9 | | | 8 | 9 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Aortic dissection | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 6 | 9 | 1 | 3 | 5 | 6 |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthenia | 11 | 11 | 2 | 2 | 9 | 9 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 4 | 4 | 4 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Burning sensation mucosal | | 1 | | 1 | | |
| Bursitis | 1 | 1 | | | 1 | 1 |
| Carotid bruit | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Cheilitis | 2 | 2 | | | 2 | 2 |
| Chest discomfort | 4 | 4 | | | 4 | 4 |
| Chest pain | 6 | 6 | | | 6 | 6 |
| Chills | 3 | 6 | 1 | 4 | 2 | 2 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Conjunctival haemorrhage | 4 | 4 | | | 4 | 4 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Cough | 3 | 3 |
| COVID-19 | 9 | 9 |
| Deafness unilateral | 1 | 1 |
| Death | 1 | 1 |
| Depressed level of consciousness | 2 | 2 |
| Dermatitis bullous | 1 | 1 |
| Diarrhoea | 7 | 9 |
| Disease recurrence | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 21 | 22 |
| Drug ineffective | 5 | 5 |
| Drug interaction | 1 | 1 |
| Dry mouth | 1 | 1 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 1 | 2 |
| Dysphagia | 2 | 3 |
| Dysphonia | 2 | 2 |
| Dyspnoea | 8 | 9 |
| Eczema herpeticum | 1 | 1 |
| Encephalitis | 1 | 1 |
| Epiglottitis | 1 | 1 |
| Epilepsy | 1 | 1 |
| Erythema | 10 | 10 |
| Erythema nodosum | 1 | 1 |
| Extensor plantar response | 1 | 1 |
| Extrapyramidal disorder | 1 | 1 |
| Extrasystoles | 1 | 1 |
| Eyelid oedema | 2 | 2 |
| Eye pruritus | 1 | 2 |
| Face oedema | 2 | 2 |
| Facial bones fracture | 1 | 1 |
| Facial paralysis | 4 | 4 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 3 |
| 2 | 2 | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 3 | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 5 | 16 | 17 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | 1 | 2 |
| | | 2 | 2 |
| | | 8 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 10 | 10 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 4 | 4 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Fatigue | 4 | 5 |
| Feeling hot | 3 | 3 |
| Fibrin D dimer increased | 1 | 1 |
| Flushing | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| Gastrooesophageal reflux disease | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematoma | 1 | 1 |
| Headache | 25 | 30 |
| Hemiparaesthesia | 2 | 2 |
| Hemiparesis | 1 | 1 |
| Herpes zoster | 8 | 8 |
| Herpes zoster oticus | 1 | 1 |
| Herpes zoster reactivation | 1 | 1 |
| Hyperf brinogenaemia | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 6 | 6 |
| Hypertension | 10 | 10 |
| Hypertensive crisis | 3 | 3 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 3 | 3 |
| Hypotension | | 1 |
| Hypothermia | 2 | 2 |
| Hypoxia | 1 | 1 |
| Ileus paralytic | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect route of product administration | | 1 |
| Influenza | 1 | 1 |
| Intestinal obstruction | 1 | 1 |
| Ischaemic stroke | 3 | 3 |
| Jaw fracture | 1 | 1 |
| Joint range of motion decreased | | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | 3 | 3 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 9 | 21 | 21 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 8 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 8 | 8 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 3 | 3 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lacrimation increased | 2 | 2 | | | 2 | 2 |
| Laryngeal erythema | 1 | 1 | | | 1 | 1 |
| Laryngeal oedema | 2 | 3 | | | 2 | 3 |
| Lip oedema | 2 | 2 | | | 2 | 2 |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 2 | 2 | | | 2 | 2 |
| Lymphadenopathy | 5 | 6 | | 1 | 5 | 5 |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Macroglossia | 1 | 1 | | | 1 | 1 |
| Malaise | 12 | 15 | 3 | 6 | 9 | 9 |
| Mental impairment | 2 | 2 | | | 2 | 2 |
| Migraine with aura | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 1 | 1 | | | 1 | 1 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal discomfort | 2 | 2 | | | 2 | 2 |
| Musculoskeletal pain | 2 | 2 | | | 2 | 2 |
| Myalgia | 13 | 18 | 2 | 7 | 11 | 11 |
| Myositis | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Nausea | 13 | 14 | 4 | 5 | 9 | 9 |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Neurogenic shock | 1 | 1 | | | 1 | 1 |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Noninfective gingivitis | 1 | 1 | | | 1 | 1 |
| Oedema mouth | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 2 | 2 | | | 2 | 2 |
| Oral pruritus | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 |
| Oropharyngeal oedema | 2 | 2 | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Oropharyngeal pain | | 1 |
| Overdose | 1 | 1 |
| Pain | 1 | 3 |
| Pain in extremity | 2 | 5 |
| Pain in jaw | 1 | 1 |
| Palatal oedema | 2 | 2 |
| Palatal swelling | 1 | 1 |
| Pallor | 1 | 1 |
| Palpitations | 3 | 4 |
| Panniculitis | 1 | 1 |
| Paraesthesia | 9 | 9 |
| Paraesthesia oral | 4 | 4 |
| Paraparesis | 2 | 2 |
| Partial seizures | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal erythema | 1 | 1 |
| Phlebitis | 1 | 1 |
| Photophobia | 2 | 2 |
| Pneumonia | 2 | 2 |
| Presyncope | 1 | 1 |
| Pruritus | 12 | 12 |
| Psoriasis | 1 | 1 |
| Pulmonary embolism | 1 | 1 |
| Pyrexia | 27 | 37 |
| Rash | 7 | 9 |
| Rash erythematous | 1 | 1 |
| Raynaud's phenomenon | 1 | 1 |
| Reaction to excipient | 1 | 1 |
| Renal impairment | 1 | 1 |
| Respiratory distress | 2 | 2 |
| Rhinalgia | 1 | 1 |
| Sensation of foreign body | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 1 | | |
| | 2 | 1 | 1 |
| | 2 | 2 | 3 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 9 | 9 |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 12 | 12 |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 15 | 22 | 22 |
| | 2 | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Skin lesion | 1 | 1 |
| Somnolence | 1 | 1 |
| Speech disorder | 1 | 1 |
| Sudden death | 2 | 2 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling face | 1 | 1 |
| Swollen tongue | 1 | 1 |
| Syncope | 8 | 8 |
| Tachycardia | 8 | 9 |
| Temperature regulation disorder | 3 | 3 |
| Tension headache | 1 | 2 |
| Throat irritation | 4 | 4 |
| Throat tightness | | 1 |
| Thrombophlebitis superficial | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue discomfort | | 1 |
| Tongue oedema | 2 | 2 |
| Tongue pruritus | 1 | 1 |
| Tonic clonic movements | 1 | 1 |
| Transient global amnesia | 1 | 1 |
| Transient ischaemic attack | 1 | 1 |
| Tremor | 2 | 2 |
| Type IV hypersensitivity reaction | 1 | 1 |
| Urinary retention | 1 | 1 |
| Urticaria | 5 | 5 |
| Vaccination complication | 1 | 2 |
| Vaccination site cellulitis | 2 | 2 |
| Vaccination site erosion | 1 | 1 |
| Vaccination site erythema | 1 | 1 |
| Vaccination site induration | 1 | 1 |
| Vaccination site inflammation | 3 | 4 |
| Vaccination site movement impairment | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 8 | 8 |
| | 1 | 8 | 8 |
| 2 | 2 | 1 | 1 |
| | 1 | 1 | 1 |
| | | 4 | 4 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| | 1 | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 2 | 3 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 11 | 15 | 4 | 8 | 7 | 7 |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | | 2 | | 2 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Visual acuity reduced | 1 | 1 | | | 1 | 1 |
| Vitreous detachment | 2 | 2 | | | 2 | 2 |
| Volvulus | 1 | 1 | | | 1 | 1 |
| Vomiting | 6 | 8 | 1 | 3 | 5 | 5 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| White blood cell count decreased | 1 | 1 | | | 1 | 1 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 526 | 597 | 66 | 125 | 460 | 472 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | | 1 | | | | 1 |
| Anal sphincter atony | 1 | 1 | | | 1 | 1 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 1 | 1 | 1 | 1 | | |
| Blood chloride decreased | 1 | 1 | 1 | 1 | | |
| Blood sodium decreased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bradykinesia | 1 | 1 | | | 1 | 1 |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cardiac failure acute | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Chronic respiratory failure | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Contusion | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 4 | 4 | | | 4 | 4 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | 1 | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Dehydration | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 4 | | 3 | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 3 | 4 | | | 3 | 4 |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Facial paralysis | 1 | 1 |
| Fall | 2 | 2 |
| Fatigue | 1 | 1 |
| Febrile convulsion | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Haematuria | 1 | 1 |
| Headache | 2 | 4 |
| Head injury | 1 | 1 |
| Hemiparaesthesia | 1 | 1 |
| Hypersensitivity | | 1 |
| Hypertension | 2 | 2 |
| Hypotension | 1 | 1 |
| Hypoxia | 3 | 3 |
| Increased bronchial secretion | 1 | 1 |
| Influenza like illness | 1 | 1 |
| Leukoencephalopathy | 1 | 1 |
| Lip oedema | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lung disorder | 1 | 1 |
| Lung infiltration | 1 | 1 |
| Lymphocyte percentage decreased | 1 | 1 |
| Malaise | 2 | 2 |
| Multiple organ dysfunction syndrome | | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 1 | 1 |
| Myocarditis | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nausea | 1 | 1 |
| Neutrophil count increased | 1 | 1 |
| Neutrophil percentage increased | 1 | 1 |
| Oedema peripheral | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 2 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Off label use | 1 | 1 |
| Oxygen saturation decreased | 3 | 3 |
| Pain | 1 | 1 |
| Peripheral coldness | 1 | 1 |
| Peripheral ischaemia | 1 | 1 |
| Petechiae | | 1 |
| Pneumonia | 4 | 4 |
| Product use issue | 1 | 1 |
| Pruritus | 1 | 1 |
| Pyrexia | 10 | 14 |
| Rash | 2 | 2 |
| Renal failure | 1 | 1 |
| Renal impairment | 1 | 1 |
| Respiratory distress | | 1 |
| Rhinorrhoea | 1 | 1 |
| Seizure | 2 | 2 |
| Skin necrosis | 1 | 1 |
| Skin reaction | 1 | 1 |
| Slow speech | 1 | 1 |
| Status epilepticus | 1 | 1 |
| Sudden death | | 1 |
| Syncope | 6 | 6 |
| Tachypnoea | 1 | 1 |
| Tremor | 1 | 1 |
| Urinary sediment present | 1 | 1 |
| Urinary tract infection | 2 | 2 |
| Urticaria | 1 | 1 |
| Vaccination site inflammation | | 1 |
| Vaccination site joint erythema | 1 | 1 |
| Vaccination site pain | 1 | 3 |
| Vision blurred | 1 | 1 |
| Vomiting | 2 | 3 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| 3 | 7 | 7 | 7 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| White blood cell count increased | 1 | 1 | 1 | 1 | 98 | 104 |
| | 125 | 145 | 27 | 41 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Acute leukaemia | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 2 | 4 | | | 2 | 4 |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Angular cheilitis | | 1 | | 1 | | |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | | 1 | | 1 | | |
| Aspiration | | 1 | | | | 1 |
| Asthenia | 3 | 4 | | 1 | 3 | 3 |
| Asymptomatic COVID-19 | 4 | 4 | | | 4 | 4 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 2 | 2 | | | 2 | 2 |
| Autoantibody negative | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Balance disorder | | 1 | | 1 | | |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure diastolic decreased | 1 | 1 | | | 1 | 1 |
| Bradycardia | 3 | 3 | | | 3 | 3 |
| Bronchospasm | 3 | 3 | | | 3 | 3 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 3 | 3 | | | 3 | 3 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cardio-respiratory arrest | 2 | 2 | | | 2 | 2 |
| Cardio-respiratory distress | | 1 | | | | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | | 1 | | | | 1 |
| Chest pain | | 1 | | | | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | | | 2 | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| COVID-19 | 6 | 6 |
| COVID-19 pneumonia | 4 | 4 |
| C-reactive protein increased | 1 | 1 |
| Cyanosis | 2 | 2 |
| Deep vein thrombosis | 2 | 2 |
| Depressed level of consciousness | 5 | 5 |
| Depressed mood | | 1 |
| Diarrhoea | 5 | 10 |
| Discomfort | 1 | 1 |
| Disorientation | 1 | 1 |
| Dizziness | 1 | 1 |
| Drug ineffective | 7 | 7 |
| Drug interaction | | 1 |
| Dysarthria | 1 | 2 |
| Dyspnoea | 12 | 15 |
| Electrocardiogram QRS complex prolonged | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | 1 |
| Electrocardiogram ST-T change | 1 | 1 |
| Epidermal necrosis | 1 | 1 |
| Euphoric mood | 1 | 2 |
| Eyelid oedema | 1 | 1 |
| Facial paralysis | 1 | 1 |
| Fatigue | 2 | 3 |
| Gamma-glutamyltransferase increased | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Haematocrit decreased | 1 | 1 |
| Haematoma muscle | | 1 |
| Haemoglobin decreased | 1 | 1 |
| Haemorrhagic stroke | 1 | 1 |
| Headache | 2 | 4 |
| Hepatitis acute | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 6 | 6 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 5 | 5 |
| | 1 | | |
| | 5 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 7 | 7 |
| | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | 11 | 14 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 3 | | |
| | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Herpes zoster | 1 | 1 | | | 1 | 1 |
| Herpes zoster cutaneous disseminated | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypernatraemia | 2 | 2 | | | 2 | 2 |
| Hypersexuality | 1 | 1 | | | 1 | 1 |
| Hypertensive crisis | 2 | 2 | | | 2 | 2 |
| Hypertensive urgency | 1 | 1 | | | 1 | 1 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 5 | | 1 | 2 | 4 |
| Hypoxia | 5 | 6 | | | 5 | 6 |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Incorrect dose administered | | 1 | | 1 | | |
| Infection | 1 | 1 | | | 1 | 1 |
| Inflammatory bowel disease | 1 | 1 | | | 1 | 1 |
| Intestinal ischaemia | | 1 | | | | 1 |
| Intestinal obstruction | 1 | 1 | | | 1 | 1 |
| Ischaemic stroke | 3 | 3 | | | 3 | 3 |
| Localised infection | 1 | 1 | | | 1 | 1 |
| Lung infiltration | 1 | 1 | 1 | 1 | | |
| Malaise | 5 | 8 | 1 | 2 | 4 | 6 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Muscle contractions involuntary | | 1 | | 1 | | |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Myalgia | 2 | 3 | | 1 | 2 | 2 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Necrosis | 1 | 1 | | | 1 | 1 |
| Neoplasm | 1 | 1 | 1 | 1 | | |
| Nervous system disorder | 1 | 1 | | | 1 | 1 |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| Odynophagia | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Overdose | | 1 | | | | |
| Oxygen saturation decreased | 3 | 3 | | 1 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palpitations | | 1 | | | | 1 |
| Pancytopenia | 1 | 1 | | | 1 | 1 |
| Peripheral ischaemia | | 1 | | | | 1 |
| Petit mal epilepsy | 1 | 1 | | | 1 | 1 |
| Platelet count increased | 1 | 1 | 1 | 1 | | |
| Pleural effusion | | 1 | | | | 1 |
| Pneumonia | 1 | 2 | | | 1 | 2 |
| Presyncope | | 1 | | | | 1 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Prothrombin time prolonged | 1 | 1 | 1 | 1 | | |
| Psychomotor hyperactivity | | 1 | | 1 | | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pulmonary thrombosis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 17 | 33 | 2 | 15 | 15 | 18 |
| Rash | | 1 | | 1 | | |
| Rectal haemorrhage | 1 | 2 | | | 1 | 2 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory failure | 1 | 2 | | | 1 | 2 |
| Respiratory tract infection | 2 | 2 | | | 2 | 2 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sepsis | | 1 | | | | 1 |
| Skin necrosis | 1 | 1 | | | 1 | 1 |
| Skin ulcer | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 2 | | 1 | 1 | 1 |
| Sudden death | 2 | 4 | | | 2 | 4 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Tachyarrhythmia | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 3 | 3 | | | 3 | 3 |
| Tachypnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Troponin T increased | | 1 | | | | 1 |
| Vaccination complication | | 1 | | | | 1 |
| Vaccination failure | 3 | 3 | | | 3 | 3 |
| Vaccination site inflammation | | 5 | | 5 | | |
| Vaccination site joint erythema | | 1 | | 1 | | |
| Vaccination site pain | | 2 | | 2 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Vomiting | 5 | 7 | 1 | 3 | 4 | 4 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| | 210 | 291 | 29 | 78 | 181 | 213 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | | 1 | | 1 | | |
| Allergic oedema | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | | 1 | | | | 1 |
| Bruxism | | 1 | | 1 | | |
| Carotid bruit | 1 | 1 | | | 1 | 1 |
| Cellulitis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 2 | | | 1 | 2 |
| Chills | 1 | 1 | 1 | 1 | | |
| Circumstance or information capable of leading to medication error | 1 | 1 | 1 | 1 | | |
| Confusional state | | 1 | | | | 1 |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 6 | 10 | 1 | 1 | 5 | 9 |
| Diabetes mellitus | 1 | 1 | | | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 | | | 1 | 1 |
| Diarrhoea | | 2 | | 2 | | |
| Discomfort | | 1 | | 1 | | |
| Dizziness | 2 | 3 | | | 2 | 3 |
| Drug ineffective | 7 | 12 | | | 7 | 12 |
| Dry mouth | | 1 | | | | 1 |
| Dysgeusia | | 1 | | 1 | | |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | | 1 | | | | 1 |
| Exposure during pregnancy | | 1 | | 1 | | |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Facial paralysis | 1 | 1 |
| Fatigue | | 3 |
| Feeling abnormal | | 1 |
| Feeling hot | | 1 |
| Gingivitis | 1 | 1 |
| Headache | 4 | 9 |
| Heart rate increased | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypertension | 4 | 4 |
| Hypoaesthesia | | 1 |
| Hypoaesthesia oral | | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Influenza like illness | | 1 |
| Jaw disorder | | 1 |
| Loss of consciousness | | 1 |
| Malaise | | 2 |
| Muscle contracture | | 1 |
| Muscle tightness | | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | | 1 |
| Myoclonus | | 1 |
| Nasal congestion | | 1 |
| Nasopharyngitis | | 1 |
| Nausea | | 1 |
| Off label use | 1 | 3 |
| Oral discomfort | | 1 |
| Pain in extremity | | 2 |
| Palpitations | | 1 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 1 | 3 |
| Paraesthesia oral | | 1 |
| Peripheral swelling | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 2 | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 4 | 9 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| 1 | 3 | | |
| | 1 | | |
| | 2 | | |
| | | | 1 |
| | | 1 | 1 |
| | 2 | 1 | 1 |
| | 1 | | |
| | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pertussis | 2 | 2 | | | 2 | 2 |
| Product use issue | 1 | 3 | 1 | 3 | | |
| Pruritus | | 2 | | 1 | | 1 |
| Pyrexia | | 2 | | 2 | | |
| Rash | | 1 | | 1 | | |
| Respiratory arrest | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test positive | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | 1 | 2 | 1 | 1 | | 1 |
| Sense of oppression | 1 | 1 | | | 1 | 1 |
| Skin lesion | | 1 | | 1 | | |
| Somnolence | | 1 | | 1 | | |
| Speech disorder | | 1 | | | | 1 |
| Stomatitis | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 2 | 3 | | | 2 | 3 |
| Tension headache | 1 | 2 | | 1 | 1 | 1 |
| Throat irritation | | 1 | | 1 | | |
| Tongue eruption | | 1 | | 1 | | |
| Tongue pruritus | | 1 | | 1 | | |
| Underdose | | 1 | | 1 | | |
| Urinary tract infection | | 1 | | 1 | | |
| Vaccination site pain | 1 | 8 | 1 | 8 | | |
| | 63 | 147 | 23 | 83 | 40 | 64 |

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Country Where Event Occurred

SWEDEN

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Feeling abnormal | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 |
| Pharyngeal swelling | 1 | 1 | 1 | 1 |
| Rash | 1 | 1 | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acne | 1 | 1 | 1 | 1 | | |
| Allodynia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 2 | | 1 | 1 | 1 |
| Axillary pain | 2 | 2 | 2 | 2 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 2 | 3 | 1 | 2 | 1 | 1 |
| Cough | 1 | 2 | 1 | 2 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 4 | 4 | 4 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 3 | 3 | 2 | 2 | 1 | 1 |
| Epistaxis | | 1 | | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 2 | 2 | | | 2 | 2 |
| Fatigue | 11 | 13 | 10 | 12 | 1 | 1 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | 3 | 3 | 3 | 3 | | |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Fluid retention | 1 | 1 | | | 1 | 1 |
| Furuncle | 1 | 1 | | | 1 | 1 |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Headache | 17 | 20 | 16 | 19 | 1 | 1 |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 2 | 2 | 2 | 2 | | |
| Hypersensitivity | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypoaesthesia | 3 | 3 | 2 | 2 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 | | |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 2 | 1 | 2 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Local reaction | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 2 | 2 | 2 | 2 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 4 | 4 | 3 | 3 | 1 | 1 |
| Muscle contractions involuntary | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Myalgia | 4 | 5 | 4 | 5 | | |
| Nasal congestion | 2 | 2 | 1 | 1 | 1 | 1 |
| Nausea | 2 | 3 | 2 | 3 | | |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Oral herpes | 1 | 1 | 1 | 1 | | |
| Oral pain | 1 | 1 | 1 | 1 | | |
| Oropharyngeal discomfort | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 7 | 7 | 5 | 5 | 2 | 2 |
| Pain | 5 | 6 | 5 | 6 | | |
| Pain in extremity | 10 | 11 | 9 | 10 | 1 | 1 |
| Palpitations | | 1 | | 1 | | |
| Periorbital pain | 1 | 1 | 1 | 1 | | |
| Pharyngeal disorder | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 3 | 3 | | | 3 | 3 |
| Product preparation issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 15 | 15 | 14 | 14 | 1 | 1 |
| Rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 2 | 3 | 2 | 3 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Seizure | 1 | 1 | | | 1 | 1 |
| Skin ulcer | 1 | 1 | | | 1 | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Taste disorder | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Underdose | 1 | 1 | 1 | 1 | | |
| Urticaria | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 13 | 13 | 13 | 13 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 1 | 2 | 1 | 2 | | |
| Vaccination site urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Visual impairment | 1 | 1 | 1 | 1 | | |
| | 178 | 197 | 137 | 156 | 41 | 41 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 2 | 1 | 2 | | |
| Abdominal pain upper | | 1 | | 1 | | |
| Ageusia | 3 | 3 | 2 | 2 | 1 | 1 |
| Anaphylactic reaction | 4 | 5 | | | 4 | 5 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Anosmia | 3 | 3 | 2 | 2 | 1 | 1 |
| Anxiety | 2 | 2 | 1 | 1 | 1 | 1 |
| Areflexia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 8 | 9 | 7 | 8 | 1 | 1 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Asthenia | 3 | 3 | | | 3 | 3 |
| Axillary pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Back pain | 4 | 4 | 3 | 3 | 1 | 1 |
| Blindness | 1 | 1 | | | 1 | 1 |
| Blister | 1 | 1 | 1 | 1 | | |
| Blood glucose increased | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Blood pressure systolic increased | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 5 | 5 | 2 | 2 | 3 | 3 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 12 | 17 | 8 | 13 | 4 | 4 |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| Condition aggravated | 2 | 2 | 1 | 1 | 1 | 1 |
| Cough | 4 | 4 | 2 | 2 | 2 | 2 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | | 1 | | | | 1 |
| Depressed mood | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 3 | 2 | 3 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Dizziness | 17 | 19 |
| Drug ineffective | 1 | 1 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 2 | 2 |
| Dyspepsia | | 1 |
| Dysphagia | 1 | 1 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 10 | 10 |
| Ear discomfort | 1 | 1 |
| Eczema | 1 | 1 |
| Erythema | 7 | 7 |
| Extrasystoles | 1 | 1 |
| Eye pain | 1 | 1 |
| Eye pruritus | 2 | 2 |
| Eye swelling | 1 | 1 |
| Face injury | 1 | 1 |
| Facial neuralgia | 1 | 1 |
| Facial paralysis | 3 | 3 |
| Facial paresis | 2 | 2 |
| Fall | 1 | 1 |
| Fatigue | 35 | 40 |
| Feeling abnormal | 2 | 3 |
| Feeling cold | 5 | 5 |
| Feeling hot | 5 | 6 |
| Feeling of body temperature change | 1 | 1 |
| Flank pain | 1 | 1 |
| Flushing | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Generalised oedema | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Hallucination | 1 | 1 |
| Headache | 38 | 46 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 9 | 10 | 8 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 8 | 8 |
| | | 1 | 1 |
| 1 | 1 | | |
| 4 | 4 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| 20 | 23 | 15 | 17 |
| | 1 | 2 | 2 |
| 3 | 3 | 2 | 2 |
| 2 | 3 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 26 | 33 | 12 | 13 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Head discomfort | 2 | 2 |
| Heart rate increased | 3 | 3 |
| Hemiparesis | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 12 | 12 |
| Hypersomnia | 1 | 1 |
| Hypertension | 2 | 2 |
| Hypoaesthesia | 14 | 14 |
| Hypoaesthesia oral | 4 | 4 |
| Hypoglycaemia | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hypotension | 1 | 1 |
| Immunisation reaction | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Increased upper airway secretion | 1 | 1 |
| Influenza like illness | 2 | 2 |
| Injected limb mobility decreased | | 1 |
| Insomnia | 1 | 1 |
| Joint swelling | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Lip swelling | 1 | 1 |
| Lymphadenopathy | 2 | 2 |
| Lymph node pain | 3 | 3 |
| Malaise | 4 | 5 |
| Memory impairment | 1 | 2 |
| Migraine | | 2 |
| Muscle spasms | 1 | 1 |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal stiffness | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 12 | 12 |
| | | 1 | 1 |
| 2 | 2 | | |
| 5 | 5 | 9 | 9 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 2 | 2 | 1 | 1 |
| 3 | 4 | 1 | 1 |
| 1 | 1 | | 1 |
| | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Myalgia | 19 | 23 |
| Nasal congestion | 3 | 3 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 16 | 19 |
| Neck pain | | 1 |
| Nightmare | 1 | 1 |
| Nodule | 1 | 1 |
| Obstructive airways disorder | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Off label use | 1 | 1 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal pain | 6 | 7 |
| Oropharyngeal spasm | | 1 |
| Overdose | 1 | 1 |
| Pain | 6 | 8 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 14 | 18 |
| Pallor | 1 | 1 |
| Palpitations | 6 | 7 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 10 | 12 |
| Paraesthesia oral | 4 | 5 |
| Parosmia | 1 | 1 |
| Peripheral coldness | | 1 |
| Pharyngeal erythema | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 2 |
| Pharyngeal swelling | 1 | 2 |
| Pleural effusion | 1 | 1 |
| Pleurisy | 1 | 1 |
| Poor quality product administered | | 2 |
| Post viral fatigue syndrome | | 1 |
| Presyncope | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 10 | 13 | 9 | 10 |
| | | 3 | 3 |
| | | 1 | 1 |
| 9 | 12 | 7 | 7 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 5 | 6 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 3 | 4 | 3 | 4 |
| 1 | 1 | | |
| 12 | 16 | 2 | 2 |
| | | 1 | 1 |
| 1 | 2 | 5 | 5 |
| | | 1 | 1 |
| 2 | 3 | 8 | 9 |
| 1 | 2 | 3 | 3 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| | 1 | | |
| | | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Product colour issue | | 2 |
| Productive cough | | 1 |
| Product preparation issue | 3 | 3 |
| Product use issue | 1 | 1 |
| Pruritus | 7 | 7 |
| Psoriasis | 1 | 1 |
| Pulse pressure decreased | 1 | 1 |
| Pyrexia | 28 | 35 |
| Rash | 6 | 6 |
| Rash erythematous | 3 | 3 |
| Rash pruritic | 1 | 1 |
| Respiratory distress | 3 | 3 |
| Rhinorrhoea | 4 | 4 |
| Sensation of foreign body | | 1 |
| Sensory disturbance | 1 | 1 |
| Sinus disorder | 1 | 1 |
| Sinus tachycardia | 1 | 1 |
| Skin burning sensation | 1 | 1 |
| Skin warm | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Sleep paralysis | 1 | 1 |
| Somnolence | 2 | 2 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling | 1 | 1 |
| Swelling face | 2 | 2 |
| Swollen tongue | 4 | 4 |
| Syncope | 3 | 3 |
| Tachycardia | 1 | 1 |
| Throat irritation | 1 | 1 |
| Throat tightness | 1 | 2 |
| Tinnitus | 1 | 1 |
| Tongue discomfort | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| | | | 1 |
| 3 | 3 | | |
| 1 | 1 | | |
| 3 | 3 | 4 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| 20 | 25 | 8 | 10 |
| 3 | 3 | 3 | 3 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| | | 3 | 3 |
| 4 | 4 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 4 | 4 |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 3 | 1 | 1 | 2 | 2 |
| Underdose | 2 | 2 | 2 | 2 | | |
| Upper respiratory tract congestion | | 1 | | 1 | | |
| Upper respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Urticaria | 7 | 7 | 4 | 4 | 3 | 3 |
| Vaccination site erythema | 8 | 8 | 6 | 6 | 2 | 2 |
| Vaccination site pain | 38 | 42 | 35 | 39 | 3 | 3 |
| Vaccination site pruritus | 4 | 4 | 3 | 3 | 1 | 1 |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 12 | 13 | 8 | 9 | 4 | 4 |
| Vaccination site warmth | 2 | 2 | 2 | 2 | | |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vertigo positional | | 1 | | 1 | | |
| Visual field defect | 2 | 2 | | | 2 | 2 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 3 | 3 | 2 | 2 | 1 | 1 |
| | 566 | 645 | 294 | 357 | 272 | 288 |

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 * AE=Adverse Event
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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 5 | 6 | 5 | 6 | | |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 2 | 2 | | | 2 | 2 |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anxiety | 2 | 2 | 2 | 2 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 8 | 9 | 6 | 7 | 2 | 2 |
| Asthenia | 2 | 3 | 2 | 3 | | |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blindness transient | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | | 1 | | | | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 15 | 18 | 12 | 14 | 3 | 4 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Constipation | 1 | 1 | 1 | 1 | | |
| Cough | 4 | 4 | 3 | 3 | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 2 | 2 | | | 2 | 2 |
| Dermatitis | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 7 | 9 | 7 | 9 | | |
| Discomfort | 2 | 2 | 2 | 2 | | |
| Dizziness | 5 | 6 | 1 | 2 | 4 | 4 |
| Dysgeusia | 3 | 3 | 1 | 1 | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dysphonia | 1 | 1 |
| Dyspnoea | 6 | 6 |
| Encephalitis | 1 | 1 |
| Encephalopathy | 1 | 1 |
| Epilepsy | 2 | 2 |
| Epistaxis | 1 | 1 |
| Erysipelas | | 1 |
| Erythema | 8 | 8 |
| Facial paralysis | | 1 |
| Facial paresis | | 1 |
| Fatigue | 19 | 20 |
| Feeling abnormal | 1 | 2 |
| Feeling cold | 2 | 2 |
| Feeling hot | 6 | 6 |
| Flatulence | 1 | 1 |
| Flushing | 1 | 1 |
| Formication | | 1 |
| General physical health deterioration | | 1 |
| Hallucination, visual | | 1 |
| Headache | 30 | 33 |
| Heart rate increased | 2 | 3 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 6 | 6 |
| Hypertension | 1 | 1 |
| Hypoaesthesia | 6 | 6 |
| Hypoaesthesia oral | 2 | 2 |
| Jaw disorder | 1 | 1 |
| Joint range of motion decreased | | 1 |
| Lip swelling | 3 | 4 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Lymph node pain | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | | 1 |
| 5 | 5 | 3 | 3 |
| | | | 1 |
| | | | 1 |
| 15 | 16 | 4 | 4 |
| | 1 | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | 5 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| 24 | 27 | 6 | 6 |
| 2 | 2 | | 1 |
| 1 | 1 | | |
| 3 | 3 | 3 | 3 |
| 1 | 1 | | |
| 4 | 4 | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | 2 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Malaise | 12 | 12 |
| Memory impairment | 1 | 1 |
| Meningitis herpes | 1 | 1 |
| Mental fatigue | 1 | 1 |
| Migraine | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Muscle spasms | 2 | 2 |
| Muscular weakness | | 1 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 13 | 15 |
| Myocarditis | 1 | 1 |
| Nausea | 9 | 12 |
| Neck pain | 2 | 2 |
| Oral herpes | 1 | 1 |
| Oral pruritus | 4 | 5 |
| Oropharyngeal pain | 3 | 4 |
| Pain | 7 | 7 |
| Pain in extremity | 10 | 11 |
| Pain in jaw | 1 | 1 |
| Pain of skin | 1 | 1 |
| Palpitations | 2 | 3 |
| Paraesthesia | 6 | 6 |
| Paraesthesia ear | 1 | 1 |
| Paraesthesia oral | 1 | 1 |
| Periorbital swelling | 2 | 2 |
| Peripheral coldness | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal erythema | 1 | 1 |
| Pharyngeal hypoaesthesia | 1 | 1 |
| Pneumonia | | 1 |
| Presyncope | 1 | 1 |
| Pruritus | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 8 | 8 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | | |
| 2 | 2 | | |
| 10 | 12 | 3 | 3 |
| | | 1 | 1 |
| 7 | 9 | 2 | 3 |
| 2 | 2 | | |
| 1 | 1 | | |
| 3 | 3 | 1 | 2 |
| 3 | 3 | | 1 |
| 3 | 3 | 4 | 4 |
| 7 | 8 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | 2 | 2 |
| 2 | 2 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 3 | 3 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Pyrexia | 26 | 29 |
| Rash macular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Reading disorder | 1 | 1 |
| Renal pain | 2 | 2 |
| Respiratory distress | | 1 |
| Rhinalgia | 1 | 1 |
| Rhinorrhoea | 4 | 4 |
| Seizure | 1 | 1 |
| Seizure like phenomena | 1 | 1 |
| Sensory disturbance | 1 | 1 |
| Sinus congestion | 1 | 1 |
| Skin reaction | 1 | 1 |
| Sleep talking | | 1 |
| Sneezing | 1 | 1 |
| Stress | 1 | 1 |
| Swelling face | 2 | 3 |
| Swollen tongue | 2 | 2 |
| Syncope | 1 | 1 |
| Tachycardia | 1 | 2 |
| Throat irritation | 3 | 4 |
| Throat tightness | 1 | 1 |
| Tongue pruritus | 1 | 2 |
| Upper respiratory tract infection | | 1 |
| Urticaria | 4 | 4 |
| Vaccination site erythema | 3 | 5 |
| Vaccination site induration | 1 | 1 |
| Vaccination site movement impairment | 2 | 2 |
| Vaccination site pain | 20 | 23 |
| Vaccination site pruritus | | 1 |
| Vaccination site reaction | 1 | 1 |
| Vaccination site swelling | 6 | 9 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 21 | 23 | 5 | 6 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 4 | 4 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| 1 | 1 | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | | 1 |
| 3 | 3 | 1 | 1 |
| 3 | 4 | | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| 17 | 19 | 3 | 4 |
| | 1 | | |
| 1 | 1 | | |
| 5 | 7 | 1 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site warmth | 1 | 3 | 1 | 2 | | 1 |
| Vision blurred | 2 | 2 | 1 | 1 | 1 | 1 |
| Vomiting | | 1 | | 1 | | |
| | 374 | 431 | 238 | 271 | 136 | 160 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal behaviour | | 1 | | 1 | | |
| Acute kidney injury | | 1 | | | | 1 |
| Acute left ventricular failure | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | | 1 | | | | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anxiety | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Arthralgia | | 1 | | | | 1 |
| Ascites | | 1 | | | | 1 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Autonomic nervous system imbalance | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 1 | 1 | | | 1 | 1 |
| Blood pressure abnormal | | 1 | | | | 1 |
| Blood pressure fluctuation | | 1 | | | | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 2 | 2 | | | 2 | 2 |
| Cardiac failure | 2 | 2 | | | 2 | 2 |
| Cardiac failure acute | 1 | 2 | | | 1 | 2 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Chronic obstructive pulmonary disease | 2 | 2 | | | 2 | 2 |
| Confusional state | 2 | 2 | | | 2 | 2 |
| Cough | 1 | 1 | 1 | 1 | | |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | 8 | 8 | | | 8 | 8 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Deep vein thrombosis | 1 | 1 |
| Dehydration | 1 | 2 |
| Depressed level of consciousness | 3 | 3 |
| Dermatitis | | 1 |
| Diarrhoea | 1 | 1 |
| Discomfort | 1 | 1 |
| Dizziness | 3 | 3 |
| Dysphagia | 2 | 3 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 6 | 9 |
| Dysstasia | 1 | 1 |
| Erythema | 2 | 2 |
| Fall | 1 | 1 |
| Fatigue | 6 | 7 |
| Feeling cold | 1 | 1 |
| Fibromyalgia | | 1 |
| Fluid intake reduced | 1 | 1 |
| General physical health deterioration | 1 | 2 |
| Goitre | | 1 |
| Haematemesis | 1 | 1 |
| Haematoma | 1 | 1 |
| Haemoglobin decreased | 1 | 1 |
| Head injury | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Hiccups | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 2 | 2 |
| Hypertension | | 1 |
| Hypoaesthesia | | 1 |
| Hypokinesia | 1 | 1 |
| Hypotension | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 3 | 3 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 2 | 3 | | |
| 1 | 1 | | |
| | | 6 | 9 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 5 | 5 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Infection | 1 | 3 | | | 1 | 3 |
| Infrequent bowel movements | 1 | 1 | 1 | 1 | | |
| Insomnia | | 1 | | 1 | | |
| Intestinal haemorrhage | | 1 | | | | 1 |
| Intestinal ischaemia | | 1 | | | | 1 |
| Lactic acidosis | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | | | 1 | 1 |
| Lip pruritus | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 2 | | | 2 | 2 |
| Muscle tone disorder | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | | 1 | | | | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Myocardial ischaemia | | 1 | | | | 1 |
| Nail discolouration | 1 | 1 | | | 1 | 1 |
| Nausea | 4 | 5 | 2 | 3 | 2 | 2 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Oral discomfort | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Periorbital oedema | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pharyngitis | | 1 | | 1 | | |
| Pneumonia | | 1 | | | | 1 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Pruritus | 2 | 2 | | | 2 | 2 |
| Pulmonary artery thrombosis | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pulmonary oedema | 2 | 3 | | | 2 | 3 |

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Age Range

65 - 79 years

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|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|-----|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Pulse abnormal | | 1 | | | | | 1 |
| Pyrexia | 7 | 10 | 3 | 5 | 4 | | 5 |
| Rash | 1 | 1 | 1 | 1 | | | |
| Renal failure | | 1 | | | | | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | | 1 |
| Respiratory distress | 1 | 1 | | | 1 | | 1 |
| Respiratory rate increased | | 1 | | | | | 1 |
| Restless legs syndrome | 1 | 1 | | | 1 | | 1 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | | |
| Seizure | 1 | 1 | | | 1 | | 1 |
| Sepsis | 1 | 1 | | | 1 | | 1 |
| Skin ulcer | | 1 | | | | | 1 |
| Somnolence | 1 | 1 | | | 1 | | 1 |
| Swelling face | 1 | 1 | | | 1 | | 1 |
| Thrombosis | 1 | 1 | | | 1 | | 1 |
| Tongue discomfort | 1 | 1 | | | 1 | | 1 |
| Tongue pruritus | 1 | 1 | | | 1 | | 1 |
| Underdose | | 1 | | 1 | | | |
| Urinary incontinence | 1 | 1 | | | 1 | | 1 |
| Urticaria | 1 | 1 | | | 1 | | 1 |
| Vaccination site discomfort | 1 | 1 | | | 1 | | 1 |
| Vaccination site erythema | 3 | 3 | | | 3 | | 3 |
| Vaccination site pain | 1 | 1 | 1 | 1 | | | |
| Vaccination site rash | 1 | 1 | | | 1 | | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | | |
| Vomiting | 2 | 3 | 1 | 2 | 1 | | 1 |
| Wheezing | 2 | 2 | | | 2 | | 2 |
| | 143 | 185 | 25 | 36 | 118 | | 149 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abnormal behaviour | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anxiety | 2 | 3 | | | 2 | 3 |
| Apnoea | | 1 | | | | 1 |
| Arteriosclerosis | | 1 | | | | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Asthenia | 3 | 3 | 1 | 1 | 2 | 2 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 2 | 2 | | | 2 | 2 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 4 | 5 | 1 | 1 | 3 | 4 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature decreased | 2 | 2 | | | 2 | 2 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bone disorder | 1 | 1 | 1 | 1 | | |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| Bundle branch block left | 1 | 1 | | | 1 | 1 |
| Cachexia | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 1 | 4 | | | 1 | 4 |
| Cardiac disorder | | 1 | | | | 1 |
| Cardiac failure | 4 | 5 | | | 4 | 5 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cerebral infarction | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 4 | 5 | | | 4 | 5 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # | Cumulative Total # |
|---------------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Chest discomfort | 1 | 1 |
| Chest pain | 3 | 3 |
| Chills | 4 | 4 |
| Chronic obstructive pulmonary disease | 2 | 3 |
| Chronic respiratory failure | | 1 |
| Circulatory collapse | 1 | 3 |
| Condition aggravated | 3 | 4 |
| Confusional state | 5 | 6 |
| Cough | 4 | 6 |
| COVID-19 | 4 | 5 |
| C-reactive protein increased | 2 | 2 |
| Crepitations | 1 | 2 |
| Death | 11 | 17 |
| Decreased appetite | 9 | 9 |
| Decubitus ulcer | | 1 |
| Deep vein thrombosis | 1 | 1 |
| Dehydration | 1 | 1 |
| Delusional disorder, unspecified type | 1 | 1 |
| Dementia | 1 | 1 |
| Depressed level of consciousness | 6 | 7 |
| Diarrhoea | 6 | 8 |
| Discomfort | 1 | 1 |
| Disorganised speech | 1 | 1 |
| Disorientation | 1 | 1 |
| Dissociation | 1 | 1 |
| Diverticulitis | 1 | 1 |
| Dizziness | 4 | 5 |
| Drug eruption | 1 | 1 |
| Drug ineffective | 4 | 5 |
| Dry mouth | 1 | 1 |
| Dysarthria | 1 | 1 |
| Dysphagia | 3 | 3 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 4 | 4 |
| | | 2 | 3 |
| | | | 1 |
| | | 1 | 3 |
| | | 3 | 4 |
| | | 5 | 6 |
| 1 | 1 | 3 | 5 |
| | | 4 | 5 |
| 2 | 2 | | |
| | 1 | 1 | 1 |
| | | 11 | 17 |
| 4 | 4 | 5 | 5 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 6 | 7 |
| 1 | 2 | 5 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 3 | 3 |
| 1 | 1 | | |
| | | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dyspnoea | 17 | 21 |
| Dysstasia | | 1 |
| Erysipelas | 1 | 1 |
| Erythema | 2 | 3 |
| Escherichia infection | 1 | 1 |
| Escherichia sepsis | | 1 |
| Eye disorder | 2 | 2 |
| Facial paralysis | 2 | 2 |
| Facial paresis | 3 | 3 |
| Fatigue | 19 | 21 |
| Feeling hot | 1 | 1 |
| Food refusal | 1 | 1 |
| Gait disturbance | 1 | 1 |
| General physical health deterioration | 16 | 19 |
| Haematoma | 1 | 1 |
| Haemoptysis | 1 | 1 |
| Hallucination | 2 | 2 |
| Headache | 3 | 3 |
| Head injury | 1 | 1 |
| Heart rate decreased | 2 | 2 |
| Heart rate increased | 2 | 2 |
| Heart rate irregular | 1 | 1 |
| Hemiparesis | 4 | 4 |
| Herpes zoster | 3 | 3 |
| Hyperglycaemia | 1 | 1 |
| Hypernatraemia | 1 | 1 |
| Hypersensitivity | 5 | 6 |
| Hypertension | 1 | 1 |
| Hypoaesthesia | | 1 |
| Hypoaesthesia oral | 1 | 2 |
| Hypoglycaemia | 1 | 1 |
| Hypokalaemia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | 15 | 19 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 3 | 3 |
| 6 | 7 | 13 | 14 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 4 | 13 | 15 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 4 | 4 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 6 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Hypotension | 6 | 8 | 1 | 1 | 5 | 7 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Incontinence | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Infection | 3 | 4 | | | 3 | 4 |
| Ischaemic stroke | | 2 | | | | 2 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 4 | 5 | | | 4 | 5 |
| Lymphadenopathy | | 1 | | | | 1 |
| Malaise | 3 | 3 | | | 3 | 3 |
| Myalgia | 2 | 2 | | | 2 | 2 |
| Myelosuppression | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 3 | 4 | | | 3 | 4 |
| Myocardial rupture | | 1 | | | | 1 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 2 | 2 | | | 2 | 2 |
| Nausea | 9 | 9 | 2 | 2 | 7 | 7 |
| Neoplasm progression | | 1 | | | | 1 |
| Obstructive airways disorder | 1 | 1 | | | 1 | 1 |
| Oxygen saturation abnormal | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 6 | 10 | | 2 | 6 | 8 |
| Pain | 4 | 5 | 1 | 1 | 3 | 4 |
| Pain in extremity | 2 | 2 | | | 2 | 2 |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Paraesthesia | 2 | 2 | | | 2 | 2 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Pericardial haemorrhage | | 1 | | | | 1 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 1 | 1 | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 3 | 3 | | | 3 | 3 |
| Pneumonia bacterial | | 1 | | | | 1 |
| Pneumonia pneumococcal | 1 | 1 | | | 1 | 1 |
| Pneumonia streptococcal | 1 | 1 | | | 1 | 1 |
| Postoperative wound complication | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 2 | | | 1 | 2 |
| Pruritus | 1 | 2 | | | 1 | 2 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pulmonary oedema | 2 | 4 | | | 2 | 4 |
| Pulse abnormal | 2 | 2 | 2 | 2 | | |
| Pyrexia | 32 | 33 | 11 | 11 | 21 | 22 |
| Rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 3 | 4 | | | 3 | 4 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory rate increased | 4 | 4 | | | 4 | 4 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sepsis | 4 | 5 | | | 4 | 5 |
| Skin discolouration | 1 | 1 | | | 1 | 1 |
| Slow speech | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | | | 2 | 2 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 1 | | | 1 | 1 |
| Streptococcal bacteraemia | 1 | 1 | | | 1 | 1 |
| Sudden death | | 2 | | | | 2 |
| Swelling | 1 | 2 | | 1 | 1 | 1 |
| Swelling face | 1 | 2 | | 1 | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Systemic inflammatory response syndrome | | 1 | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 2 | | 1 | 1 | 1 |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Toxic epidermal necrolysis | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | 2 | 2 | | | 2 | 2 |
| Upper gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 2 | | | 1 | 2 |
| Urine output decreased | 1 | 1 | | | 1 | 1 |
| Urosepsis | 1 | 3 | | | 1 | 3 |
| Urticaria | 4 | 5 | 1 | 2 | 3 | 3 |
| Vaccination site erythema | 6 | 6 | 4 | 4 | 2 | 2 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site pruritus | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 2 | 2 | | | 2 | 2 |
| Vaccination site swelling | 3 | 3 | 1 | 1 | 2 | 2 |
| Vascular dementia | 1 | 1 | | | 1 | 1 |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vomiting | 19 | 19 | 3 | 3 | 16 | 16 |
| Wheezing | 2 | 3 | | 1 | 2 | 2 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| White blood cells urine positive | 1 | 1 | 1 | 1 | | |
| | 417 | 501 | 68 | 86 | 349 | 415 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Circumstance or information capable of leading to medication error | | 29 | | 29 | | |
| COVID-19 | 19 | 19 | 18 | 18 | 1 | 1 |
| Death | 2 | 2 | | | 2 | 2 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 2 | 2 | 2 | | |
| Incorrect route of product administration | 3 | 3 | 3 | 3 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 3 | 1 | 3 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Neurological symptom | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 2 | 7 | 2 | 7 | | |
| Paraesthesia | | 1 | | 1 | | |
| Poor quality product administered | | 33 | | 33 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product colour issue | | 34 | | 34 | | |
| Pyrexia | 1 | 3 | 1 | 3 | | |
| Throat irritation | 1 | 1 | 1 | 1 | | |
| Underdose | | 1 | | 1 | | |
| Vaccination site hypoesthesia | | 1 | | 1 | | |
| Vaccination site joint movement impairment | 3 | 3 | 3 | 3 | | |
| Vaccination site pain | 4 | 4 | 4 | 4 | | |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |

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Age Range

Unknown

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 46 | 155 | 6 | 6 |

52

161

46

155

6

6

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Country Where Event Occurred
SWITZERLAND

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Gait disturbance | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Asthma | 2 | 2 | | | 2 | 2 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Drug interaction | 1 | 1 | 1 | 1 | | |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 26 | 26 | 6 | 6 | 20 | 20 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Asthenia | | 1 | | 1 | | |
| Blindness transient | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | 1 | 1 | 1 | 1 |
| Dyspnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Fatigue | | 1 | | 1 | | |
| Feeling cold | | 1 | | 1 | | |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Myalgia | | 1 | | | | 1 |
| Nausea | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Platelet count increased | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | | 1 | | | | 1 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Urticaria | | 1 | | | | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | | 1 | | 1 | | |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vomiting | 2 | 2 | | | 2 | 2 |
| | 25 | 32 | 13 | 17 | 12 | 15 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Agitation | 1 | 1 | | | 1 | 1 |
| Aphasia | 2 | 2 | | | 2 | 2 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Central nervous system lesion | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Dizziness | | 1 | | 1 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysgeusia | | 1 | | 1 | | |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | | | 1 | 1 |
| Hypertensive emergency | 1 | 1 | | | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | | | 1 | 1 |
| Malaise | 1 | 1 | | | 1 | 1 |
| Nausea | | 1 | | 1 | | |
| Pleocytosis | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Somnolence | 2 | 2 | | | 2 | 2 |
| Urinary incontinence | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | | 1 | | 1 | | |
| | 26 | 30 | 6 | 10 | 20 | 20 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 2 | | 1 | | 1 |
| Acute myocardial infarction | | 1 | | | | 1 |
| Acute pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Anal haemorrhage | | 1 | | 1 | | |
| Anaphylactic reaction | | 1 | | | | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Aphasia | | 1 | | | | 1 |
| Arteriosclerosis | | 1 | | | | 1 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Atrophy | | 1 | | | | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure decreased | | 1 | | | | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | | 1 | | | | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Chronic obstructive pulmonary disease | | 1 | | | | 1 |
| Coma | 1 | 2 | | | 1 | 2 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | | 1 | | | | 1 |
| Death | 1 | 3 | | | 1 | 3 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Embolism | | 1 | | | | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Fall | | 1 | | | | 1 |
| Fatigue | 1 | 1 | | | 1 | 1 |
| Gastric disorder | | 1 | | | | 1 |
| General physical health deterioration | 1 | 2 | | | 1 | 2 |
| Haemorrhagic stroke | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Heart rate decreased | | 1 | | | | 1 |
| Hemiplegia | | 1 | | | | 1 |
| Hepatic cirrhosis | | 1 | | | | 1 |
| Hyperthermia | 1 | 1 | 1 | 1 | | |
| Malaise | | 2 | | 1 | | 1 |
| Muscle disorder | 1 | 1 | | | 1 | 1 |
| Nausea | | 1 | | | | 1 |
| Oxygen saturation decreased | 1 | 2 | | | 1 | 2 |
| Pain | 1 | 1 | 1 | 1 | | |
| Peripheral vascular disorder | 1 | 1 | | | 1 | 1 |
| Pneumonia | | 1 | | | | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 2 | 2 | | | 2 | 2 |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory failure | | 1 | | | | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Somnolence | | 2 | | | | 2 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Swollen tongue | | 1 | | | | 1 |
| Tachycardia | | 1 | | | | 1 |
| Tachypnoea | | 1 | | | | 1 |
| Type I hypersensitivity | | 1 | | | | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| | 33 | 70 | 9 | 14 | 24 | 56 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chills | | 1 | | 1 | | |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Fatigue | | 1 | | 1 | | |
| Pain in extremity | | 1 | | 1 | | |
| SARS-CoV-2 test positive | 2 | 2 | | | 2 | 2 |
| Underdose | 1 | 1 | 1 | 1 | | |
| Wrong product administered | 1 | 1 | 1 | 1 | | |
| | 6 | 9 | 2 | 5 | 4 | 4 |

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Country Where Event Occurred

TURKS AND CAICOS ISLANDS

Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nodule | 1 | 1 | 1 | 1 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Tonic convulsion | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 3 | 3 | 2 | 2 |

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Country Where Event Occurred
UNITED ARAB EMIRATES

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Swelling | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 2 | 2 | 3 | 3 |

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Dizziness | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Nausea | 2 | 2 | 2 | 2 |
| Vomiting | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Chest pain | | 1 | | | | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Depressed level of consciousness | | 1 | | | | 1 |
| Depressed mood | | 1 | | | | 1 |
| Dizziness | | 1 | | | | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Headache | | 1 | | | | 1 |
| Hypertension | | 1 | | | | 1 |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Nausea | 2 | 3 | 2 | 2 | | 1 |
| Neurotoxicity | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 2 | 2 | 2 | | |
| Rash | 1 | 1 | 1 | 1 | | |
| Skin irritation | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 17 | 24 | 16 | 16 | 1 | 8 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Back pain | 1 | 1 | 1 | 1 |
| Diarrhoea | | 1 | | 1 |
| Fatigue | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| | 1 | 4 | 1 | 4 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| COVID-19 | | 1 | | | | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Rectal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | | 2 | | 2 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| | 5 | 10 | 3 | 6 | 2 | 4 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | | 1 | | 1 | | |
| COVID-19 | 3 | 4 | | | 3 | 4 |
| Drug ineffective | 3 | 4 | | | 3 | 4 |
| Erectile dysfunction | | 1 | | | | 1 |
| Facial paralysis | | 1 | | | | 1 |
| Headache | 1 | 2 | 1 | 2 | | |
| Hypertension | | 1 | | 1 | | |
| Hypoacusis | | 1 | | | | 1 |
| Hypoaesthesia | | 1 | | | | 1 |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Off label use | | 1 | | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Product use issue | | 1 | | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Sciatica | 1 | 1 | 1 | 1 | | |
| | 11 | 22 | 5 | 10 | 6 | 12 |

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Country Where Event Occurred
UNITED KINGDOM

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Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 2 | | 2 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Angioedema | | 1 | | | | 1 |
| Arthralgia | 3 | 7 | | | 3 | 7 |
| Asthenia | 3 | 3 | | | 3 | 3 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 2 | 2 | | |
| Balance disorder | | 1 | | 1 | | |
| Blepharospasm | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | | 1 | | | | 1 |
| Blood urine present | | 1 | | 1 | | |
| Body temperature increased | | 2 | | 1 | | 1 |
| Cellulitis | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 8 | | 2 | 4 | 6 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | | 1 | | | | 1 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Death neonatal | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 3 | | 1 | 1 | 2 |
| Diarrhoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Dizziness | 4 | 5 | | 1 | 4 | 4 |
| Dizziness exertional | | 1 | | 1 | | |
| Dizziness postural | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dyspnoea | | 1 | | | | 1 |
| Erythema | | 1 | | | | 1 |
| Exertional headache | | 1 | | 1 | | |
| Exposure via breast milk | 5 | 7 | 4 | 6 | 1 | 1 |
| External ear pain | 1 | 1 | | | 1 | 1 |

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Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Facial paralysis | 3 | 3 |
| Fatigue | 8 | 16 |
| Feeling abnormal | 1 | 3 |
| Feeling hot | 1 | 1 |
| Feeling of body temperature change | | 1 |
| Flushing | | 1 |
| Gait disturbance | | 1 |
| Gastrointestinal pain | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Headache | 16 | 20 |
| Head discomfort | 1 | 1 |
| Hyperhidrosis | 1 | 2 |
| Hypertension | 1 | 1 |
| Hypokalaemic syndrome | 1 | 1 |
| Hypotension | 1 | 1 |
| Illness | 4 | 5 |
| Infantile vomiting | 1 | 1 |
| Influenza | 1 | 1 |
| Insomnia | 1 | 1 |
| International normalised ratio decreased | 1 | 1 |
| Lethargy | 1 | 2 |
| Limb discomfort | 1 | 1 |
| Lymphadenopathy | 4 | 5 |
| Malaise | 2 | 5 |
| Mastitis | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 1 |
| Mobility decreased | 2 | 3 |
| Muscle fatigue | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Myalgia | 2 | 5 |
| Myoclonus | 1 | 1 |
| Nausea | 8 | 12 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 3 |
| 1 | 4 | 7 | 12 |
| | 2 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 5 | 13 | 15 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| | | 4 | 5 |
| 1 | 3 | 1 | 2 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 3 |
| | | 1 | 1 |
| | 3 | 8 | 9 |

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Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Off label use | 19 | 21 | 19 | 21 | | |
| Oropharyngeal pain | | 1 | | | | 1 |
| Pain | 2 | 5 | 1 | 3 | 1 | 2 |
| Pain in extremity | 7 | 8 | 2 | 2 | 5 | 6 |
| Pain in jaw | 1 | 1 | | | 1 | 1 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 2 | 2 | | | 2 | 2 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Poor quality sleep | 1 | 1 | | | 1 | 1 |
| Post laminectomy syndrome | 1 | 1 | | | 1 | 1 |
| Premature baby | 1 | 1 | | | 1 | 1 |
| Product administered at inappropriate site | 1 | 1 | 1 | 1 | | |
| Product administered to patient of inappropriate age | 33 | 43 | 30 | 39 | 3 | 4 |
| Product use issue | 8 | 9 | 8 | 9 | | |
| Pruritus | 1 | 3 | | | 1 | 3 |
| Pyrexia | 9 | 16 | 2 | 6 | 7 | 10 |
| Q fever | | 1 | | | | 1 |
| Rash | | 1 | | | | 1 |
| Rash papular | | 1 | | | | 1 |
| Rash pruritic | | 2 | | | | 2 |
| Renal failure | | 1 | | | | 1 |
| Respiratory rate decreased | | 1 | | | | 1 |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| Skin irritation | 1 | 1 | | | 1 | 1 |
| Sleep disorder | | 1 | | 1 | | |
| Spinal pain | | 1 | | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |

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Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Suspected COVID-19 | 1 | 2 | 1 | 1 | | 1 |
| Swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 3 | | | 1 | 3 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Tongue ulceration | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Urticaria | | 1 | | | | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 4 | 8 | 1 | 4 | 3 | 4 |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 2 | | | 1 | 2 |
| Vulvovaginal candidiasis | 1 | 1 | | | 1 | 1 |
| Wheezing | 2 | 2 | | | 2 | 2 |
| | 225 | 329 | 88 | 142 | 137 | 187 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 4 | 6 | | | | | 4 | 6 |
| Abdominal distension | 1 | 4 | | | | 3 | 1 | 1 |
| Abdominal pain | 16 | 25 | | | 2 | 5 | 14 | 20 |
| Abdominal pain lower | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Abdominal pain upper | 19 | 38 | | | 2 | 11 | 17 | 27 |
| Abdominal tenderness | | 1 | | | | | | 1 |
| Abnormal dreams | | 4 | | | | 3 | | 1 |
| Abnormal sensation in eye | 1 | 1 | | | | | 1 | 1 |
| Abortion spontaneous | 1 | 2 | | | | | 1 | 2 |
| Acne | 1 | 1 | | | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | | | 1 | 1 |
| Administration site joint movement impairment | 1 | 1 | | | | | 1 | 1 |
| Ageusia | 4 | 10 | | | | 2 | 4 | 8 |
| Agitation | 3 | 4 | | | | | 3 | 4 |
| Alanine aminotransferase increased | | 1 | | | | | | 1 |
| Allergic reaction to excipient | 2 | 2 | | | | | 2 | 2 |
| Allergy to vaccine | 1 | 2 | | | | | 1 | 2 |
| Allodynia | | 1 | | | | | | 1 |
| Alopecia | 1 | 1 | | | | | 1 | 1 |
| Amnesia | 1 | 1 | | | | | 1 | 1 |
| Anal haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Anal incontinence | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 11 | 22 | | | | | 11 | 22 |
| Anaphylactoid reaction | 1 | 2 | | | | | 1 | 2 |
| Angioedema | 7 | 9 | | | | | 7 | 9 |
| Ankylosing spondylitis | 1 | 1 | | | | | 1 | 1 |
| Anosmia | 3 | 6 | | | | 2 | 3 | 4 |
| Anovulatory cycle | 1 | 1 | | | | | 1 | 1 |
| Anticholinergic syndrome | | 1 | | | | | | 1 |
| Anxiety | 8 | 13 | | | 3 | 7 | 5 | 6 |
| Aphasia | | 1 | | | | | | 1 |
| Aphonia | 1 | 1 | | | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Aphthous ulcer | 1 | 1 |
| Appendicitis | 1 | 1 |
| Arthralgia | 91 | 182 |
| Arthritis | | 1 |
| Aspartate aminotransferase increased | | 1 |
| Asthenia | 34 | 55 |
| Asthenopia | 3 | 3 |
| Asthma | 4 | 8 |
| Aura | | 2 |
| Autoimmune disorder | 1 | 1 |
| Axillary mass | 1 | 3 |
| Axillary pain | 12 | 28 |
| Bacille Calmette-Guerin scar reactivation | 1 | 1 |
| Back pain | 30 | 54 |
| Balance disorder | 1 | 2 |
| Behcet's syndrome | 1 | 1 |
| Binocular eye movement disorder | 1 | 1 |
| Blepharospasm | | 1 |
| Blindness | 1 | 1 |
| Blister | 1 | 1 |
| Blood glucose decreased | 1 | 1 |
| Blood glucose fluctuation | 2 | 2 |
| Blood glucose increased | 2 | 3 |
| Blood ketone body increased | 1 | 1 |
| Blood ketone body present | | 1 |
| Blood potassium decreased | 1 | 1 |
| Blood pressure decreased | 2 | 4 |
| Blood pressure increased | 2 | 2 |
| Blood pressure orthostatic decreased | | 1 |
| Blood test abnormal | | 1 |
| Blood testosterone increased | 1 | 1 |
| Blue toe syndrome | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 14 | 44 | 77 | 138 |
| | | | | | 1 |
| | | | | | 1 |
| | | 10 | 21 | 24 | 34 |
| | | | | 3 | 3 |
| | | 1 | 1 | 3 | 7 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | 2 | 9 | 10 | 19 |
| | | 1 | 1 | | |
| | | 2 | 11 | 28 | 43 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 2 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Body temperature abnormal | 1 | 2 |
| Body temperature decreased | 1 | 2 |
| Body temperature increased | 3 | 8 |
| Bone pain | 9 | 17 |
| Bradycardia | 1 | 3 |
| Bradykinesia | 1 | 1 |
| Bradyphrenia | 2 | 2 |
| Breast pain | 3 | 3 |
| Breast tenderness | 2 | 2 |
| Breath odour | 1 | 1 |
| Burning sensation | 3 | 7 |
| Bursitis | 1 | 1 |
| Candida infection | 1 | 1 |
| Cardiac arrest | 1 | 2 |
| Cardiac disorder | | 1 |
| Cardiac flutter | 2 | 2 |
| Cardiovascular disorder | 1 | 1 |
| Cellulitis | 3 | 5 |
| Cerebrovascular accident | 1 | 1 |
| Chest discomfort | 14 | 29 |
| Chest pain | 32 | 50 |
| Chills | 139 | 299 |
| Choking | 1 | 1 |
| Choking sensation | 1 | 1 |
| Chromaturia | | 1 |
| Circulatory collapse | 1 | 1 |
| Cluster headache | 3 | 4 |
| Cold sweat | 13 | 24 |
| Condition aggravated | 1 | 3 |
| Confusional state | 12 | 15 |
| Conjunctival haemorrhage | | 1 |
| Constipation | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | 2 | 3 | 6 |
| | | 3 | 7 | 6 | 10 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 2 | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | 3 | 7 | 11 | 22 |
| | | 4 | 8 | 28 | 42 |
| | | 19 | 83 | 120 | 216 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | 6 | 11 | 7 | 13 |
| | | | 1 | 1 | 2 |
| | | | | 12 | 15 |
| | | | | | 1 |
| | | | | 2 | 3 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Contusion | 3 | 8 |
| Coronavirus test positive | 1 | 1 |
| Cortisol decreased | | 1 |
| Costochondritis | 1 | 1 |
| Cough | 25 | 50 |
| COVID-19 | 18 | 27 |
| Crying | 2 | 3 |
| Cyanosis | 1 | 2 |
| Deafness | | 1 |
| Death | 1 | 1 |
| Decreased appetite | 26 | 39 |
| Dehydration | 1 | 6 |
| Delirium | 2 | 3 |
| Delusion | | 1 |
| Depressed mood | 3 | 3 |
| Dermatitis | 2 | 4 |
| Dermatitis allergic | 2 | 5 |
| Diabetes mellitus inadequate control | | 1 |
| Diabetic complication | | 1 |
| Diabetic ketoacidosis | | 1 |
| Diarrhoea | 53 | 78 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplopia | | 1 |
| Discoloured vomit | | 1 |
| Discomfort | 4 | 10 |
| Disease recurrence | 5 | 10 |
| Disorientation | 4 | 6 |
| Dissociative disorder | 1 | 1 |
| Disturbance in attention | 7 | 8 |
| Dizziness | 115 | 206 |
| Dizziness postural | 7 | 14 |
| Drug eruption | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 3 | 3 | 5 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 9 | 24 | 41 |
| | | 2 | 3 | 16 | 24 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 10 | 15 | 16 | 24 |
| | | | 1 | 1 | 5 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | 2 | 3 |
| | | | | 2 | 5 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 5 | 17 | 48 | 61 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 5 | 2 | 5 |
| | | | 1 | 5 | 9 |
| | | | | 4 | 6 |
| | | 1 | 1 | | |
| | | | 1 | 7 | 7 |
| | | 23 | 67 | 92 | 139 |
| | | 2 | 3 | 5 | 11 |
| | | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 27 | 49 |
| Dry eye | | 1 |
| Dry mouth | 7 | 11 |
| Dry skin | 3 | 3 |
| Dry throat | | 1 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 5 | 11 |
| Dyskinesia | 1 | 2 |
| Dysmenorrhoea | 3 | 3 |
| Dysphagia | 6 | 8 |
| Dysphonia | 2 | 4 |
| Dyspnoea | 46 | 81 |
| Dyspnoea at rest | 1 | 1 |
| Dyspnoea exertional | 1 | 3 |
| Dysstasia | 4 | 5 |
| Dystonia | | 1 |
| Ear discomfort | 1 | 2 |
| Ear infection | 1 | 1 |
| Ear pain | 8 | 14 |
| Ear pruritus | | 1 |
| Ear swelling | 1 | 1 |
| Eating disorder symptom | 1 | 1 |
| Eczema | 2 | 4 |
| Emotional disorder | 1 | 1 |
| Encephalitis | 1 | 1 |
| Enlarged uvula | 1 | 1 |
| Eosinophil count increased | 1 | 1 |
| Epilepsy | 2 | 2 |
| Epistaxis | 5 | 6 |
| Erectile dysfunction | 1 | 1 |
| Eructation | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 1 | 27 | 48 |
| | | | | | 1 |
| | | 3 | 6 | 4 | 5 |
| | | 1 | 1 | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 4 | 8 |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 2 | 5 | 6 |
| | | | | 2 | 4 |
| | | 4 | 9 | 42 | 72 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | 2 | 2 | 2 | 3 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 8 | 13 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 5 | 6 |
| | | | | 1 | 1 |
| | | | | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Erythema | 26 | 53 |
| Erythema multiforme | 4 | 4 |
| Exfoliative rash | 1 | 1 |
| Expired product administered | | 1 |
| Exposure during pregnancy | 2 | 3 |
| Exposure to SARS-CoV-2 | | 1 |
| Eye discharge | 1 | 1 |
| Eye disorder | 1 | 2 |
| Eye injury | 1 | 1 |
| Eye irritation | 2 | 5 |
| Eyelid function disorder | 1 | 1 |
| Eyelid pain | 1 | 1 |
| Eyelid rash | 1 | 1 |
| Eye pain | 14 | 30 |
| Eye pruritus | 3 | 5 |
| Eye swelling | 7 | 8 |
| Face injury | 1 | 1 |
| Facial pain | 2 | 5 |
| Facial paralysis | 7 | 10 |
| Facial paresis | | 1 |
| Facial spasm | 1 | 2 |
| Fall | 1 | 2 |
| Fatigue | 283 | 506 |
| Fear | 1 | 1 |
| Feeding disorder | 1 | 1 |
| Feeling abnormal | 16 | 23 |
| Feeling cold | 21 | 36 |
| Feeling drunk | 1 | 3 |
| Feeling hot | 20 | 40 |
| Feeling jittery | 1 | 2 |
| Feeling of body temperature change | 9 | 15 |
| Feeling of despair | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 20 | 21 | 33 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 3 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 7 | 12 | 23 |
| | | | 1 | 3 | 4 |
| | | 1 | 1 | 6 | 7 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 4 |
| | | | | 7 | 10 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| 1 | 1 | 51 | 148 | 232 | 358 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 4 | 14 | 19 |
| | | 5 | 14 | 16 | 22 |
| | | | | 1 | 3 |
| | | 7 | 19 | 13 | 21 |
| | | | 1 | 1 | 1 |
| | | 1 | 4 | 8 | 11 |
| | | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Flank pain | | 1 |
| Fluid intake reduced | | 1 |
| Flushing | 5 | 10 |
| Folliculitis | | 1 |
| Food refusal | 1 | 1 |
| Foreign body sensation in eyes | 1 | 1 |
| Formication | | 1 |
| Frequent bowel movements | 2 | 4 |
| Frustration tolerance decreased | | 1 |
| Gait disturbance | 4 | 5 |
| Gait inability | 3 | 5 |
| Gastric disorder | 1 | 1 |
| Gastritis | 2 | 2 |
| Gastroenteritis | | 1 |
| Gastroenteritis viral | | 1 |
| Gastrointestinal motility disorder | | 1 |
| Gastrointestinal pain | 1 | 1 |
| Gastrooesophageal reflux disease | | 2 |
| Generalised tonic-clonic seizure | | 1 |
| Genital pain | 2 | 2 |
| Gingival pain | 2 | 2 |
| Gingivitis | 1 | 1 |
| Glucose tolerance impaired | 1 | 1 |
| Groin pain | 3 | 4 |
| Haematemesis | 2 | 4 |
| Haematochezia | | 1 |
| Haematoma | | 1 |
| Haematuria | 3 | 3 |
| Haemoptysis | 2 | 2 |
| Haemorrhage | 2 | 2 |
| Haemorrhage subcutaneous | | 1 |
| Haemorrhoids | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 5 | 9 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 2 | 4 |
| | | | 1 | | |
| | | 1 | 2 | 3 | 3 |
| | | | 1 | 3 | 4 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | 3 | 3 |
| | | | | 2 | 4 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Hallucination | 5 | 10 |
| Hallucination, olfactory | | 1 |
| Hallucinations, mixed | 1 | 1 |
| Hallucination, tactile | | 1 |
| Hangover | 1 | 1 |
| Headache | 347 | 667 |
| Head discomfort | 2 | 4 |
| Head injury | 1 | 3 |
| Heart rate abnormal | | 1 |
| Heart rate increased | 10 | 19 |
| Heat stroke | | 1 |
| Hemiplegia | 1 | 1 |
| Hemiplegic migraine | 1 | 1 |
| Herpes zoster | 4 | 4 |
| Hormone level abnormal | 1 | 1 |
| Hot flush | 13 | 24 |
| Hunger | 2 | 3 |
| Hyperacusis | 1 | 1 |
| Hyperaesthesia | 3 | 6 |
| Hyperaesthesia teeth | 1 | 1 |
| Hyperglycaemia | | 1 |
| Hyperhidrosis | 34 | 62 |
| Hyperpyrexia | | 1 |
| Hypersensitivity | 11 | 21 |
| Hypersomnia | 4 | 5 |
| Hypertension | 5 | 10 |
| Hyperventilation | 1 | 1 |
| Hypoacusis | | 1 |
| Hypoaesthesia | 28 | 49 |
| Hypoaesthesia oral | 3 | 7 |
| Hypoglycaemia | 2 | 5 |
| Hypokinesia | 3 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 5 | 10 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 57 | 198 | 290 | 469 |
| | | 1 | 1 | 1 | 3 |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | 2 | 5 | 8 | 14 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 2 | 9 | 11 | 15 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 12 | 23 | 22 | 39 |
| | | | | | 1 |
| | | 1 | 4 | 10 | 17 |
| | | | | 4 | 5 |
| | | | 3 | 5 | 7 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 9 | 25 | 40 |
| | | 2 | 4 | 1 | 3 |
| | | | 1 | 2 | 4 |
| | | 2 | 2 | 1 | 2 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypopnoea | 3 | 4 |
| Hyporeflexia | | 1 |
| Hyposomnia | 1 | 1 |
| Hypotension | 2 | 5 |
| Hypothermia | | 1 |
| Idiopathic intracranial hypertension | | 1 |
| Illness | 30 | 41 |
| Immune-mediated adverse reaction | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Impaired work ability | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |
| Incontinence | 1 | 1 |
| Incorrect route of product administration | 3 | 8 |
| Induration | 1 | 1 |
| Infected skin ulcer | 1 | 1 |
| Infection | 1 | 2 |
| Infectious mononucleosis | 1 | 1 |
| Inflammation | 2 | 4 |
| Influenza | 17 | 28 |
| Influenza like illness | 24 | 51 |
| Initial insomnia | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 |
| Injection related reaction | 1 | 1 |
| Injection site erythema | | 1 |
| Injection site pain | 2 | 6 |
| Injection site rash | | 1 |
| Injection site swelling | | 1 |
| Injection site warmth | | 2 |
| Insomnia | 15 | 38 |
| Irregular breathing | 1 | 1 |
| Irritability | 4 | 5 |
| Irritable bowel syndrome | | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 4 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 5 | 29 | 36 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 8 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | 3 | 9 | 14 | 19 |
| | | 2 | 17 | 22 | 34 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 4 | 2 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | 2 | 13 | 13 | 25 |
| | | | | 1 | 1 |
| | | 2 | 3 | 2 | 2 |
| | | | 1 | | 2 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Joint dislocation | 1 | 1 |
| Joint range of motion decreased | 2 | 4 |
| Joint stiffness | 2 | 4 |
| Joint swelling | 3 | 5 |
| Labyrinthitis | 1 | 1 |
| Lacrimation increased | 2 | 5 |
| Lacunar infarction | | 1 |
| Laziness | 1 | 1 |
| Lethargy | 33 | 67 |
| Limb discomfort | 14 | 40 |
| Limb mass | 2 | 2 |
| Lip dry | 2 | 2 |
| Lip exfoliation | 1 | 1 |
| Lip swelling | 9 | 14 |
| Lip ulceration | 1 | 1 |
| Livedo reticularis | 1 | 1 |
| Localised infection | 1 | 1 |
| Local reaction | 2 | 3 |
| Loss of consciousness | 12 | 19 |
| Loss of personal independence in daily activities | 2 | 3 |
| Lower respiratory tract infection | 1 | 2 |
| Lymphadenitis | 2 | 3 |
| Lymphadenopathy | 75 | 139 |
| Lymphangitis | 1 | 1 |
| Lymph node pain | 10 | 25 |
| Lymphoedema | 2 | 3 |
| Lymphoma | 1 | 1 |
| Malaise | 70 | 135 |
| Mass | 2 | 2 |
| Maternal exposure during pregnancy | 2 | 4 |
| Melaena | 1 | 1 |
| Memory impairment | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 3 |
| | | | 1 | 2 | 3 |
| | | | 1 | 3 | 4 |
| | | | | 1 | 1 |
| | | 1 | 3 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 5 | 16 | 28 | 51 |
| | | 5 | 18 | 9 | 22 |
| | | 2 | 2 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 9 | 12 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | 12 | 19 |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 2 |
| | | 1 | 2 | 1 | 1 |
| | | 12 | 42 | 63 | 97 |
| | | | | 1 | 1 |
| | | | 11 | 10 | 14 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 8 | 40 | 62 | 95 |
| | | 2 | 2 | | |
| | | 1 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Menopausal symptoms | | 1 |
| Menorrhagia | 2 | 2 |
| Menstrual disorder | 1 | 1 |
| Menstruation delayed | 1 | 2 |
| Menstruation irregular | 3 | 3 |
| Mental fatigue | 3 | 4 |
| Metastases to lymph nodes | 1 | 1 |
| Metrorrhagia | 1 | 1 |
| Micturition urgency | | 1 |
| Middle insomnia | 2 | 5 |
| Migraine | 43 | 79 |
| Migraine with aura | 1 | 4 |
| Miliaria | 1 | 1 |
| Mobility decreased | 7 | 9 |
| Monoplegia | 1 | 3 |
| Mood altered | | 2 |
| Mouth swelling | 1 | 1 |
| Mouth ulceration | 5 | 8 |
| Movement disorder | 3 | 5 |
| Muscle fatigue | 5 | 10 |
| Muscle rigidity | | 1 |
| Muscle spasms | 8 | 14 |
| Muscle swelling | | 1 |
| Muscle tightness | 1 | 1 |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 12 | 25 |
| Musculoskeletal chest pain | 1 | 3 |
| Musculoskeletal discomfort | 1 | 3 |
| Musculoskeletal pain | | 1 |
| Musculoskeletal stiffness | 15 | 28 |
| Myalgia | 144 | 337 |
| Mydriasis | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 4 | 1 | 1 |
| | | 4 | 12 | 39 | 67 |
| | | | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | 4 | 5 | 3 | 4 |
| | | | | 1 | 3 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 5 | 7 |
| | | | | 3 | 5 |
| | | | 2 | 5 | 8 |
| | | | | | 1 |
| | | 2 | 5 | 6 | 9 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 9 | 9 | 16 |
| | | | 1 | 1 | 2 |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | 1 | 5 | 14 | 23 |
| | | 13 | 82 | 131 | 255 |
| | | | | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Myofascial pain syndrome | 1 | 1 |
| Nasal congestion | | 3 |
| Nasopharyngitis | 10 | 23 |
| Nausea | 206 | 399 |
| Neck mass | | 1 |
| Neck pain | 21 | 40 |
| Nerve compression | 2 | 2 |
| Nervousness | 4 | 4 |
| Neuralgia | 2 | 2 |
| Neurogenic shock | | 2 |
| Neurological symptom | 1 | 1 |
| Neuropathy peripheral | 2 | 2 |
| Neutropenia | 3 | 3 |
| Nightmare | 3 | 6 |
| Night sweats | 10 | 23 |
| Nipple pain | 1 | 1 |
| Nodule | | 1 |
| Non-cardiac chest pain | 1 | 1 |
| Nuchal rigidity | 1 | 1 |
| Numb chin syndrome | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | 2 | 2 |
| Odynophagia | 3 | 4 |
| Oedema | 1 | 1 |
| Oedema peripheral | 3 | 3 |
| Off label use | 22 | 29 |
| Oral discomfort | 1 | 1 |
| Oral herpes | | 1 |
| Oral mucosal exfoliation | 1 | 1 |
| Oral pain | 2 | 2 |
| Oropharyngeal blistering | 1 | 2 |
| Oropharyngeal discomfort | 1 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 3 | | |
| | | 3 | 12 | 7 | 11 |
| | | 28 | 101 | 178 | 298 |
| | | | | | 1 |
| | | 2 | 6 | 19 | 34 |
| | | | | 2 | 2 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | 1 | 3 | 2 | 3 |
| | | 2 | 11 | 8 | 12 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 21 | 28 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | 1 | | 3 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Oropharyngeal pain | 27 | 57 |
| Oropharyngeal spasm | 1 | 1 |
| Oversensing | 1 | 1 |
| Ovulation pain | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 107 | 209 |
| Painful respiration | | 2 |
| Pain in extremity | 163 | 268 |
| Pain in jaw | 4 | 4 |
| Pain of skin | 6 | 11 |
| Palatal swelling | 1 | 1 |
| Palatal ulcer | 1 | 1 |
| Pallor | 4 | 12 |
| Palpitations | 19 | 33 |
| Panic attack | 1 | 2 |
| Papule | | 2 |
| Paraesthesia | 33 | 55 |
| Paraesthesia oral | 8 | 16 |
| Paralysis | 2 | 2 |
| Paranasal sinus discomfort | 1 | 1 |
| Paranasal sinus inflammation | | 1 |
| Parosmia | 1 | 3 |
| Pelvic pain | 1 | 1 |
| Pericarditis | | 1 |
| Periorbital oedema | 1 | 1 |
| Periorbital swelling | 2 | 2 |
| Peripheral coldness | 4 | 7 |
| Peripheral swelling | 37 | 59 |
| Persistent postural-perceptual dizziness | 1 | 1 |
| Petechiae | | 2 |
| Pharyngeal inflammation | | 1 |
| Pharyngeal oedema | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 18 | 24 | 39 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | 30 | 75 | 77 | 134 |
| | | | | | 2 |
| | | 36 | 83 | 127 | 185 |
| | | | | 4 | 4 |
| | | 1 | 3 | 5 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 7 | 2 | 5 |
| | | 3 | 9 | 16 | 24 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | 7 | 17 | 26 | 38 |
| | | | 1 | 8 | 15 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 3 | 3 | 4 |
| | | 7 | 14 | 30 | 45 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | | | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pharyngeal swelling | 6 | 8 |
| Pharyngitis streptococcal | | 1 |
| Phonophobia | | 1 |
| Photophobia | 9 | 16 |
| Photopsia | 3 | 3 |
| Photosensitivity reaction | 2 | 3 |
| pH urine | | 1 |
| Piloerection | 1 | 1 |
| Pleurisy | 2 | 3 |
| Pleuritic pain | | 1 |
| Pollakiuria | | 1 |
| Polymerase chain reaction positive | 1 | 1 |
| Poor quality sleep | 6 | 7 |
| Postural orthostatic tachycardia syndrome | 1 | 1 |
| Presyncope | 11 | 21 |
| Primary cough headache | 1 | 1 |
| Proctalgia | 1 | 1 |
| Product administered at inappropriate site | | 1 |
| Productive cough | | 2 |
| Product use issue | 22 | 28 |
| Proteinuria | 1 | 1 |
| Pruritus | 34 | 63 |
| Psoriasis | 1 | 1 |
| Psychogenic seizure | 2 | 2 |
| Pulmonary embolism | 2 | 2 |
| Pulmonary pain | 3 | 4 |
| Pulmonary thrombosis | 1 | 1 |
| Pulpitis dental | 1 | 1 |
| Puncture site bruise | 1 | 1 |
| Pupillary reflex impaired | | 1 |
| Pupils unequal | | 2 |
| Purpura | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 6 | 8 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 2 | 9 | 14 |
| | | | | 3 | 3 |
| | | 1 | 1 | 1 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | 3 | 4 |
| | | 1 | 1 | | |
| | | 1 | 7 | 10 | 14 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 1 | | 1 |
| | | 21 | 27 | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | 9 | 24 | 25 | 39 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 2 |
| | | | 1 | | 1 |

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* I=Interval, C=Cumulative
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Pyrexia | 262 | 524 |
| Rash | 38 | 68 |
| Rash erythematous | 8 | 23 |
| Rash macular | 2 | 9 |
| Rash maculo-papular | 1 | 1 |
| Rash papular | | 3 |
| Rash pruritic | 11 | 18 |
| Raynaud's phenomenon | 1 | 1 |
| Rectal discharge | 1 | 1 |
| Rectal haemorrhage | 2 | 2 |
| Renal pain | | 1 |
| Respiration abnormal | | 1 |
| Respiratory rate increased | 2 | 2 |
| Restless legs syndrome | | 2 |
| Restlessness | | 3 |
| Retching | 1 | 1 |
| Rhabdomyolysis | | 2 |
| Rhinitis | | 2 |
| Rhinorrhoea | 6 | 13 |
| Right ventricular failure | 1 | 1 |
| Sacroiliitis | 1 | 1 |
| Salivary hypersecretion | | 1 |
| Scratch | 1 | 1 |
| Screaming | 1 | 1 |
| Scrotal pain | | 1 |
| Seasonal allergy | | 1 |
| Seizure | 8 | 11 |
| Sensation of foreign body | 1 | 2 |
| Sense of a foreshortened future | 1 | 1 |
| Sensitive skin | 5 | 8 |
| Sensory disturbance | 2 | 3 |
| Sensory loss | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 33 | 110 | 229 | 414 |
| | | 7 | 17 | 31 | 51 |
| | | 2 | 9 | 6 | 14 |
| | | | 5 | 2 | 4 |
| | | | | 1 | 1 |
| | | | 1 | | 2 |
| | | 1 | 4 | 10 | 14 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | 1 |
| | | | 3 | | |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | 2 | | |
| | | | 4 | 6 | 9 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 8 | 11 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 5 | 7 |
| | | 2 | 2 | | 1 |
| | | | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Serositis | | 1 |
| Sinus bradycardia | | 1 |
| Sinus congestion | | 1 |
| Sinus headache | 4 | 7 |
| Sinusitis | 2 | 2 |
| Sinus pain | 4 | 7 |
| Sinus tachycardia | 2 | 3 |
| Skin burning sensation | | 3 |
| Skin discolouration | 3 | 6 |
| Skin exfoliation | | 1 |
| Skin fissures | 1 | 1 |
| Skin irritation | 1 | 1 |
| Skin mass | 1 | 1 |
| Skin reaction | 2 | 2 |
| Skin swelling | 1 | 3 |
| Skin tightness | | 1 |
| Skin ulcer | 1 | 1 |
| Skin warm | 5 | 8 |
| Sleep disorder | 5 | 8 |
| Sleep disorder due to a general medical condition | 1 | 3 |
| Sleep disorder due to general medical condition, insomnia type | 2 | 2 |
| Sleep paralysis | 1 | 1 |
| Sneezing | 3 | 6 |
| Somnolence | 14 | 26 |
| Speech disorder | 1 | 1 |
| Spinal pain | 1 | 1 |
| Stress | 2 | 3 |
| Stridor | 2 | 2 |
| Sudden visual loss | 1 | 1 |
| Suicide attempt | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 3 | 3 | 1 | 4 |
| | | | | 2 | 2 |
| | | | | 4 | 7 |
| | | | 1 | 2 | 2 |
| | | | | | 3 |
| | | | | 3 | 6 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 2 | 3 | 3 | 5 |
| | | 2 | 3 | 3 | 5 |
| | | 1 | 2 | | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | | 2 | 3 | 4 |
| | | 4 | 9 | 10 | 17 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Supraventricular tachycardia | 1 | 1 |
| Suspected COVID-19 | 23 | 38 |
| Sweating fever | 5 | 11 |
| Swelling | 30 | 39 |
| Swelling face | 7 | 10 |
| Swelling of eyelid | 1 | 4 |
| Swollen tongue | 7 | 10 |
| Symptom recurrence | | 1 |
| Syncope | 41 | 61 |
| Synovial cyst | | 1 |
| Systemic lupus erythematosus | 1 | 1 |
| Tachycardia | 16 | 33 |
| Tachyphrenia | 1 | 1 |
| Tachypnoea | 1 | 2 |
| Taste disorder | 1 | 2 |
| Tearfulness | | 1 |
| Temperature regulation disorder | 2 | 2 |
| Temporomandibular joint syndrome | | 1 |
| Tenderness | 4 | 7 |
| Tension headache | 9 | 15 |
| Therapeutic product effect increased | 1 | 1 |
| Thirst | | 3 |
| Throat irritation | 4 | 7 |
| Throat tightness | 7 | 13 |
| Thrombocytopenia | 1 | 1 |
| Thrombosis | 1 | 1 |
| Thunderclap headache | | 1 |
| Tinnitus | 8 | 13 |
| Tongue spasm | 1 | 1 |
| Tonic convulsion | 1 | 1 |
| Tonsillar hypertrophy | 1 | 3 |
| Tonsillar inflammation | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 4 | 4 | 19 | 34 |
| | | | | 5 | 11 |
| | | 8 | 14 | 22 | 25 |
| | | 1 | 1 | 6 | 9 |
| | | | | 1 | 4 |
| | | | 1 | 7 | 9 |
| | | | 1 | | |
| | | | | 41 | 61 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 8 | 14 | 25 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | 2 | 2 | 2 | 5 |
| | | 1 | 3 | 8 | 12 |
| | | | | 1 | 1 |
| | | | 2 | | 1 |
| | | | | 4 | 7 |
| | | 1 | 1 | 6 | 12 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 3 | 7 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Tonsillitis | 1 | 3 |
| Toothache | 1 | 2 |
| Transient ischaemic attack | | 1 |
| Tremor | 24 | 45 |
| Ulnar nerve injury | 1 | 1 |
| Unresponsive to stimuli | 1 | 3 |
| Upper-airway cough syndrome | | 1 |
| Upper airway obstruction | 1 | 1 |
| Upper limb fracture | 1 | 1 |
| Urinary retention | 3 | 4 |
| Urinary tract infection | 1 | 2 |
| Urine output decreased | | 1 |
| Urine output increased | | 1 |
| Urticaria | 29 | 50 |
| Uterine pain | 1 | 1 |
| Uveitis | 2 | 2 |
| Vaccination complication | 1 | 2 |
| Vaccination site bruising | 4 | 7 |
| Vaccination site discolouration | | 2 |
| Vaccination site discomfort | 2 | 8 |
| Vaccination site erythema | 23 | 49 |
| Vaccination site hypersensitivity | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 4 |
| Vaccination site induration | | 2 |
| Vaccination site infection | 1 | 2 |
| Vaccination site inflammation | 3 | 10 |
| Vaccination site joint movement impairment | 1 | 3 |
| Vaccination site joint pain | | 3 |
| Vaccination site lymphadenopathy | 1 | 1 |
| Vaccination site mass | 7 | 13 |
| Vaccination site movement impairment | 4 | 9 |
| Vaccination site necrosis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 3 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 3 | 10 | 21 | 35 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | 3 | 14 | 26 | 36 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | 2 | 4 | 2 | 3 |
| | | | 2 | | |
| | | 1 | 5 | 1 | 3 |
| | | 5 | 21 | 18 | 28 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 2 |
| | | | 2 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 5 | 2 | 5 |
| | | 1 | 1 | | 2 |
| | | | 1 | | 2 |
| | | | | 1 | 1 |
| | | 1 | 4 | 6 | 9 |
| | | 2 | 2 | 2 | 7 |
| | | | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Vaccination site oedema | | 1 |
| Vaccination site pain | 95 | 234 |
| Vaccination site papule | 1 | 1 |
| Vaccination site paraesthesia | 1 | 4 |
| Vaccination site pruritus | 7 | 19 |
| Vaccination site rash | 3 | 10 |
| Vaccination site reaction | 3 | 5 |
| Vaccination site swelling | 17 | 41 |
| Vaccination site urticaria | 2 | 4 |
| Vaccination site warmth | 11 | 28 |
| Vaginal haemorrhage | 3 | 4 |
| Vasodilatation | | 1 |
| Vein discolouration | | 1 |
| Ventricular fibrillation | | 1 |
| Vertigo | 9 | 20 |
| Vertigo positional | 1 | 1 |
| Vestibular neuronitis | 1 | 1 |
| Viral labyrinthitis | | 1 |
| Viral pharyngitis | | 1 |
| Vision blurred | 9 | 18 |
| Visual impairment | 2 | 5 |
| Vitreous floaters | 1 | 1 |
| Vomiting | 75 | 121 |
| Vomiting projectile | 1 | 3 |
| Weight decreased | 1 | 1 |
| Wheezing | 6 | 10 |
| Wound complication | 1 | 1 |
| Yawning | 1 | 1 |
| | 1 | 2 |
| | 4,370 | 8,158 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|----|---------|------|------|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | | 1 | | | | |
| 1 | 1 | 21 | 90 | 74 | 144 | | |
| | | | | 1 | 1 | | |
| | | | 1 | 1 | 3 | | |
| | | 1 | 6 | 6 | 13 | | |
| | | | 3 | 3 | 7 | | |
| | | 2 | 2 | 1 | 3 | | |
| | | 2 | 13 | 15 | 28 | | |
| | | | 1 | 2 | 3 | | |
| | | 3 | 14 | 8 | 14 | | |
| | | 1 | 1 | 2 | 3 | | |
| | | | | | 1 | | |
| | | | 1 | | | | |
| | | | | | 1 | | |
| | | | 2 | 9 | 18 | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | | 1 | | | | |
| | | 1 | 4 | 8 | 14 | | |
| | | 1 | 2 | 1 | 3 | | |
| | | | | 1 | 1 | | |
| | | 10 | 26 | 65 | 95 | | |
| | | | | 1 | 3 | | |
| | | | | 1 | 1 | | |
| | | | 1 | 6 | 9 | | |
| | | | | 1 | 1 | | |
| | | 1 | 1 | | | | |
| | | 1 | 2 | | | | |
| | | 4 | 4 | 745 | 2252 | 3625 | 5906 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 20 | 30 | | | 2 | 8 | 18 | 22 |
| Abdominal distension | 5 | 7 | | | 1 | 3 | 4 | 4 |
| Abdominal pain | 37 | 63 | | | 8 | 21 | 29 | 42 |
| Abdominal pain lower | 2 | 4 | | | 1 | 2 | 1 | 2 |
| Abdominal pain upper | 74 | 100 | | | 5 | 17 | 69 | 83 |
| Abdominal rigidity | 2 | 2 | | | | | 2 | 2 |
| Abdominal tenderness | | 1 | | | | | | 1 |
| Abnormal dreams | 3 | 7 | | | 1 | 4 | 2 | 3 |
| Abnormal sensation in eye | 2 | 4 | | | | 1 | 2 | 3 |
| Abortion spontaneous | 5 | 6 | | | | | 5 | 6 |
| Abscess | 1 | 1 | | | | | 1 | 1 |
| Accidental overdose | 1 | 1 | | | 1 | 1 | | |
| Acute abdomen | 1 | 1 | | | | | 1 | 1 |
| Acute kidney injury | 1 | 1 | | | | | 1 | 1 |
| Adnexa uteri pain | 2 | 2 | | | | | 2 | 2 |
| Aerophagia | | 1 | | | | | | 1 |
| Ageusia | 14 | 25 | | | 2 | 7 | 12 | 18 |
| Aggression | 1 | 1 | | | | | 1 | 1 |
| Agitation | 5 | 6 | | | | | 5 | 6 |
| Alcohol interaction | 1 | 2 | | | | | 1 | 2 |
| Allergic cough | | 1 | | | | | | 1 |
| Allergy to vaccine | 3 | 10 | | | | 2 | 3 | 8 |
| Alopecia | 4 | 6 | | | 2 | 3 | 2 | 3 |
| Amnesia | 2 | 2 | | | | | 2 | 2 |
| Anaemia | 1 | 1 | | | | | 1 | 1 |
| Anal haemorrhage | 1 | 2 | | | | | 1 | 2 |
| Anal incontinence | 1 | 1 | | | 1 | 1 | | |
| Anal sphincter atony | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 37 | 74 | | | | | 37 | 74 |
| Anaphylactic shock | 1 | 1 | | | | | 1 | 1 |
| Anaphylactoid reaction | 2 | 4 | | | | | 2 | 4 |
| Anaphylactoid shock | 1 | 1 | | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Anger | 1 | 1 |
| Angina pectoris | 2 | 3 |
| Angioedema | 11 | 19 |
| Ankylosing spondylitis | 1 | 1 |
| Anorgasmia | | 1 |
| Anosmia | 5 | 11 |
| Antibody test positive | | 1 |
| Anxiety | 24 | 43 |
| Apathy | | 1 |
| Aphasia | 2 | 3 |
| Aphonia | 2 | 5 |
| Aphthous ulcer | | 2 |
| Apnoea | 1 | 1 |
| Appendicitis | | 1 |
| Arrhythmia | 4 | 6 |
| Arrhythmia supraventricular | | 1 |
| Arthralgia | 288 | 526 |
| Arthritis | 8 | 10 |
| Arthritis bacterial | 1 | 1 |
| Arthritis reactive | 3 | 4 |
| Arthropathy | 3 | 3 |
| Asthenia | 73 | 123 |
| Asthenopia | 8 | 11 |
| Asthma | 20 | 30 |
| Asthma prophylaxis | | 1 |
| Asymptomatic COVID-19 | 1 | 2 |
| Atrial fibrillation | 1 | 2 |
| Atrial tachycardia | 1 | 1 |
| Aura | | 3 |
| Auricular swelling | 1 | 1 |
| Autoimmune disorder | 1 | 1 |
| Autonomic nervous system imbalance | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | 11 | 19 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 3 | 4 | 8 |
| | | | 1 | | |
| | | 5 | 10 | 19 | 33 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | | 1 | 2 | 4 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 4 | 6 |
| | | | | | 1 |
| 1 | 2 | 25 | 118 | 263 | 408 |
| | | | | 8 | 10 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | 1 | 1 | 2 | 2 |
| | | 15 | 38 | 58 | 85 |
| | | | 2 | 8 | 9 |
| | | 2 | 6 | 18 | 24 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | | 1 | | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Axillary mass | 5 | 10 |
| Axillary pain | 38 | 82 |
| Back pain | 79 | 127 |
| Balance disorder | 8 | 14 |
| Bedridden | 2 | 2 |
| Behaviour disorder | 1 | 1 |
| Behcet's syndrome | 1 | 1 |
| Bladder disorder | 3 | 3 |
| Bleeding time abnormal | 1 | 1 |
| Blepharitis | | 1 |
| Blepharospasm | 2 | 3 |
| Blindness | 3 | 3 |
| Blindness transient | 1 | 1 |
| Blister | 5 | 10 |
| Blood blister | 1 | 1 |
| Blood glucose decreased | | 1 |
| Blood glucose increased | 2 | 3 |
| Blood lactic acid increased | 1 | 2 |
| Blood potassium abnormal | | 1 |
| Blood potassium decreased | 1 | 1 |
| Blood pressure abnormal | 1 | 1 |
| Blood pressure decreased | 3 | 4 |
| Blood pressure diastolic decreased | 1 | 1 |
| Blood pressure increased | 16 | 43 |
| Blood pressure systolic increased | 2 | 2 |
| Blood test abnormal | | 1 |
| Blood urine present | 2 | 3 |
| Blue toe syndrome | 1 | 1 |
| Body temperature | | 3 |
| Body temperature abnormal | 4 | 9 |
| Body temperature decreased | 4 | 7 |
| Body temperature fluctuation | 3 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 4 | 5 | 6 |
| | | 11 | 30 | 27 | 52 |
| | | 11 | 36 | 68 | 91 |
| | | | 1 | 8 | 13 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 3 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 4 | 4 | 6 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | 6 | 22 | 10 | 21 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | 2 |
| | | 2 | 2 | 2 | 7 |
| | | | 1 | 4 | 6 |
| | | 1 | 2 | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Body temperature increased | 18 | 38 |
| Bone pain | 17 | 24 |
| Bone swelling | 1 | 3 |
| Bowel movement irregularity | 1 | 1 |
| Bradycardia | 3 | 8 |
| Bradykinesia | 1 | 1 |
| Bradyphrenia | 1 | 2 |
| Breast abscess | | 1 |
| Breast cyst | 1 | 1 |
| Breast discomfort | 1 | 1 |
| Breast mass | 4 | 5 |
| Breast pain | 10 | 21 |
| Breast swelling | 4 | 6 |
| Breast tenderness | 2 | 2 |
| Breath odour | 1 | 1 |
| Bronchiectasis | 1 | 1 |
| Bronchitis | 1 | 1 |
| Bronchospasm | 1 | 4 |
| Burning sensation | 11 | 24 |
| Burns second degree | 1 | 1 |
| Cardiac arrest | 4 | 6 |
| Cardiac flutter | 7 | 7 |
| Catarrh | | 1 |
| Catatonia | 1 | 1 |
| Cellulitis | 7 | 15 |
| Cerebral haemorrhage | 1 | 1 |
| Cerebrovascular accident | 4 | 4 |
| Chalazion | 1 | 1 |
| Chapped lips | 1 | 1 |
| Cheilitis | 2 | 2 |
| Chest discomfort | 55 | 110 |
| Chest pain | 86 | 127 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 10 | 13 | 28 |
| | | 2 | 8 | 15 | 16 |
| | | 1 | 2 | | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 4 |
| | | 2 | 7 | 8 | 14 |
| | | | 2 | 4 | 4 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 4 |
| | | 3 | 4 | 8 | 20 |
| | | 1 | 1 | | |
| | | | | 4 | 6 |
| | | | | 7 | 7 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 7 | 15 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 7 | 25 | 48 | 85 |
| | | 8 | 24 | 78 | 103 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Chillblains | | 1 |
| Chills | 344 | 654 |
| Choking | 1 | 1 |
| Cholecystitis infective | | 1 |
| Chronic fatigue syndrome | 2 | 2 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Chronic spontaneous urticaria | 1 | 1 |
| Circulatory collapse | 1 | 3 |
| Clonic convulsion | 2 | 2 |
| Clumsiness | | 1 |
| Cluster headache | 4 | 9 |
| Coagulation time prolonged | 1 | 1 |
| Cognitive disorder | 3 | 4 |
| Cold sweat | 26 | 55 |
| Coma scale abnormal | | 1 |
| Condition aggravated | 18 | 28 |
| Confusional state | 27 | 41 |
| Conjunctival haemorrhage | 2 | 2 |
| Conjunctivitis | 1 | 4 |
| Consciousness fluctuating | 3 | 3 |
| Constipation | 4 | 6 |
| Contraindicated product administered | | 1 |
| Contusion | 9 | 17 |
| Coordination abnormal | 4 | 5 |
| Costochondritis | 1 | 3 |
| Costovertebral angle tenderness | | 1 |
| Cough | 64 | 115 |
| COVID-19 | 38 | 62 |
| Crohn's disease | 1 | 1 |
| Crying | 4 | 5 |
| Cutaneous symptom | 1 | 1 |
| Cyanosis | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| 1 | 2 | 48 | 158 | 296 | 496 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 4 | 8 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | 2 | 13 | 24 | 42 |
| | | | | | 1 |
| | | 2 | 5 | 16 | 23 |
| | | 4 | 8 | 23 | 33 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 3 |
| | | | | 3 | 3 |
| | | | 1 | 4 | 5 |
| | | | | | 1 |
| | | 3 | 5 | 6 | 12 |
| | | | 1 | 4 | 4 |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | 10 | 24 | 54 | 91 |
| 1 | 1 | 3 | 4 | 35 | 58 |
| | | | | 1 | 1 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Cyst | 1 | 1 |
| Cystitis | 2 | 2 |
| Deafness | 6 | 7 |
| Deafness neurosensory | 1 | 1 |
| Deafness unilateral | 1 | 1 |
| Death | 3 | 5 |
| Decreased appetite | 49 | 89 |
| Deep vein thrombosis | | 1 |
| Defaecation urgency | 1 | 2 |
| Dehydration | 7 | 13 |
| Delirium | 4 | 10 |
| Dementia with Lewy bodies | 1 | 1 |
| Depersonalisation/derealisation disorder | | 2 |
| Depressed level of consciousness | 3 | 4 |
| Depressed mood | 14 | 16 |
| Depression | 5 | 6 |
| Dermatitis | | 1 |
| Dermatitis allergic | 3 | 8 |
| Dermatitis atopic | 1 | 1 |
| Diabetic ketoacidosis | | 1 |
| Diarrhoea | 165 | 260 |
| Diarrhoea haemorrhagic | | 1 |
| Diplopia | 2 | 6 |
| Discomfort | 11 | 17 |
| Disease progression | 1 | 1 |
| Disease recurrence | 15 | 16 |
| Disorganised speech | | 1 |
| Disorientation | 12 | 19 |
| Dissociation | 1 | 3 |
| Disturbance in attention | 19 | 30 |
| Dizziness | 306 | 522 |
| Dizziness exertional | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 6 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| | | 8 | 19 | 41 | 70 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | 6 | 7 | 7 |
| | | | | 4 | 10 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 3 | 4 |
| | | 1 | 1 | 13 | 15 |
| | | | | 5 | 6 |
| | | | 1 | | |
| | | | 2 | 3 | 6 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 17 | 57 | 148 | 203 |
| | | | | | 1 |
| | | | 2 | 2 | 4 |
| | | | 3 | 11 | 14 |
| | | | | 1 | 1 |
| | | 2 | 2 | 13 | 14 |
| | | | 1 | | |
| | | 1 | 3 | 11 | 16 |
| | | | 2 | 1 | 1 |
| | | 4 | 8 | 15 | 22 |
| 1 | 2 | 30 | 135 | 276 | 387 |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Dizziness postural | 14 | 26 |
| Dreamy state | 1 | 1 |
| Drooling | 1 | 1 |
| Drug hypersensitivity | 1 | 2 |
| Drug ineffective | 62 | 121 |
| Drug withdrawal syndrome | 1 | 1 |
| Dry eye | 5 | 6 |
| Dry mouth | 21 | 37 |
| Dry skin | 2 | 7 |
| Dry throat | 7 | 13 |
| Dysaesthesia | 1 | 1 |
| Dysarthria | 10 | 11 |
| Dyschezia | 1 | 1 |
| Dysentery | 1 | 1 |
| Dysgeusia | 38 | 80 |
| Dyshidrotic eczema | 1 | 1 |
| Dyskinesia | 2 | 3 |
| Dysmenorrhoea | 4 | 6 |
| Dysmorphism | 1 | 1 |
| Dyspepsia | 12 | 18 |
| Dysphagia | 15 | 23 |
| Dysphonia | 3 | 8 |
| Dyspnoea | 131 | 215 |
| Dyspnoea at rest | 2 | 2 |
| Dyspnoea exertional | 8 | 12 |
| Dysstasia | 1 | 2 |
| Dystonia | 2 | 2 |
| Dysuria | 2 | 3 |
| Ear congestion | | 1 |
| Ear discomfort | 4 | 9 |
| Ear disorder | 2 | 3 |
| Ear infection | 3 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 13 | 23 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| 1 | 1 | 1 | 1 | 61 | 120 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 5 |
| | | 5 | 10 | 16 | 27 |
| | | | 5 | 2 | 2 |
| | | 1 | 3 | 6 | 10 |
| | | | | 1 | 1 |
| | | | | 10 | 11 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 7 | 36 | 31 | 44 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | 1 | 2 | 3 | 4 |
| | | | | 1 | 1 |
| | | 2 | 5 | 10 | 13 |
| | | 4 | 5 | 11 | 18 |
| | | | 1 | 3 | 7 |
| | | 14 | 42 | 117 | 173 |
| | | | | 2 | 2 |
| | | 1 | 3 | 7 | 9 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 2 | 2 |
| | | | 1 | | |
| | | | 3 | 4 | 6 |
| | | | | 2 | 3 |
| | | 1 | 2 | 2 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Ear infection bacterial | 1 | 1 |
| Ear pain | 24 | 46 |
| Ear pruritus | | 1 |
| Ear swelling | 2 | 3 |
| Eating disorder | 1 | 1 |
| Eczema | 7 | 9 |
| Eczema weeping | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Emotional disorder | 2 | 2 |
| Emotional distress | 3 | 3 |
| Encephalitis | 1 | 1 |
| Endometriosis | 1 | 1 |
| Enuresis | | 1 |
| Epicondylitis | 1 | 1 |
| Epididymitis | 1 | 1 |
| Epigastric discomfort | 1 | 1 |
| Epilepsy | 4 | 6 |
| Episcleritis | 1 | 2 |
| Epistaxis | 11 | 19 |
| Epstein-Barr virus infection | 1 | 1 |
| Erectile dysfunction | 1 | 2 |
| Eructation | 2 | 3 |
| Erythema | 49 | 104 |
| Erythema annulare | 1 | 1 |
| Erythema multiforme | 1 | 2 |
| Erythema nodosum | 1 | 1 |
| Erythema of eyelid | 1 | 1 |
| Essential tremor | 1 | 1 |
| Euphoric mood | 1 | 1 |
| Eustachian tube disorder | 1 | 1 |
| Exercise tolerance decreased | | 1 |
| Exposure during pregnancy | 6 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 3 | 16 | 21 | 30 |
| | | | 1 | | |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | 6 | 8 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 6 |
| | | | | 1 | 2 |
| | | 2 | 6 | 9 | 13 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | 11 | 39 | 38 | 65 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 6 | 7 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Exposure to SARS-CoV-2 | 1 | 1 |
| Extensor plantar response | 1 | 1 |
| External ear cellulitis | 1 | 1 |
| Extraocular muscle paresis | 1 | 1 |
| Extrasystoles | 5 | 8 |
| Eye contusion | | 3 |
| Eye discharge | 1 | 1 |
| Eye disorder | 4 | 6 |
| Eye haemorrhage | 1 | 1 |
| Eye inflammation | 1 | 1 |
| Eye irritation | 2 | 6 |
| Eyelid exfoliation | | 1 |
| Eyelid function disorder | | 1 |
| Eyelid irritation | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eyelid pain | 1 | 2 |
| Eyelid ptosis | 1 | 1 |
| Eyelid rash | | 2 |
| Eyelids pruritus | | 1 |
| Eye movement disorder | | 2 |
| Eye oedema | 1 | 1 |
| Eye pain | 32 | 56 |
| Eye paraesthesia | | 1 |
| Eye pruritus | 3 | 12 |
| Eye swelling | 20 | 35 |
| Face crushing | | 1 |
| Facial discomfort | 1 | 1 |
| Facial neuralgia | | 1 |
| Facial pain | 9 | 15 |
| Facial paralysis | 30 | 46 |
| Facial paresis | 4 | 7 |
| Facial spasm | 2 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 4 | 5 |
| | | | 1 | | 2 |
| | | 1 | 2 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 5 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | | 1 |
| | | | | | 2 |
| | | 1 | 1 | | |
| 1 | 1 | 4 | 13 | 28 | 43 |
| | | | 1 | | |
| | | | 2 | 3 | 10 |
| | | 1 | 2 | 19 | 33 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 4 | 8 | 11 |
| | | | 1 | 30 | 45 |
| | | | 1 | 4 | 6 |
| | | | 2 | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Faeces discoloured | 1 | 2 |
| Faeces pale | | 1 |
| Fall | 5 | 6 |
| Familial hemiplegic migraine | 1 | 1 |
| Fatigue | 765 | 1,239 |
| Fear | | 1 |
| Fear of injection | | 1 |
| Febrile convulsion | 1 | 1 |
| Feeding disorder | 2 | 3 |
| Feeling abnormal | 59 | 101 |
| Feeling cold | 50 | 89 |
| Feeling drunk | 5 | 9 |
| Feeling hot | 67 | 129 |
| Feeling jittery | 2 | 4 |
| Feeling of body temperature change | 20 | 40 |
| Fibromyalgia | 4 | 5 |
| Flank pain | | 1 |
| Flatulence | 10 | 10 |
| Fluid retention | | 1 |
| Flushing | 23 | 54 |
| Food allergy | 1 | 1 |
| Food aversion | 1 | 1 |
| Food poisoning | 1 | 1 |
| Foreign body sensation in eyes | 1 | 2 |
| Formication | 2 | 2 |
| Fracture blisters | 1 | 1 |
| Frequent bowel movements | 1 | 3 |
| Furuncle | | 1 |
| Gait disturbance | 12 | 23 |
| Gait inability | 2 | 4 |
| Gastric disorder | 2 | 2 |
| Gastritis | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 3 | 4 | 2 | 2 |
| | | | | 1 | 1 |
| 2 | 5 | 101 | 294 | 664 | 945 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 8 | 27 | 51 | 74 |
| | | 11 | 28 | 39 | 61 |
| | | 1 | 2 | 4 | 7 |
| | | 23 | 54 | 44 | 75 |
| | | | 1 | 2 | 3 |
| | | 5 | 17 | 15 | 23 |
| | | | | 4 | 5 |
| | | | 1 | | |
| | | 2 | 2 | 8 | 8 |
| | | | 1 | | |
| | | 2 | 16 | 21 | 38 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | 2 | 1 | 1 |
| | | | 1 | | |
| | | 2 | 5 | 10 | 18 |
| | | | 1 | 2 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Gastroenteritis | 3 | 3 |
| Gastrointestinal haemorrhage | 1 | 1 |
| Gastrointestinal pain | 1 | 2 |
| Gastrointestinal sounds abnormal | 2 | 2 |
| Gastrointestinal stoma complication | | 1 |
| Gastrooesophageal reflux disease | 4 | 7 |
| Generalised tonic-clonic seizure | 2 | 3 |
| Genital ulceration | 1 | 1 |
| Genitourinary symptom | 1 | 1 |
| Gingival bleeding | | 2 |
| Gingival blister | | 2 |
| Gingival discomfort | | 1 |
| Gingival pain | 2 | 4 |
| Gingivitis ulcerative | 1 | 2 |
| Glossitis | | 1 |
| Glossodynia | 10 | 14 |
| Gout | 1 | 2 |
| Granulomatous lymphadenitis | 2 | 2 |
| Grip strength | 1 | 1 |
| Grip strength decreased | | 1 |
| Groin pain | 3 | 7 |
| Haematemesis | 1 | 2 |
| Haematocrit increased | 1 | 1 |
| Haematoma | | 1 |
| Haematuria | | 1 |
| Haemoglobin decreased | 1 | 2 |
| Haemoglobin increased | 1 | 1 |
| Haemoptysis | 1 | 2 |
| Haemorrhage | 3 | 3 |
| Haemorrhage urinary tract | | 1 |
| Haemorrhoids | 1 | 1 |
| Hallucination | 7 | 12 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 4 | 6 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | 2 | | |
| | | | 1 | | |
| | | | 1 | 2 | 3 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | 2 | 5 | 8 | 9 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | 3 | 6 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 7 | 12 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Hallucination, auditory | 1 | 1 |
| Hallucination, visual | | 1 |
| Hangover | 3 | 4 |
| Headache | 857 | 1,538 |
| Head discomfort | 11 | 18 |
| Head injury | 1 | 5 |
| Heart rate abnormal | 4 | 5 |
| Heart rate decreased | 6 | 6 |
| Heart rate increased | 30 | 65 |
| Heart rate irregular | 2 | 4 |
| Heat oedema | 1 | 2 |
| Hemiparaesthesia | | 1 |
| Hemiparesis | | 1 |
| Hemiplegia | 1 | 1 |
| Hemiplegic migraine | 1 | 1 |
| Hepatic pain | 2 | 3 |
| Herpes simplex | 2 | 2 |
| Herpes virus infection | 1 | 1 |
| Herpes zoster | 12 | 22 |
| Herpes zoster reactivation | 1 | 1 |
| Histamine intolerance | 1 | 1 |
| Hordeolum | | 1 |
| Hot flush | 26 | 53 |
| Hyperacusis | 2 | 3 |
| Hyperaesthesia | 3 | 6 |
| Hypercapnia | 1 | 1 |
| Hyperchlorhydria | 3 | 3 |
| Hypergeusia | 1 | 1 |
| Hyperglycaemia | 2 | 7 |
| Hyperhidrosis | 76 | 125 |
| Hyperreflexia | 1 | 1 |
| Hypersensitivity | 23 | 45 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 3 |
| 4 | 7 | 110 | 380 | 747 | 1158 |
| | | 1 | 6 | 10 | 12 |
| | | 1 | 4 | | 1 |
| | | | 1 | 4 | 4 |
| | | 1 | 1 | 5 | 5 |
| | | 5 | 19 | 25 | 46 |
| | | | | 2 | 4 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 6 | 11 | 16 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 13 | 23 | 40 |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 2 | 2 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 5 |
| | | 12 | 32 | 64 | 93 |
| | | | | 1 | 1 |
| | | 2 | 6 | 21 | 39 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypersomnia | 12 | 17 |
| Hypertension | 16 | 43 |
| Hyperventilation | 2 | 2 |
| Hypoacusis | 4 | 4 |
| Hypoaesthesia | 75 | 124 |
| Hypoaesthesia eye | | 1 |
| Hypoaesthesia oral | 23 | 45 |
| Hypoaesthesia teeth | 1 | 1 |
| Hypoglycaemia | 2 | 4 |
| Hypokinesia | 2 | 2 |
| Hypomenorrhoea | 1 | 1 |
| Hypophagia | 1 | 1 |
| Hypopnoea | 4 | 4 |
| Hyposmia | | 3 |
| Hypotension | 17 | 34 |
| Hypothermia | 2 | 3 |
| Hypothyroidism | 1 | 1 |
| Hypoxia | 2 | 2 |
| Illness | 40 | 66 |
| Immune system disorder | 2 | 2 |
| Immune thrombocytopenia | | 1 |
| Impaired driving ability | | 2 |
| Impaired gastric emptying | 1 | 1 |
| Impaired work ability | 2 | 2 |
| Inappropriate schedule of product administration | 1 | 3 |
| Incision site pain | | 1 |
| Incontinence | 1 | 3 |
| Incorrect dose administered | | 1 |
| Incorrect route of product administration | 2 | 8 |
| Increased bronchial secretion | 1 | 1 |
| Increased tendency to bruise | 2 | 2 |
| Increased upper airway secretion | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 8 | 8 | 9 |
| | | 1 | 11 | 15 | 32 |
| | | 2 | 2 | | |
| | | 2 | 2 | 2 | 2 |
| 1 | 1 | 17 | 40 | 58 | 84 |
| | | | | | 1 |
| | | 3 | 15 | 20 | 30 |
| | | 1 | 1 | | |
| | | | | 2 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | 2 | | 1 |
| | | 3 | 12 | 14 | 22 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 4 | 13 | 36 | 53 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | | 1 |
| | | | | 2 | 2 |
| | | | 2 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 1 | |
| | | 1 | 1 | 1 | 1 |
| | | | | | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Increased viscosity of upper respiratory secretion | 1 | 3 |
| Indifference | 1 | 2 |
| Infected dermal cyst | 1 | 1 |
| Infection | 4 | 5 |
| Infertility | 1 | 1 |
| Inflammation | 7 | 15 |
| Influenza | 51 | 72 |
| Influenza like illness | 80 | 156 |
| Infusion related reaction | 1 | 1 |
| Initial insomnia | | 1 |
| Injected limb mobility decreased | 4 | 5 |
| Injection related reaction | | 1 |
| Injection site erythema | | 3 |
| Injection site joint movement impairment | 1 | 1 |
| Injection site pain | 2 | 11 |
| Injection site pruritus | | 1 |
| Injection site swelling | | 1 |
| Injection site warmth | | 1 |
| Injury | 1 | 1 |
| Inner ear disorder | 2 | 2 |
| Insomnia | 64 | 100 |
| Intentional self-injury | | 1 |
| Internal haemorrhage | 1 | 1 |
| Intestinal pseudo-obstruction | 1 | 1 |
| Intranasal hypoaesthesia | | 1 |
| Intranasal paraesthesia | 1 | 1 |
| Iridocyclitis | | 1 |
| Irregular breathing | 3 | 3 |
| Irritability | 7 | 9 |
| Irritable bowel syndrome | 2 | 4 |
| Itching scar | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | 2 | 6 | 5 | 9 |
| | | 10 | 20 | 41 | 52 |
| | | 18 | 53 | 62 | 103 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 4 | 5 |
| | | | | | 1 |
| | | | 3 | | |
| | | | | 1 | 1 |
| | | | 8 | 2 | 3 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 13 | 33 | 51 | 67 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | | | 7 | 9 |
| | | | 1 | 2 | 3 |
| | | | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Jaundice | 1 | 1 |
| Jaw clicking | | 1 |
| Joint effusion | | 2 |
| Joint injury | 3 | 3 |
| Joint range of motion decreased | 15 | 20 |
| Joint stiffness | 7 | 12 |
| Joint swelling | 14 | 20 |
| Joint warmth | | 2 |
| Ketoacidosis | 1 | 1 |
| Kidney infection | 1 | 1 |
| Labyrinthitis | 2 | 2 |
| Lack of spontaneous speech | 2 | 2 |
| Lacrimation increased | 2 | 10 |
| Laryngeal disorder | 1 | 1 |
| Lethargy | 88 | 154 |
| Limb discomfort | 47 | 94 |
| Limb immobilisation | | 1 |
| Limb injury | 3 | 3 |
| Limb mass | 2 | 2 |
| Lip blister | 1 | 2 |
| Lip discolouration | | 1 |
| Lip disorder | 1 | 2 |
| Lip dry | 1 | 4 |
| Lip exfoliation | 1 | 1 |
| Lip haemorrhage | 1 | 1 |
| Lip oedema | 2 | 3 |
| Lip pain | | 3 |
| Lip swelling | 27 | 46 |
| Listless | 1 | 1 |
| Livedo reticularis | 1 | 2 |
| Localised infection | 1 | 2 |
| Localised oedema | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 2 |
| | | 1 | 1 | 2 | 2 |
| | | 3 | 5 | 12 | 15 |
| | | 2 | 3 | 5 | 9 |
| | | 4 | 5 | 10 | 15 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 10 |
| | | | | 1 | 1 |
| | | 14 | 38 | 74 | 116 |
| | | 10 | 33 | 37 | 61 |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 2 | | 1 |
| | | | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 1 | | 2 |
| | | 1 | 6 | 26 | 40 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Local reaction | 3 | 3 |
| Locked-in syndrome | | 1 |
| Long thoracic nerve palsy | 1 | 1 |
| Loss of consciousness | 10 | 15 |
| Loss of control of legs | 1 | 1 |
| Loss of personal independence in daily activities | 12 | 19 |
| Lower respiratory tract infection | 5 | 6 |
| Lung disorder | 1 | 1 |
| Lymphadenitis | 2 | 4 |
| Lymphadenopathy | 186 | 354 |
| Lymphatic disorder | | 1 |
| Lymph node pain | 53 | 87 |
| Lymph node palpable | | 1 |
| Lymphoedema | 1 | 5 |
| Macule | 1 | 1 |
| Maculopathy | | 1 |
| Malaise | 215 | 394 |
| Malnutrition | | 1 |
| Mass | | 1 |
| Mastication disorder | 1 | 1 |
| Mastitis | | 2 |
| Maternal exposure during pregnancy | 18 | 20 |
| Maternal exposure timing unspecified | 1 | 2 |
| Mechanical urticaria | | 1 |
| Melanocytic naevus | 1 | 1 |
| Memory impairment | 2 | 4 |
| Meniere's disease | 1 | 1 |
| Menorrhagia | 9 | 14 |
| Menstrual disorder | 1 | 1 |
| Menstruation delayed | 8 | 8 |
| Menstruation irregular | | 2 |
| Mental disorder | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 2 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 10 | 15 |
| | | | | 1 | 1 |
| | | 2 | 3 | 10 | 16 |
| | | | | 5 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 3 |
| 2 | 2 | 24 | 104 | 162 | 250 |
| | | | 1 | | |
| | | 8 | 27 | 45 | 60 |
| | | | 1 | | |
| | | | | 1 | 5 |
| | | | | 1 | 1 |
| | | | | | 1 |
| 1 | 1 | 39 | 106 | 176 | 288 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | 16 | 18 | 2 | 2 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 1 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | | 2 | 9 | 12 |
| | | | | 1 | 1 |
| | | 1 | 1 | 7 | 7 |
| | | | 1 | | 1 |
| | | | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Mental fatigue | 9 | 13 |
| Mental impairment | 1 | 1 |
| Metabolic acidosis | 1 | 1 |
| Metamorphopsia | | 1 |
| Metastases to lymph nodes | 1 | 1 |
| Metrorrhagia | | 1 |
| Middle ear inflammation | | 1 |
| Middle insomnia | 3 | 4 |
| Migraine | 77 | 128 |
| Migraine with aura | 6 | 8 |
| Miliaria | | 3 |
| Miosis | 1 | 1 |
| Moaning | 1 | 1 |
| Mobility decreased | 13 | 18 |
| Monocytosis | 1 | 1 |
| Mononeuropathy | | 1 |
| Monoparesis | 2 | 4 |
| Monoplegia | 2 | 4 |
| Mood altered | 1 | 2 |
| Mood swings | 3 | 3 |
| Motion sickness | 1 | 3 |
| Motor dysfunction | 1 | 1 |
| Mouth breathing | 2 | 2 |
| Mouth cyst | | 1 |
| Mouth swelling | 5 | 6 |
| Mouth ulceration | 18 | 28 |
| Movement disorder | 5 | 9 |
| Multiple injuries | 1 | 1 |
| Multiple sclerosis | | 1 |
| Multiple sclerosis relapse | 3 | 5 |
| Muscle contractions involuntary | 2 | 3 |
| Muscle fatigue | 19 | 26 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 8 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | 2 | 3 |
| | | 3 | 23 | 74 | 105 |
| | | 1 | 1 | 5 | 7 |
| | | | | | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 7 | 9 | 11 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 1 | 2 | 3 |
| | | | | 2 | 4 |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | 1 | 5 | 5 |
| | | 7 | 14 | 11 | 14 |
| | | 1 | 2 | 4 | 7 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 3 | 5 |
| | | 1 | 2 | 1 | 1 |
| | | 2 | 3 | 17 | 23 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Muscle rupture | 1 | 1 |
| Muscle spasms | 27 | 45 |
| Muscle swelling | 1 | 2 |
| Muscle tightness | 2 | 3 |
| Muscle twitching | 12 | 22 |
| Muscular weakness | 22 | 43 |
| Musculoskeletal chest pain | 5 | 8 |
| Musculoskeletal discomfort | 3 | 6 |
| Musculoskeletal disorder | 3 | 5 |
| Musculoskeletal pain | 3 | 7 |
| Musculoskeletal stiffness | 36 | 58 |
| Myalgia | 378 | 711 |
| Myasthenia gravis | 2 | 2 |
| Mydriasis | 1 | 1 |
| Myelitis transverse | 4 | 4 |
| Myocardial infarction | 2 | 2 |
| Myocardial oedema | | 1 |
| Myocarditis | 1 | 4 |
| Myoclonus | | 1 |
| Myofascial pain syndrome | 1 | 1 |
| Myositis | | 1 |
| Nail discolouration | 1 | 2 |
| Nasal congestion | 11 | 17 |
| Nasal discharge discolouration | | 1 |
| Nasal discomfort | 1 | 2 |
| Nasal disorder | 1 | 1 |
| Nasal oedema | 1 | 2 |
| Nasal pruritus | 2 | 2 |
| Nasopharyngitis | 32 | 43 |
| Nausea | 470 | 813 |
| Neck mass | | 1 |
| Neck pain | 64 | 123 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 2 | 7 | 25 | 38 |
| | | 1 | 2 | | |
| | | | 1 | 2 | 2 |
| | | 1 | 6 | 11 | 16 |
| | | 1 | 11 | 21 | 32 |
| | | 1 | 1 | 4 | 7 |
| | | 1 | 4 | 2 | 2 |
| | | | 1 | 3 | 4 |
| | | | 2 | 3 | 5 |
| | | 3 | 12 | 33 | 46 |
| 3 | 5 | 47 | 172 | 331 | 539 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 4 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | 4 | 7 | 7 | 10 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | 6 | 10 | 26 | 33 |
| | 2 | 61 | 203 | 409 | 610 |
| | | | 1 | | |
| | | 11 | 37 | 53 | 86 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Neoplasm malignant | 1 | 1 |
| Nephritis | 1 | 1 |
| Nephrotic syndrome | 1 | 2 |
| Nerve compression | 1 | 1 |
| Nerve injury | 1 | 1 |
| Nervousness | 6 | 11 |
| Neuralgia | 9 | 13 |
| Neurogenic shock | 2 | 3 |
| Neurological symptom | 1 | 1 |
| Neurologic neglect syndrome | 1 | 1 |
| Neuropathy peripheral | 6 | 8 |
| Neutropenia | 1 | 1 |
| Nightmare | 4 | 7 |
| Night sweats | 14 | 31 |
| Nipple pain | 2 | 5 |
| Nipple swelling | | 2 |
| No adverse event | | 1 |
| Nodule | 1 | 1 |
| Non-cardiac chest pain | 2 | 2 |
| Nuchal rigidity | 1 | 1 |
| Obstructive airways disorder | | 1 |
| Occipital neuralgia | 1 | 1 |
| Occupational exposure to SARS-CoV-2 | | 1 |
| Ocular discomfort | 3 | 4 |
| Ocular hyperaemia | 7 | 12 |
| Odynophagia | 2 | 2 |
| Oedema | 1 | 1 |
| Oedema mouth | 1 | 2 |
| Oedema peripheral | 2 | 3 |
| Oesophageal pain | 1 | 2 |
| Oesophageal spasm | | 1 |
| Oesophageal stenosis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 9 |
| | | 2 | 2 | 7 | 11 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 8 |
| | | | | 1 | 1 |
| | | | 1 | 4 | 6 |
| 1 | 1 | 2 | 7 | 12 | 24 |
| | | | 2 | 2 | 3 |
| | | | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 3 | 1 | 1 |
| | | 1 | 2 | 6 | 10 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Off label use | 97 | 117 |
| Oligomenorrhoea | 1 | 1 |
| Ophthalmoplegia | 1 | 1 |
| Optic nerve disorder | 1 | 1 |
| Optic neuritis | 2 | 3 |
| Oral blood blister | | 1 |
| Oral discomfort | 3 | 6 |
| Oral disorder | 1 | 1 |
| Oral herpes | 7 | 9 |
| Oral mucosa erosion | | 1 |
| Oral mucosal blistering | 2 | 4 |
| Oral pain | 6 | 8 |
| Oral pruritus | 1 | 1 |
| Orchitis | 1 | 1 |
| Oropharyngeal blistering | 2 | 4 |
| Oropharyngeal discomfort | 7 | 9 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 98 | 160 |
| Orthostatic hypertension | 1 | 1 |
| Orthostatic hypotension | 1 | 1 |
| Oscillopsia | | 1 |
| Otitis externa | 1 | 1 |
| Overdose | 1 | 4 |
| Oversensing | | 1 |
| Oxygen saturation decreased | 5 | 10 |
| Pain | 280 | 467 |
| Painful respiration | 2 | 5 |
| Pain in extremity | 361 | 623 |
| Pain in jaw | 7 | 21 |
| Pain of skin | 12 | 18 |
| Palatal oedema | 1 | 1 |
| Palatal swelling | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 95 | 114 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | 1 | 2 | 2 | 4 |
| | | 1 | 1 | | |
| | | 2 | 4 | 5 | 5 |
| | | | 1 | | |
| | | | 1 | 2 | 3 |
| | | | 2 | 6 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 7 | 9 |
| | | | | 1 | 1 |
| | | 12 | 43 | 86 | 117 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | 1 | 1 | 4 | 9 |
| 2 | 2 | 54 | 134 | 226 | 333 |
| | | | 2 | 2 | 3 |
| 1 | 4 | 73 | 191 | 288 | 432 |
| | | 1 | 7 | 6 | 14 |
| | | 1 | 2 | 11 | 16 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Pallor | 7 | 17 |
| Palpitations | 74 | 127 |
| Panic attack | 3 | 4 |
| Panic reaction | 4 | 4 |
| Papule | 1 | 2 |
| Paraesthesia | 101 | 182 |
| Paraesthesia oral | 45 | 100 |
| Paralysis | 3 | 5 |
| Paranasal sinus discomfort | 3 | 3 |
| Paranoia | 1 | 1 |
| Paresis | 1 | 1 |
| Parosmia | 5 | 6 |
| Partial seizures | | 1 |
| Peak expiratory flow rate decreased | 1 | 1 |
| Pelvic pain | 2 | 2 |
| Penile swelling | | 1 |
| Periarthritis | 1 | 2 |
| Pericarditis | 3 | 3 |
| Periorbital oedema | 1 | 2 |
| Periorbital swelling | 6 | 8 |
| Peripheral circulatory failure | | 2 |
| Peripheral coldness | 18 | 32 |
| Peripheral sensory neuropathy | 1 | 2 |
| Peripheral swelling | 71 | 121 |
| Peroneal nerve palsy | | 1 |
| Petechiae | 5 | 7 |
| Petit mal epilepsy | 3 | 3 |
| Pharyngeal erythema | 1 | 1 |
| Pharyngeal haemorrhage | 1 | 1 |
| Pharyngeal hypoaesthesia | 1 | 3 |
| Pharyngeal inflammation | 2 | 4 |
| Pharyngeal oedema | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 5 | 6 | 12 |
| | | 6 | 21 | 68 | 106 |
| | | | | 3 | 4 |
| | | | | 4 | 4 |
| | | | 1 | 1 | 1 |
| 1 | 1 | 13 | 57 | 88 | 125 |
| | | 13 | 37 | 32 | 63 |
| | | | | 3 | 5 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 2 |
| | | | 1 | 6 | 7 |
| | | | | | 2 |
| | | 2 | 7 | 16 | 25 |
| | | | | 1 | 2 |
| | | 12 | 28 | 59 | 93 |
| | | | | | 1 |
| | | | | 5 | 7 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 2 | 4 |
| | | | | | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pharyngeal paraesthesia | 3 | 7 |
| Pharyngeal swelling | 18 | 32 |
| Pharyngeal ulceration | 1 | 2 |
| Pharyngitis | | 1 |
| Photophobia | 16 | 33 |
| Photopsia | 3 | 3 |
| Photosensitivity reaction | 7 | 7 |
| Piloerection | 1 | 3 |
| Pleural effusion | 1 | 1 |
| Pleurisy | | 1 |
| Plicated tongue | | 1 |
| Pneumonia | 1 | 1 |
| Pneumonitis | 1 | 1 |
| Poisoning | | 1 |
| Pollakiuria | 1 | 1 |
| Polymenorrhoea | | 2 |
| Poor quality sleep | 9 | 15 |
| Postictal state | 1 | 1 |
| Post procedural complication | 1 | 1 |
| Postural orthostatic tachycardia syndrome | 1 | 1 |
| Post viral fatigue syndrome | 1 | 3 |
| Pre-existing condition improved | | 1 |
| Presyncope | 26 | 46 |
| Primary cough headache | | 1 |
| Procedural dizziness | 1 | 1 |
| Procedural nausea | | 1 |
| Product administered at inappropriate site | 1 | 1 |
| Productive cough | 9 | 10 |
| Product preparation error | 1 | 1 |
| Product taste abnormal | 1 | 1 |
| Product use issue | 96 | 117 |
| Prophylaxis of nausea and vomiting | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 3 | 6 |
| | | 1 | 6 | 17 | 26 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 3 | 9 | 13 | 24 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | 6 | 6 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | 1 |
| | | 2 | 5 | 7 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | 1 | | |
| 1 | 1 | 6 | 17 | 20 | 29 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 3 | 3 | 6 | 7 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 95 | 115 | 1 | 2 |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Pruritus | 105 | 204 |
| Psychomotor hyperactivity | 2 | 2 |
| Psychotic disorder | 1 | 1 |
| Pulmonary embolism | 2 | 2 |
| Pulmonary oedema | | 1 |
| Pulmonary pain | 2 | 3 |
| Pulmonary thrombosis | 1 | 1 |
| Pulse abnormal | 1 | 1 |
| Purpura | 2 | 2 |
| Pustule | | 1 |
| Pyelonephritis | | 1 |
| Pyrexia | 526 | 1,045 |
| Q fever | 1 | 1 |
| Radial pulse abnormal | 1 | 1 |
| Radiculopathy | | 1 |
| Rales | 1 | 2 |
| Rash | 96 | 178 |
| Rash erythematous | 33 | 62 |
| Rash macular | 12 | 32 |
| Rash maculo-papular | 3 | 4 |
| Rash morbilliform | 1 | 2 |
| Rash papular | 8 | 12 |
| Rash pruritic | 22 | 46 |
| Rash pustular | 1 | 2 |
| Rash vesicular | 3 | 4 |
| Raynaud's phenomenon | 1 | 2 |
| Reaction to preservatives | | 1 |
| Rectal haemorrhage | 2 | 3 |
| Renal pain | 6 | 12 |
| Respiration abnormal | 4 | 4 |
| Respiratory arrest | 1 | 1 |
| Respiratory disorder | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 18 | 68 | 87 | 136 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| 2 | 5 | 67 | 257 | 459 | 788 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 9 | 48 | 87 | 130 |
| | | 4 | 19 | 29 | 43 |
| | | 3 | 16 | 9 | 16 |
| | | | | 3 | 4 |
| | | | | 1 | 2 |
| | | 1 | 3 | 7 | 9 |
| | | 1 | 7 | 21 | 39 |
| | | | | 1 | 2 |
| | | | 1 | 3 | 3 |
| | | 1 | 1 | | 1 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | 1 | 5 | 5 | 7 |
| | | 1 | 1 | 3 | 3 |
| 1 | 1 | 1 | 1 | | |
| | | | | 1 | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Respiratory distress | 2 | 3 |
| Respiratory rate decreased | 1 | 1 |
| Respiratory rate increased | 3 | 6 |
| Respiratory symptom | 1 | 1 |
| Respiratory tract irritation | 1 | 2 |
| Respiratory tract oedema | 1 | 1 |
| Restless legs syndrome | 5 | 7 |
| Restlessness | 7 | 16 |
| Retching | 3 | 5 |
| Retinal migraine | 2 | 3 |
| Retinal vein occlusion | 1 | 1 |
| Rheumatoid arthritis | 2 | 3 |
| Rhinalgia | 2 | 2 |
| Rhinitis | 2 | 4 |
| Rhinitis allergic | 1 | 1 |
| Rhinorrhoea | 22 | 35 |
| Salivary gland pain | | 1 |
| Salivary hypersecretion | 1 | 3 |
| SARS-CoV-2 ant body test negative | 2 | 3 |
| SARS-CoV-2 ant body test positive | | 1 |
| SARS-CoV-2 test false positive | | 1 |
| SARS-CoV-2 test negative | 1 | 1 |
| SARS-CoV-2 test positive | 8 | 12 |
| Sciatica | 1 | 2 |
| Scleral discolouration | 1 | 1 |
| Scleroderma associated digital ulcer | 1 | 1 |
| Scratch | 2 | 2 |
| Scrotal pain | 1 | 1 |
| Secretion discharge | | 1 |
| Sedation | 2 | 3 |
| Seizure | 20 | 24 |
| Seizure cluster | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 4 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 6 |
| | | | 4 | 7 | 12 |
| | | | | 3 | 5 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 3 |
| | | 1 | 1 | | |
| | | 3 | 9 | 19 | 26 |
| | | | | | 1 |
| | | | | | |
| | | | 1 | 1 | 2 |
| | | | | | |
| | | | | | 1 |
| | | | 1 | 1 | |
| | | | | | |
| | | 1 | 1 | | |
| | | | | | |
| | | 1 | 1 | 7 | 11 |
| | | 1 | 1 | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 2 | 2 |
| | | | | 20 | 24 |
| | | | | 1 | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Sensation of foreign body | 1 | 3 |
| Sense of a foreshortened future | 1 | 1 |
| Sensitive skin | 7 | 9 |
| Sensory disturbance | 1 | 6 |
| Sensory loss | 2 | 3 |
| Sepsis | 1 | 1 |
| Sinonasal obstruction | | 1 |
| Sinus congestion | 3 | 5 |
| Sinus headache | 7 | 12 |
| Sinus pain | 6 | 12 |
| Sinus tachycardia | 3 | 9 |
| Skin abrasion | 1 | 2 |
| Skin burning sensation | 5 | 15 |
| Skin discolouration | 4 | 5 |
| Skin disorder | 2 | 3 |
| Skin erosion | 1 | 1 |
| Skin exfoliation | 1 | 2 |
| Skin irritation | 3 | 5 |
| Skin laceration | | 1 |
| Skin laxity | 1 | 1 |
| Skin lesion | 3 | 3 |
| Skin mass | 1 | 2 |
| Skin reaction | 2 | 3 |
| Skin sensitisation | | 2 |
| Skin temperature | 1 | 1 |
| Skin tightness | 2 | 6 |
| Skin warm | 8 | 16 |
| Sleep deficit | | 1 |
| Sleep disorder | 12 | 22 |
| Sleep disorder due to a general medical condition | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | 6 | 7 |
| | | | 3 | 1 | 3 |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 1 | 2 | 2 | 3 |
| | | 1 | 1 | 6 | 11 |
| | | 1 | 3 | 5 | 9 |
| | | 1 | 3 | 2 | 6 |
| | | 1 | 1 | | 1 |
| | | 1 | 3 | 4 | 12 |
| | | 1 | 2 | 3 | 3 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | 2 | 3 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | 1 | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | 1 | 3 | 1 | 3 |
| | | 1 | 3 | 7 | 13 |
| | | | | | 1 |
| | | 4 | 10 | 8 | 12 |
| | | | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Sleep disorder due to general medical condition, insomnia type | 2 | 4 |
| Sleep paralysis | 1 | 1 |
| Slow response to stimuli | 1 | 2 |
| Slow speech | 1 | 1 |
| Sluggishness | 1 | 1 |
| Sneezing | 15 | 21 |
| Snoring | | 1 |
| Somatic symptom disorder | | 1 |
| Somnolence | 35 | 58 |
| Speech disorder | 1 | 1 |
| Spinal disorder | | 1 |
| Spinal pain | 1 | 2 |
| Splenomegaly | 1 | 1 |
| Sputum abnormal | 1 | 1 |
| Sputum purulent | | 1 |
| Status epilepticus | 4 | 4 |
| Stiff leg syndrome | | 1 |
| Stiff tongue | | 1 |
| Stomatitis | 1 | 1 |
| Stridor | 1 | 1 |
| Subcutaneous abscess | 1 | 1 |
| Sudden hearing loss | | 1 |
| Suicidal ideation | 2 | 2 |
| Superficial injury of eye | | 1 |
| Superficial vein prominence | | 1 |
| Supraventricular tachycardia | 2 | 4 |
| Suspected COVID-19 | 46 | 82 |
| Sweating fever | 5 | 7 |
| Swelling | 47 | 88 |
| Swelling face | 33 | 62 |
| Swelling of eyelid | 5 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 5 | 12 | 16 |
| | | | | | 1 |
| | | | | | 1 |
| | | 7 | 19 | 28 | 39 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 2 | 4 |
| | | 7 | 10 | 39 | 72 |
| | | | | 5 | 7 |
| | | 11 | 33 | 36 | 55 |
| | | 4 | 10 | 29 | 52 |
| | | | | 5 | 6 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Swollen joint count increased | 1 | 1 |
| Swollen tongue | 19 | 41 |
| Syncope | 53 | 90 |
| Synovial cyst | 2 | 2 |
| Systemic inflammatory response syndrome | | 1 |
| Systemic lupus erythematosus | | 1 |
| Tachycardia | 41 | 106 |
| Tachypnoea | 2 | 3 |
| Taste disorder | 7 | 13 |
| Tearfulness | 2 | 3 |
| Temporomandibular joint syndrome | | 1 |
| Tenderness | 8 | 16 |
| Tendonitis | 2 | 2 |
| Tension headache | 6 | 16 |
| Terminal insomnia | 1 | 1 |
| Testicular pain | 1 | 1 |
| Testicular torsion | 1 | 1 |
| Therapeutic response unexpected | 2 | 3 |
| Thinking abnormal | 3 | 3 |
| Thirst | 10 | 17 |
| Throat clearing | | 1 |
| Throat irritation | 12 | 20 |
| Throat tightness | 23 | 46 |
| Thrombocytopenia | 1 | 2 |
| Thrombosis | | 1 |
| Tinnitus | 19 | 30 |
| Tongue biting | 1 | 1 |
| Tongue discolouration | 1 | 1 |
| Tongue discomfort | 2 | 4 |
| Tongue disorder | 3 | 4 |
| Tongue dry | | 1 |
| Tongue eruption | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 2 | 7 | 17 | 34 |
| | | | | 53 | 90 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | 4 | 24 | 37 | 82 |
| | | | | 2 | 3 |
| | | 4 | 9 | 3 | 4 |
| | | 2 | 2 | | 1 |
| | | | 1 | | |
| | | 1 | 6 | 7 | 10 |
| | | | | 2 | 2 |
| | | 1 | 3 | 5 | 13 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 3 | 3 |
| | | 1 | 4 | 9 | 13 |
| | | | | | 1 |
| | | 2 | 5 | 10 | 15 |
| | | 3 | 9 | 20 | 37 |
| | | | | 1 | 2 |
| 1 | 1 | | | | 1 |
| | | 2 | 8 | 17 | 22 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 2 | 2 |
| | | 1 | 1 | 2 | 3 |
| | | | 1 | | |
| | | | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Tongue erythema | | 1 |
| Tongue injury | 1 | 1 |
| Tongue movement disturbance | | 1 |
| Tongue oedema | 4 | 5 |
| Tongue pruritus | 1 | 2 |
| Tongue ulceration | | 3 |
| Tonic convulsion | 2 | 2 |
| Tonsillar erythema | 1 | 1 |
| Tonsillar hypertrophy | 2 | 3 |
| Tonsillar ulcer | 1 | 1 |
| Tonsillitis | | 2 |
| Tonsillitis bacterial | 1 | 2 |
| Toothache | 1 | 3 |
| Torticollis | | 1 |
| Tremor | 59 | 100 |
| Trigeminal neuralgia | 1 | 2 |
| Trismus | 2 | 2 |
| Troponin increased | 1 | 2 |
| Tunnel vision | 1 | 1 |
| Type 1 diabetes mellitus | 1 | 1 |
| Type IV hypersensitivity reaction | | 2 |
| Ulcer | 1 | 1 |
| Ulcerative keratitis | 1 | 1 |
| Ulnar nerve injury | 1 | 1 |
| Underdose | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 |
| Urinary incontinence | 3 | 4 |
| Urinary retention | 3 | 3 |
| Urinary tract infection | 7 | 8 |
| Urine flow decreased | 1 | 1 |
| Urine output increased | 1 | 1 |
| Urticaria | 43 | 81 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 4 | 4 |
| | | | | 1 | 2 |
| | | | 1 | | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 2 |
| | | 1 | 2 | | 1 |
| | | | | | 1 |
| | | 11 | 21 | 48 | 79 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 7 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 23 | 38 | 58 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Urticaria thermal | 1 | 1 |
| Uveitis | 1 | 1 |
| Vaccination complication | 3 | 6 |
| Vaccination site abscess | 2 | 3 |
| Vaccination site bruising | 10 | 19 |
| Vaccination site cellulitis | 5 | 10 |
| Vaccination site discolouration | | 2 |
| Vaccination site discomfort | 3 | 7 |
| Vaccination site dryness | 1 | 1 |
| Vaccination site erythema | 38 | 85 |
| Vaccination site haemorrhage | 2 | 3 |
| Vaccination site hyperaesthesia | 2 | 2 |
| Vaccination site hypoaesthesia | 3 | 7 |
| Vaccination site induration | 5 | 11 |
| Vaccination site infection | 3 | 3 |
| Vaccination site inflammation | 2 | 6 |
| Vaccination site joint movement impairment | 1 | 5 |
| Vaccination site joint pain | | 4 |
| Vaccination site lymphadenopathy | 4 | 5 |
| Vaccination site macule | | 1 |
| Vaccination site mass | 20 | 31 |
| Vaccination site movement impairment | 6 | 13 |
| Vaccination site necrosis | 1 | 1 |
| Vaccination site pain | 238 | 519 |
| Vaccination site paraesthesia | 4 | 6 |
| Vaccination site pruritus | 15 | 29 |
| Vaccination site rash | 6 | 19 |
| Vaccination site reaction | 3 | 12 |
| Vaccination site scar | 1 | 1 |
| Vaccination site swelling | 61 | 126 |
| Vaccination site urticaria | | 1 |
| Vaccination site vesicles | 1 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | 3 | 5 |
| | | 1 | 1 | 1 | 2 |
| | 1 | 2 | 4 | 8 | 15 |
| | | | 1 | 5 | 9 |
| | | | | | 2 |
| | | 1 | 4 | 2 | 3 |
| | | | | 1 | 1 |
| | | 10 | 34 | 28 | 51 |
| | | | | 2 | 3 |
| | | | | 2 | 2 |
| | | | 1 | 3 | 6 |
| | | 3 | 6 | 2 | 5 |
| | | | | 3 | 3 |
| | | | 2 | 2 | 4 |
| | | | 2 | 1 | 3 |
| | | | | 2 | 2 |
| | | | | 4 | 5 |
| | | | 1 | | |
| | | 3 | 10 | 17 | 21 |
| | | 4 | 7 | 2 | 6 |
| | | | | 1 | 1 |
| 1 | 3 | 39 | 177 | 199 | 342 |
| | | 2 | 4 | 2 | 2 |
| | | 5 | 15 | 10 | 14 |
| | | 2 | 9 | 4 | 10 |
| | | 1 | 6 | 2 | 6 |
| | | | | 1 | 1 |
| | | 5 | 37 | 56 | 89 |
| | | | 1 | | |
| | | | | 1 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Vaccination site warmth | 24 | 54 |
| Vaginal disorder | 1 | 1 |
| Vaginal haemorrhage | 6 | 9 |
| Vein disorder | | 1 |
| Vein rupture | | 1 |
| Ventricular extrasystoles | 2 | 5 |
| Vertigo | 30 | 44 |
| Vertigo positional | 3 | 3 |
| Viral infection | 1 | 1 |
| Viral pharyngitis | 2 | 2 |
| Viral rash | 2 | 4 |
| Viral test | 1 | 1 |
| Vision blurred | 24 | 47 |
| Visual field defect | 1 | 3 |
| Visual impairment | 7 | 15 |
| Vital capacity | 1 | 1 |
| Vitreous detachment | 1 | 1 |
| Vitreous floaters | 1 | 2 |
| Vocal cord disorder | | 1 |
| Vomiting | 107 | 199 |
| Vomiting projectile | 2 | 4 |
| Vulvovaginal candidiasis | | 1 |
| Weight bearing difficulty | 1 | 1 |
| Weight decreased | 5 | 5 |
| Wheezing | 23 | 40 |
| White blood cell count decreased | | 1 |
| Yawning | 2 | 2 |
| Yellow skin | | 1 |
| | 2 | 8 |
| | 11,414 | 20,173 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 7 | 21 | 17 | 33 |
| | | 1 | 1 | | |
| | | | | 6 | 9 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 2 | 1 | 3 |
| | | | 4 | 30 | 40 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | | 13 | 24 | 34 |
| | | | 1 | 1 | 2 |
| | | 2 | 3 | 5 | 12 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | | 1 |
| | 1 | 15 | 53 | 92 | 146 |
| | | | 1 | 2 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | 5 | 11 | 18 | 29 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 2 | 8 | | |
| | | 30 | 53 | 1785 | 5311 |
| | | | | 9629 | 14862 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 17 | 22 | | | 2 | 5 | 15 | 17 |
| Abdominal distension | 4 | 6 | | | 1 | 1 | 3 | 5 |
| Abdominal pain | 19 | 35 | | | 2 | 10 | 17 | 25 |
| Abdominal pain lower | 1 | 2 | | | | 1 | 1 | 1 |
| Abdominal pain upper | 44 | 58 | | | 4 | 6 | 40 | 52 |
| Abdominal tenderness | | 2 | | | | 2 | | |
| Abnormal dreams | | 3 | | | | 1 | | 2 |
| Abnormal sensation in eye | | 1 | | | | | | 1 |
| Abscess | 1 | 1 | | | 1 | 1 | | |
| Abscess oral | 1 | 1 | | | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | | | 1 | 1 |
| Adrenocortical insufficiency acute | 1 | 1 | | | | | 1 | 1 |
| Adverse drug reaction | 2 | 3 | | | | 1 | 2 | 2 |
| Ageusia | 4 | 12 | | | | 2 | 4 | 10 |
| Agitation | | 2 | | | | 1 | | 1 |
| Airway burns | 1 | 1 | | | | | 1 | 1 |
| Alanine aminotransferase increased | | 1 | | | | 1 | | |
| Allergic cough | | 1 | | | | | | 1 |
| Allergic oedema | | 1 | | | | | | 1 |
| Allergy to vaccine | 3 | 8 | | | 1 | 5 | 2 | 3 |
| Altered state of consciousness | 2 | 2 | | | | | 2 | 2 |
| Amblyopia | | 1 | | | | 1 | | |
| Amnesia | 1 | 1 | | | | | 1 | 1 |
| Anaemia | 1 | 1 | | | 1 | 1 | | |
| Anaphylactic reaction | 25 | 36 | | | | | 25 | 36 |
| Anaphylactic shock | | 2 | | | | | | 2 |
| Anaphylactoid reaction | 1 | 3 | | | | | 1 | 3 |
| Angioedema | 7 | 11 | | | | | 7 | 11 |
| Anisocytosis | 1 | 1 | | | | | 1 | 1 |
| Anosmia | 7 | 11 | | | | 3 | 7 | 8 |
| Anxiety | 7 | 17 | | | 2 | 8 | 5 | 9 |
| Aortic stenosis | 1 | 1 | | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Apathy | 1 | 1 |
| Aphonia | 2 | 3 |
| Apparent death | 1 | 1 |
| Appetite disorder | | 1 |
| Arrhythmia | 1 | 2 |
| Arrhythmia supraventricular | | 1 |
| Arteritis | 1 | 1 |
| Arthralgia | 177 | 330 |
| Arthritis | 4 | 6 |
| Arthropathy | 2 | 2 |
| Aspiration | 1 | 1 |
| Asthenia | 51 | 76 |
| Asthenopia | 1 | 2 |
| Asthma | 8 | 10 |
| Ataxia | 1 | 1 |
| Atrial fibrillation | 3 | 6 |
| Atrial flutter | 1 | 1 |
| Atypical femur fracture | 1 | 1 |
| Aura | | 1 |
| Auricular swelling | | 1 |
| Autoimmune haemolytic anaemia | 1 | 1 |
| Autoscopy | 1 | 1 |
| Axillary mass | 1 | 4 |
| Axillary pain | 23 | 33 |
| Back pain | 51 | 78 |
| Bacterial diarrhoea | 1 | 1 |
| Balance disorder | 14 | 17 |
| Bedridden | 1 | 1 |
| Bladder discomfort | | 1 |
| Bladder irritation | 1 | 1 |
| Blindness | 3 | 3 |
| Blister | 5 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 23 | 74 | 154 | 256 |
| | | | 2 | 4 | 4 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 10 | 18 | 41 | 58 |
| | | | | 1 | 2 |
| | | 1 | 2 | 7 | 8 |
| | | | | 1 | 1 |
| | | | | 3 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 2 |
| | | 3 | 8 | 20 | 25 |
| | | 5 | 14 | 46 | 64 |
| | | | | 1 | 1 |
| | | 1 | 1 | 13 | 16 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | 2 | 5 | 6 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Blood alkaline phosphatase increased | | 1 |
| Blood creatinine increased | 1 | 1 |
| Blood glucose decreased | 1 | 2 |
| Blood glucose increased | 3 | 4 |
| Blood pH increased | | 1 |
| Blood pressure decreased | 2 | 4 |
| Blood pressure increased | 8 | 19 |
| Blood pressure systolic decreased | 1 | 2 |
| Blood pressure systolic increased | 1 | 3 |
| Blood urine present | 1 | 1 |
| Body temperature abnormal | 4 | 11 |
| Body temperature decreased | 7 | 7 |
| Body temperature fluctuation | 2 | 5 |
| Body temperature increased | 14 | 31 |
| Bone pain | 9 | 17 |
| Bradypnea | 1 | 1 |
| Breast discomfort | | 1 |
| Breast pain | 7 | 8 |
| Breast swelling | 2 | 4 |
| Breast tenderness | 2 | 2 |
| Breath sounds abnormal | 1 | 1 |
| Bronchial disorder | 1 | 1 |
| Bronchitis | 1 | 1 |
| Bronchopulmonary aspergillosis | 1 | 1 |
| Burning sensation | 7 | 13 |
| Burn oesophageal | 1 | 1 |
| Bursitis | 2 | 2 |
| Cardiac arrest | 1 | 2 |
| Cardiac disorder | 1 | 1 |
| Cardiac failure | 1 | 1 |
| Cardiac flutter | 1 | 3 |
| Cataplexy | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 3 | 4 |
| | | | 1 | | |
| | | | | 2 | 4 |
| | | 4 | 8 | 4 | 11 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 3 | 3 | 8 |
| | | | | 7 | 7 |
| | | 1 | 2 | 1 | 3 |
| | 1 | 6 | 14 | 8 | 17 |
| | | 2 | 3 | 7 | 14 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 6 | 7 |
| | | 1 | 3 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 7 | 11 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Cellulitis | 6 | 12 |
| Cerebellar infarction | | 1 |
| Cerebral haemorrhage | 2 | 2 |
| Cerebrovascular accident | 3 | 4 |
| Chapped lips | 1 | 2 |
| Cheilitis | | 1 |
| Chest crushing | 1 | 1 |
| Chest discomfort | 23 | 37 |
| Chest pain | 38 | 61 |
| Chills | 235 | 427 |
| Choroidal neovascularisation | 2 | 2 |
| Chromaturia | 4 | 4 |
| Chronic fatigue syndrome | 1 | 2 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Circulatory collapse | | 4 |
| Clostridium difficile colitis | | 1 |
| Cluster headache | 3 | 4 |
| Coccydynia | 1 | 1 |
| Cognitive disorder | 3 | 3 |
| Cold sweat | 12 | 23 |
| Colitis | 1 | 1 |
| Colitis microscopic | 1 | 1 |
| Colitis ulcerative | 1 | 1 |
| Communication disorder | 1 | 1 |
| Condition aggravated | 8 | 16 |
| Confusional state | 15 | 19 |
| Conjunctival haemorrhage | 1 | 2 |
| Conjunctivitis | 3 | 4 |
| Constipation | 1 | 1 |
| Contusion | 8 | 8 |
| Coordination abnormal | 3 | 3 |
| Corneal reflex decreased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 6 | 12 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 3 | 4 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 2 | 8 | 21 | 29 |
| | | 4 | 11 | 34 | 50 |
| | | 25 | 96 | 210 | 331 |
| | | | | 2 | 2 |
| | | 3 | 3 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 4 |
| | | | | | 1 |
| | | | | 3 | 4 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 4 | 11 | 19 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 5 | 7 | 11 |
| | | | | 15 | 19 |
| | | | | 1 | 2 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | 2 | 2 | 6 | 6 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Coronary artery disease | | 1 |
| Costochondritis | 1 | 1 |
| Cough | 59 | 91 |
| COVID-19 | 16 | 33 |
| COVID-19 pneumonia | | 1 |
| Cranial nerve disorder | 1 | 1 |
| C-reactive protein increased | 1 | 1 |
| Crohn's disease | 4 | 4 |
| Crying | 2 | 2 |
| Cyanosis | | 2 |
| Cystitis | 2 | 2 |
| Deafness | 1 | 1 |
| Deafness neurosensory | 1 | 1 |
| Death | 2 | 5 |
| Decreased appetite | 43 | 63 |
| Decreased immune responsiveness | 1 | 1 |
| Decreased interest | | 1 |
| Deep vein thrombosis | 1 | 1 |
| Dehydration | 1 | 2 |
| Delirium | 2 | 2 |
| Depressed level of consciousness | 1 | 2 |
| Depressed mood | 2 | 2 |
| Depression | 1 | 1 |
| Derealisation | | 1 |
| Dermatitis | 2 | 2 |
| Dermatitis allergic | 2 | 7 |
| Diabetes mellitus | 1 | 1 |
| Diabetic ketoacidosis | | 1 |
| Diarrhoea | 101 | 162 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplopia | 5 | 7 |
| Discoloured vomit | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 9 | 18 | 50 | 73 |
| | | 1 | 1 | 15 | 32 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 5 |
| | | 11 | 17 | 32 | 46 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 4 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 14 | 34 | 87 | 128 |
| | | | | 1 | 1 |
| | | | 1 | 5 | 6 |
| | | | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Discomfort | 8 | 11 |
| Disease recurrence | 13 | 16 |
| Disorientation | 9 | 11 |
| Dissociation | 2 | 2 |
| Disturbance in attention | 12 | 18 |
| Dizziness | 138 | 237 |
| Dizziness exertional | 5 | 5 |
| Dizziness postural | 18 | 27 |
| Droling | 2 | 3 |
| Drug eruption | | 1 |
| Drug hypersensitivity | 1 | 2 |
| Drug ineffective | 20 | 50 |
| Dry eye | 2 | 4 |
| Dry mouth | 8 | 19 |
| Dry skin | 1 | 1 |
| Dry throat | 5 | 7 |
| Dysarthria | 2 | 4 |
| Dysgeusia | 17 | 33 |
| Dyskinesia | 1 | 2 |
| Dyspepsia | 1 | 3 |
| Dysphagia | 3 | 9 |
| Dysphonia | 4 | 9 |
| Dyspnoea | 71 | 99 |
| Dyspnoea exertional | 2 | 3 |
| Dysstasia | 5 | 8 |
| Dystonia | 1 | 1 |
| Dysuria | 1 | 1 |
| Ear discomfort | 2 | 3 |
| Ear infection | 2 | 3 |
| Ear pain | 12 | 18 |
| Ear pruritus | 1 | 1 |
| Eating disorder | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 4 | 6 | 7 |
| | | | | 13 | 16 |
| | | 1 | 2 | 8 | 9 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | 12 | 17 |
| 2 | 2 | 16 | 46 | 122 | 191 |
| | | | | 5 | 5 |
| | | | 3 | 18 | 24 |
| | | 1 | 1 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 20 | 50 |
| | | | 2 | 2 | 2 |
| | | 1 | 6 | 7 | 13 |
| | | | | 1 | 1 |
| | | | | 5 | 7 |
| | | 1 | 1 | 1 | 3 |
| | | 6 | 19 | 11 | 14 |
| | | | | 1 | 2 |
| | | | 2 | 1 | 1 |
| | | | 2 | 3 | 7 |
| | | 2 | 3 | 2 | 6 |
| | | 7 | 14 | 64 | 85 |
| | | 1 | 1 | 1 | 2 |
| | | 2 | 3 | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | 1 | 3 | 11 | 15 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Eating disorder symptom | 1 | 1 |
| Eczema | 1 | 2 |
| Electric shock | 1 | 1 |
| Embolism | 1 | 1 |
| Emotional distress | 2 | 3 |
| Encephalitis | 1 | 1 |
| Enlarged uvula | 1 | 2 |
| Enuresis | | 1 |
| Eosinophilia | | 1 |
| Epicondylitis | 1 | 1 |
| Epigastric discomfort | 1 | 1 |
| Epilepsy | 2 | 3 |
| Epiphyses premature fusion | 1 | 1 |
| Episcleritis | | 1 |
| Epistaxis | 5 | 7 |
| Erectile dysfunction | 1 | 1 |
| Eructation | 2 | 3 |
| Erythema | 31 | 56 |
| Erythema multiforme | | 1 |
| Erythema nodosum | 1 | 1 |
| Euphoric mood | 1 | 1 |
| Exposure during pregnancy | 1 | 2 |
| Exposure to SARS-CoV-2 | 1 | 1 |
| Eye disorder | 1 | 5 |
| Eye haematoma | 1 | 1 |
| Eye haemorrhage | 1 | 2 |
| Eye inflammation | 1 | 1 |
| Eye injury | | 1 |
| Eye irritation | 2 | 3 |
| Eyelid ptosis | 1 | 2 |
| Eyelids pruritus | | 1 |
| Eye movement disorder | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 2 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | 3 | 20 | 28 | 36 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | 2 | 1 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eye pain | 21 | 30 |
| Eye pruritus | 4 | 9 |
| Eye swelling | 12 | 18 |
| Face oedema | 1 | 1 |
| Facial asymmetry | 1 | 1 |
| Facial discomfort | 1 | 2 |
| Facial neuralgia | 2 | 2 |
| Facial pain | 5 | 9 |
| Facial paralysis | 23 | 34 |
| Facial paresis | 3 | 4 |
| Facial spasm | | 1 |
| Faeces discoloured | 1 | 1 |
| Faeces pale | 1 | 1 |
| Fall | 6 | 8 |
| Fatigue | 423 | 695 |
| Fear | | 1 |
| Feeding disorder | 8 | 11 |
| Feeling abnormal | 39 | 67 |
| Feeling cold | 33 | 67 |
| Feeling drunk | 1 | 2 |
| Feeling hot | 32 | 61 |
| Feeling jittery | 1 | 1 |
| Feeling of body temperature change | 11 | 17 |
| Fibromyalgia | 3 | 3 |
| Fixed eruption | | 1 |
| Flatulence | 3 | 3 |
| Flushing | 10 | 22 |
| Food allergy | 1 | 1 |
| Food craving | 1 | 1 |
| Forced expiratory volume increased | 1 | 1 |
| Foreign body sensation in eyes | 1 | 2 |
| Formication | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 6 | 17 | 24 |
| | | 2 | 3 | 2 | 6 |
| | | 1 | 4 | 11 | 14 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | 1 |
| | | | | 2 | 2 |
| | | | 2 | 5 | 7 |
| | | | 1 | 23 | 33 |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | 6 | 7 |
| 2 | 3 | 62 | 165 | 361 | 530 |
| | | | | | 1 |
| | | 2 | 4 | 6 | 7 |
| | | 8 | 19 | 31 | 48 |
| | | 4 | 17 | 29 | 50 |
| | | | | 1 | 2 |
| | | 8 | 25 | 24 | 36 |
| | | | | 1 | 1 |
| | | 1 | 1 | 10 | 16 |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | | 8 | 10 | 14 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Frequent bowel movements | 1 | 1 |
| Full blood count abnormal | 1 | 1 |
| Furuncle | 1 | 1 |
| Gait disturbance | 9 | 11 |
| Gait inability | 4 | 6 |
| Gastric disorder | 1 | 3 |
| Gastric varices haemorrhage | 1 | 1 |
| Gastritis | | 1 |
| Gastrointestinal disorder | 1 | 1 |
| Gastrointestinal haemorrhage | 1 | 1 |
| Gastrointestinal pain | | 2 |
| Gastrooesophageal reflux disease | 3 | 3 |
| Generalised tonic-clonic seizure | 1 | 3 |
| Genital herpes | | 1 |
| Gingival bleeding | | 1 |
| Gingival discomfort | 1 | 1 |
| Gingival pain | 2 | 4 |
| Glossodynia | 4 | 7 |
| Goitre | 1 | 1 |
| Gout | 1 | 2 |
| Grip strength decreased | 2 | 3 |
| Groin pain | 1 | 3 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematemesis | 1 | 1 |
| Haematochezia | 2 | 2 |
| Haematoma | | 1 |
| Haematuria | 1 | 1 |
| Haemoptysis | 1 | 1 |
| Haemorrhage | 2 | 2 |
| Hallucination | 5 | 6 |
| Hallucinations, mixed | 1 | 1 |
| Hangover | | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | 8 | 9 |
| | | | | 4 | 6 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | 1 | 4 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 5 | 6 |
| | | | | 1 | 1 |
| | | | 2 | | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Headache | 523 | 926 |
| Head banging | 1 | 1 |
| Head discomfort | 3 | 6 |
| Head injury | 1 | 2 |
| Heart rate abnormal | | 1 |
| Heart rate decreased | 3 | 4 |
| Heart rate increased | 22 | 36 |
| Heart rate irregular | | 1 |
| Heat illness | | 1 |
| Hepatic pain | 1 | 1 |
| Hepatitis | 1 | 2 |
| Herpes simplex | | 1 |
| Herpes virus infection | | 1 |
| Herpes zoster | 23 | 30 |
| Herpes zoster oticus | | 1 |
| Herpes zoster reactivation | | 1 |
| Hot flush | 9 | 17 |
| Hyperacusis | 1 | 1 |
| Hyperaesthesia | 1 | 4 |
| Hyperglycaemia | 1 | 1 |
| Hyperhidrosis | 52 | 83 |
| Hyperpyrexia | 1 | 1 |
| Hypersensitivity | 10 | 25 |
| Hypersomnia | 13 | 16 |
| Hypertension | 17 | 34 |
| Hypertensive crisis | | 1 |
| Hypertonic bladder | | 1 |
| Hypoacusis | 1 | 2 |
| Hypoesthesia | 30 | 51 |
| Hypoesthesia oral | 5 | 16 |
| Hypoglycaemia | 3 | 4 |
| Hypokinesia | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 2 | 4 | 64 | 208 | 459 | 718 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 5 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 3 |
| | | 4 | 9 | 18 | 27 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 23 | 29 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 6 | 8 | 11 |
| | | | | 1 | 1 |
| | | | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 17 | 47 | 66 |
| | | | | 1 | 1 |
| | | | 7 | 10 | 18 |
| | | 3 | 4 | 10 | 12 |
| | | 2 | 9 | 15 | 25 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | 8 | 22 | 22 | 29 |
| | | 1 | 7 | 4 | 9 |
| | | | | 3 | 4 |
| | | | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypophagia | 1 | 1 |
| Hypopnoea | 3 | 3 |
| Hyposmia | 1 | 2 |
| Hypotension | 9 | 17 |
| Hypothermia | 1 | 2 |
| Hypoxia | 1 | 2 |
| Illrd nerve paralysis | 2 | 2 |
| Illness | 33 | 44 |
| Immune-mediated adverse reaction | | 1 |
| Immune system disorder | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Impaired driving ability | 3 | 3 |
| Impaired work ability | 3 | 3 |
| Impetigo | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 4 |
| Incontinence | 1 | 1 |
| Incorrect dose administered | 1 | 1 |
| Incorrect route of product administration | 1 | 4 |
| Increased upper airway secretion | 1 | 1 |
| Infection | 2 | 2 |
| Inflammation | 7 | 10 |
| Inflammatory marker increased | 1 | 1 |
| Influenza | 24 | 38 |
| Influenza like illness | 64 | 116 |
| Initial insomnia | 1 | 2 |
| Injection site erythema | | 2 |
| Injection site pain | 2 | 9 |
| Injection site pruritus | | 1 |
| Injection site swelling | | 2 |
| Injury corneal | | 1 |
| Insomnia | 39 | 56 |
| International normalised ratio increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 2 |
| | | | 1 | 9 | 16 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | 5 | 7 | 28 | 37 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 4 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 3 | 7 | 7 |
| | | 1 | 1 | | |
| | | 2 | 6 | 22 | 32 |
| | | 9 | 31 | 55 | 85 |
| | | | 1 | 1 | 1 |
| | | | 2 | | |
| | | | 4 | 2 | 5 |
| | | | 1 | | |
| | | | 2 | | |
| | | | | | 1 |
| 1 | 1 | 10 | 17 | 29 | 39 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Intraocular pressure increased | | 1 |
| Iridocyclitis | 1 | 2 |
| Iritis | 1 | 1 |
| Irritability | 2 | 3 |
| Ischaemic stroke | | 1 |
| Joint effusion | 2 | 2 |
| Joint noise | | 1 |
| Joint range of motion decreased | 7 | 12 |
| Joint stiffness | 6 | 9 |
| Joint swelling | 6 | 12 |
| Ketoacidosis | 1 | 1 |
| Labile blood pressure | 1 | 1 |
| Labyrinthitis | | 4 |
| Lacrimation increased | 6 | 7 |
| Lethargy | 39 | 76 |
| Ligament sprain | 1 | 2 |
| Limb discomfort | 31 | 46 |
| Limb mass | 2 | 2 |
| Lip blister | 1 | 2 |
| Lip disorder | | 1 |
| Lip dry | 1 | 2 |
| Lip pruritus | | 1 |
| Lip scab | 1 | 1 |
| Lip swelling | 15 | 26 |
| Livedo reticularis | 3 | 3 |
| Liver function test abnormal | 1 | 1 |
| Liver function test increased | 1 | 2 |
| Liver injury | | 1 |
| Localised oedema | 1 | 1 |
| Local reaction | 2 | 6 |
| Loss of bladder sensation | 1 | 1 |
| Loss of consciousness | 9 | 12 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 3 | 6 | 9 |
| | | 1 | 1 | 5 | 8 |
| | | 2 | 4 | 4 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 3 |
| | | | 1 | 6 | 6 |
| | | 6 | 18 | 33 | 58 |
| | | | | 1 | 2 |
| | | 11 | 20 | 20 | 26 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 5 | 14 | 21 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 2 | 2 | 4 |
| | | | | 1 | 1 |
| | | | | 9 | 12 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Loss of personal independence in daily activities | 6 | 6 |
| Lower respiratory tract infection | 4 | 4 |
| Lymphadenitis | 4 | 4 |
| Lymphadenopathy | 84 | 149 |
| Lymph node pain | 17 | 37 |
| Lymphoedema | 2 | 3 |
| Lymphoma | 1 | 1 |
| Malaise | 176 | 299 |
| Mass | | 1 |
| Mast cell activation syndrome | 1 | 1 |
| Mastication disorder | | 1 |
| Maternal exposure during pregnancy | 4 | 4 |
| Medial tibial stress syndrome | 1 | 1 |
| Medication overuse headache | | 1 |
| Melaena | 1 | 1 |
| Memory impairment | 1 | 1 |
| Meningitis | 2 | 2 |
| Menopausal symptoms | | 1 |
| Mental disorder | 1 | 1 |
| Mental fatigue | 2 | 2 |
| Mental impairment | | 2 |
| Micturition disorder | | 1 |
| Middle insomnia | 3 | 5 |
| Migraine | 39 | 64 |
| Migraine with aura | 3 | 4 |
| Mobility decreased | 9 | 15 |
| Monoparesis | 4 | 4 |
| Monoplegia | 1 | 1 |
| Mood disorder due to a general medical condition | 1 | 1 |
| Morning sickness | 1 | 1 |
| Motion sickness | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 5 | 5 |
| | | | | 4 | 4 |
| | | 1 | 1 | 3 | 3 |
| | | 13 | 44 | 71 | 105 |
| | | 4 | 10 | 13 | 27 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 25 | 66 | 151 | 233 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | | | | 2 |
| | | | | | 1 |
| | | | 1 | 3 | 4 |
| | | 1 | 8 | 38 | 56 |
| | | | 1 | 3 | 3 |
| | | 2 | 4 | 7 | 11 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Motor dysfunction | 2 | 2 |
| Mouth swelling | 3 | 6 |
| Mouth ulceration | 6 | 8 |
| Movement disorder | 4 | 5 |
| Multiple sclerosis relapse | 1 | 1 |
| Muscle contractions involuntary | | 1 |
| Muscle fatigue | 7 | 8 |
| Muscle rigidity | 3 | 3 |
| Muscle spasms | 14 | 20 |
| Muscle strain | 1 | 2 |
| Muscle swelling | | 1 |
| Muscle tightness | 3 | 4 |
| Muscle twitching | 3 | 5 |
| Muscular weakness | 17 | 28 |
| Musculoskeletal chest pain | 5 | 5 |
| Musculoskeletal discomfort | 3 | 4 |
| Musculoskeletal pain | 1 | 6 |
| Musculoskeletal stiffness | 18 | 46 |
| Mutism | 2 | 2 |
| Myalgia | 232 | 434 |
| Myocardial infarction | 1 | 2 |
| Myocardial ischaemia | 1 | 1 |
| Myocarditis | | 1 |
| Myofascial pain syndrome | | 1 |
| Nail discolouration | | 1 |
| Nasal congestion | 6 | 6 |
| Nasal discomfort | 4 | 5 |
| Nasal obstruction | | 1 |
| Nasal odour | 1 | 2 |
| Nasal oedema | 2 | 2 |
| Nasal pruritus | | 1 |
| Nasopharyngitis | 11 | 20 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | | | 3 | 6 |
| | | 1 | 2 | 5 | 6 |
| | | | 1 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 6 | 7 |
| | | | | 3 | 3 |
| | | | 4 | 14 | 16 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 3 |
| | | 1 | 3 | 2 | 2 |
| | | 7 | 9 | 10 | 19 |
| | | 1 | 1 | 4 | 4 |
| | | 1 | 1 | 2 | 3 |
| | | | 1 | 1 | 5 |
| | | 4 | 14 | 14 | 32 |
| | | 1 | 1 | 1 | 1 |
| 1 | 2 | 22 | 92 | 210 | 342 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 6 | 6 |
| | | | 1 | 4 | 4 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 4 | 7 | 7 | 13 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Nausea | 277 | 489 |
| Neck mass | 1 | 2 |
| Neck pain | 49 | 78 |
| Nerve degeneration | 1 | 1 |
| Nerve injury | 1 | 1 |
| Nervousness | 11 | 13 |
| Neuralgia | 4 | 6 |
| Neurogenic shock | 1 | 1 |
| Neuropathy peripheral | 2 | 2 |
| Neutropenia | 1 | 1 |
| Nightmare | 3 | 4 |
| Night sweats | 8 | 13 |
| Noninfective gingivitis | 1 | 1 |
| Occupational exposure to SARS-CoV-2 | | 1 |
| Ocular hyperaemia | 4 | 8 |
| Oedema | | 1 |
| Oedema mouth | | 1 |
| Oedema peripheral | 1 | 1 |
| Off label use | 55 | 63 |
| Optic neuritis | 1 | 1 |
| Oral blood blister | | 1 |
| Oral candidiasis | | 1 |
| Oral discomfort | 3 | 4 |
| Oral disorder | 2 | 2 |
| Oral herpes | 6 | 9 |
| Oral mucosal blistering | 2 | 2 |
| Oral mucosal erythema | | 1 |
| Oral pain | 7 | 10 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal blistering | 1 | 1 |
| Oropharyngeal discomfort | 2 | 2 |
| Oropharyngeal pain | 51 | 81 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 3 | 3 | 28 | 107 | 249 | 382 |
| | | 1 | 1 | | 1 |
| | | 11 | 27 | 38 | 51 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 9 | 11 |
| | | 1 | 2 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | 3 | 8 | 10 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | 4 | 7 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 53 | 61 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | |
| | | | | 3 | 4 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 5 | 8 |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | | | 7 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 6 | 17 | 45 | 64 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Orthostatic hypotension | | 1 |
| Osteoarthritis | | 1 |
| Overdose | 2 | 2 |
| Oversensing | 1 | 1 |
| Oxygen saturation decreased | 9 | 11 |
| Pain | 150 | 249 |
| Painful respiration | 4 | 4 |
| Pain in extremity | 200 | 357 |
| Pain in jaw | 5 | 7 |
| Pain of skin | 9 | 12 |
| Pallor | 9 | 14 |
| Palpitations | 27 | 48 |
| Pancreatitis necrotising | 1 | 1 |
| Panic disorder | | 1 |
| Panic reaction | 2 | 2 |
| Papilloedema | 1 | 1 |
| Paraesthesia | 50 | 86 |
| Paraesthesia oral | 29 | 62 |
| Paralysis | 2 | 3 |
| Paranoia | | 1 |
| Parosmia | 4 | 5 |
| Parotid gland enlargement | | 1 |
| Parotitis | 1 | 2 |
| Pelvic pain | 3 | 4 |
| Periarthritis | | 1 |
| Periorbital oedema | 1 | 1 |
| Periorbital swelling | 3 | 5 |
| Peripheral coldness | 9 | 14 |
| Peripheral swelling | 42 | 67 |
| Peroneal nerve palsy | 1 | 1 |
| Pharyngeal hypoaesthesia | | 1 |
| Pharyngeal paraesthesia | 2 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 9 | 11 |
| | | 34 | 75 | 116 | 174 |
| | | | | 4 | 4 |
| | | 28 | 99 | 172 | 258 |
| | | | 2 | 5 | 5 |
| | | | | 9 | 12 |
| | | 1 | 3 | 8 | 11 |
| | | 1 | 10 | 26 | 38 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 8 | 29 | 42 | 57 |
| | | 5 | 24 | 24 | 38 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | 1 | 4 | 4 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 2 | 3 | 3 |
| | | 3 | 5 | 6 | 9 |
| | | 4 | 17 | 38 | 50 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 3 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pharyngeal swelling | 5 | 7 |
| Pharyngeal ulceration | 1 | 1 |
| Pharyngitis streptococcal | | 1 |
| Photophobia | 3 | 6 |
| Photopsia | 1 | 2 |
| Photosensitivity reaction | 1 | 1 |
| Physical deconditioning | 1 | 1 |
| Piloerection | | 1 |
| Platelet anisocytosis | 1 | 1 |
| Pleuritic pain | 1 | 3 |
| Pneumonia | 2 | 4 |
| Pneumonitis | 1 | 1 |
| Pollakiuria | 2 | 2 |
| Polymerase chain reaction positive | 1 | 1 |
| Polymyalgia rheumatica | 1 | 2 |
| Polymyositis | 1 | 1 |
| Poor quality product administered | 1 | 1 |
| Poor quality sleep | 6 | 8 |
| Post lumbar puncture syndrome | | 1 |
| Postmenopausal haemorrhage | 1 | 1 |
| Postprandial hypoglycaemia | 1 | 1 |
| Presyncope | 5 | 14 |
| Proctitis ulcerative | | 1 |
| Product administered at inappropriate site | 2 | 3 |
| Product dose omission issue | 1 | 1 |
| Productive cough | 7 | 8 |
| Product use issue | 58 | 67 |
| Pruritus | 48 | 82 |
| Pseudolymphoma | | 1 |
| Psoriasis | 1 | 1 |
| Psoriatic arthropathy | | 1 |
| Psychiatric symptom | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 5 | 6 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 3 | 6 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 6 | 7 |
| | | | | | 1 |
| | | 2 | 2 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 6 | 7 |
| | | 56 | 65 | 2 | 2 |
| | | 6 | 25 | 42 | 57 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Pulmonary embolism | 2 | 3 |
| Pulmonary infarction | 1 | 2 |
| Pulmonary pain | 8 | 9 |
| Pupillary disorder | 1 | 1 |
| Pustular psoriasis | 1 | 1 |
| Pyrexia | 261 | 499 |
| Q fever | 2 | 2 |
| Rash | 40 | 73 |
| Rash erythematous | 14 | 25 |
| Rash macular | 2 | 10 |
| Rash maculo-papular | | 1 |
| Rash morbilliform | 1 | 1 |
| Rash papular | 3 | 9 |
| Rash pruritic | 14 | 22 |
| Rash vesicular | 1 | 2 |
| Raynaud's phenomenon | 1 | 1 |
| Rectal haemorrhage | 1 | 2 |
| Red blood cell sedimentation rate increased | 1 | 1 |
| Renal failure | 1 | 1 |
| Renal pain | 6 | 7 |
| Respiration abnormal | 2 | 3 |
| Respiratory disorder | 2 | 5 |
| Respiratory rate increased | 4 | 7 |
| Respiratory tract oedema | 1 | 1 |
| Restless legs syndrome | 1 | 1 |
| Restlessness | 3 | 7 |
| Retching | 2 | 7 |
| Retinal haemorrhage | 2 | 2 |
| Retinal migraine | 1 | 1 |
| Retinal toxicity | 1 | 1 |
| Retinal vein occlusion | 1 | 1 |
| Reversible airways obstruction | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 3 |
| | | | | 1 | 2 |
| | | 1 | 1 | 7 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 2 | 2 | 17 | 99 | 244 | 400 |
| | | | | 2 | 2 |
| | | 7 | 22 | 33 | 51 |
| | | 1 | 5 | 13 | 20 |
| | | | 5 | 2 | 5 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 5 | 3 | 4 |
| | | 2 | 5 | 12 | 17 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 2 | 2 | 4 | 5 |
| | | | 1 | 2 | 2 |
| | | | 1 | 2 | 4 |
| | | | | 4 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 3 | 5 |
| | | | 1 | 2 | 6 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Rheumatoid arthritis | 1 | 2 |
| Rhinalgia | 1 | 1 |
| Rhinitis | 3 | 4 |
| Rhinitis allergic | 1 | 2 |
| Rhinorrhoea | 7 | 11 |
| Road traffic accident | 1 | 1 |
| Rotator cuff syndrome | 1 | 1 |
| Sacroiliitis | | 1 |
| Salivary hypersecretion | 1 | 5 |
| Salt craving | 1 | 1 |
| Sarcoidosis | 1 | 1 |
| SARS-CoV-2 ant body test | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 2 |
| Scrotal erythema | | 1 |
| Scrotal exfoliation | | 1 |
| Scrotal pain | | 1 |
| Scrotal swelling | | 1 |
| Seasonal allergy | 2 | 2 |
| Seizure | 5 | 7 |
| Sensation of foreign body | 4 | 4 |
| Sensitive skin | 2 | 4 |
| Sensitivity to weather change | 1 | 1 |
| Sensory disturbance | 2 | 6 |
| Sepsis | | 1 |
| Serum ferritin increased | 1 | 1 |
| Shock | 1 | 1 |
| Shoulder injury related to vaccine administration | 1 | 1 |
| Sinus congestion | 1 | 1 |
| Sinus headache | 4 | 5 |
| Sinusitis | 2 | 2 |
| Sinus pain | 2 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 2 |
| 1 | 1 | 2 | 5 | 5 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 2 | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 5 | 7 |
| | | | | 4 | 4 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | 1 | 4 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 4 | 4 |
| | | | | 2 | 2 |
| | | | 1 | 2 | 3 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Sinus tachycardia | 1 | 2 |
| Sjogren's syndrome | 1 | 2 |
| Skin burning sensation | 2 | 4 |
| Skin discolouration | 1 | 2 |
| Skin disorder | 1 | 1 |
| Skin erosion | 1 | 1 |
| Skin exfoliation | 1 | 2 |
| Skin induration | | 1 |
| Skin irritation | 2 | 2 |
| Skin lesion | | 2 |
| Skin mass | 1 | 1 |
| Skin reaction | 1 | 2 |
| Skin swelling | 3 | 5 |
| Skin tightness | | 2 |
| Skin warm | 3 | 10 |
| Sleep attacks | | 1 |
| Sleep disorder | 5 | 14 |
| Sleep disorder due to a general medical condition | | 1 |
| Sleep disorder due to general medical condition, insomnia type | 4 | 5 |
| Sneezing | 4 | 11 |
| Somnolence | 18 | 36 |
| Speech disorder | 4 | 5 |
| Spinal pain | 1 | 2 |
| Stoma site discharge | | 1 |
| Stomatitis | 1 | 1 |
| Stress | 2 | 2 |
| Subarachnoid haemorrhage | 1 | 1 |
| Submaxillary gland enlargement | | 1 |
| Sudden death | 1 | 1 |
| Suffocation feeling | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 4 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 3 | 5 |
| | | | | | 2 |
| | | | 3 | 3 | 7 |
| | | | | | 1 |
| | | 2 | 9 | 3 | 5 |
| | | | | | 1 |
| | | 1 | 2 | 3 | 3 |
| | | 1 | 8 | 3 | 3 |
| | | 5 | 11 | 13 | 25 |
| | | 1 | 1 | 3 | 4 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Sunburn | 1 | 1 |
| Suprapubic pain | 1 | 1 |
| Supraventricular tachycardia | | 3 |
| Suspected COVID-19 | 14 | 29 |
| Sweating fever | 6 | 7 |
| Swelling | 32 | 47 |
| Swelling face | 24 | 34 |
| Swelling of eyelid | 4 | 7 |
| Swollen tongue | 12 | 27 |
| Syncope | 30 | 47 |
| Tachycardia | 19 | 39 |
| Tachypnoea | 1 | 2 |
| Taste disorder | 7 | 12 |
| Temperature intolerance | 1 | 1 |
| Temperature regulation disorder | | 1 |
| Temporal lobe epilepsy | 1 | 1 |
| Tenderness | 4 | 10 |
| Tendon injury | | 1 |
| Tension | | 1 |
| Tension headache | 5 | 9 |
| Therapeutic response unexpected | 3 | 3 |
| Thermal burn | 2 | 2 |
| Thermal burns of eye | 1 | 1 |
| Thinking abnormal | | 1 |
| Thirst | 9 | 13 |
| Throat clearing | | 1 |
| Throat irritation | 8 | 11 |
| Throat tightness | 4 | 11 |
| Tinnitus | 13 | 21 |
| Tongue blistering | 1 | 1 |
| Tongue discomfort | 1 | 2 |
| Tongue dry | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | 2 |
| | | 3 | 4 | 11 | 25 |
| | | | | 6 | 7 |
| | | 5 | 11 | 27 | 36 |
| | | 3 | 7 | 21 | 27 |
| | | | 3 | 4 | 4 |
| | | 4 | 8 | 8 | 19 |
| | | | | 30 | 47 |
| | | | 7 | 19 | 32 |
| | | 1 | 1 | | 1 |
| | | 1 | 4 | 6 | 8 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 7 | 3 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 5 | 8 |
| | | 2 | 2 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 5 | 6 | 8 |
| | | | | | 1 |
| | | | 1 | 8 | 10 |
| | | 1 | 3 | 3 | 8 |
| | | 1 | 5 | 12 | 16 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Tongue oedema | 4 | 4 |
| Tonsillar disorder | 1 | 1 |
| Tonsillar hypertrophy | 1 | 1 |
| Tonsillar inflammation | | 1 |
| Tonsillitis | | 1 |
| Toothache | 1 | 3 |
| Toxic skin eruption | | 1 |
| Transient ischaemic attack | 2 | 2 |
| Treatment noncompliance | 1 | 1 |
| Tremor | 35 | 58 |
| Trigeminal neuralgia | 2 | 2 |
| Tri-iodothyronine decreased | | 1 |
| Tunnel vision | 1 | 1 |
| Underdose | | 2 |
| Unresponsive to stimuli | | 2 |
| Upper-airway cough syndrome | 1 | 1 |
| Upper respiratory tract congestion | | 1 |
| Urinary incontinence | 2 | 3 |
| Urinary retention | 1 | 1 |
| Urinary tract infection | 2 | 4 |
| Urinary tract pain | 1 | 1 |
| Urine abnormality | 1 | 1 |
| Urine odour abnormal | 1 | 1 |
| Urosepsis | 1 | 1 |
| Urticaria | 26 | 33 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | 2 | 5 |
| Vaccination site cellulitis | 4 | 6 |
| Vaccination site discomfort | 4 | 9 |
| Vaccination site erythema | 31 | 68 |
| Vaccination site haematoma | | 1 |
| Vaccination site haemorrhage | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 4 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 6 | 12 | 29 | 46 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 4 | 26 | 29 |
| | | | | 1 | 1 |
| | | | 2 | 2 | 3 |
| | | 2 | 2 | 2 | 4 |
| | | | 3 | 4 | 6 |
| | | 6 | 29 | 25 | 39 |
| | | | | | 1 |
| | | | | 2 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Vaccination site hyperaesthesia | | 1 |
| Vaccination site hypersensitivity | 1 | 1 |
| Vaccination site hypoaesthesia | | 1 |
| Vaccination site induration | 4 | 7 |
| Vaccination site infection | | 1 |
| Vaccination site inflammation | 1 | 5 |
| Vaccination site irritation | 3 | 3 |
| Vaccination site joint movement impairment | | 2 |
| Vaccination site joint pain | | 1 |
| Vaccination site lymphadenopathy | 1 | 1 |
| Vaccination site mass | 12 | 15 |
| Vaccination site movement impairment | 6 | 10 |
| Vaccination site oedema | 1 | 2 |
| Vaccination site pain | 139 | 287 |
| Vaccination site paraesthesia | 2 | 4 |
| Vaccination site pruritus | 12 | 24 |
| Vaccination site rash | 6 | 9 |
| Vaccination site reaction | 4 | 6 |
| Vaccination site swelling | 35 | 76 |
| Vaccination site urticaria | | 1 |
| Vaccination site warmth | 23 | 43 |
| Varicose vein | 1 | 2 |
| Vascular headache | 2 | 2 |
| Vasculitic rash | | 1 |
| Vasoconstriction | 1 | 1 |
| Vasodilatation | 1 | 2 |
| Vein disorder | 1 | 1 |
| Vena cava embolism | | 1 |
| Vena cava thrombosis | | 1 |
| Ventricular fibrillation | | 1 |
| Vertigo | 11 | 23 |
| Vertigo labyrinthine | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 4 | 3 | 3 |
| | | | | | 1 |
| | | | 3 | 1 | 2 |
| | | | | 3 | 3 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 11 | 14 |
| | | 2 | 4 | 4 | 6 |
| | | | | 1 | 2 |
| | 2 | 27 | 93 | 112 | 194 |
| | | | | 2 | 4 |
| | | 2 | 8 | 10 | 16 |
| | | 1 | 2 | 5 | 7 |
| | | 1 | 2 | 3 | 4 |
| | | 5 | 28 | 30 | 48 |
| | | | | | 1 |
| | | 5 | 18 | 18 | 25 |
| | | 1 | 2 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 2 | 11 | 21 |
| | | | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vertigo positional | 1 | 2 | | | | | 1 | 2 |
| Vestibular migraine | 1 | 2 | | | 1 | 1 | | 1 |
| Vestibular neuronitis | | 2 | | | | | | 2 |
| Viral pharyngitis | 1 | 1 | | | | | 1 | 1 |
| Viral rash | | 1 | | | | | | 1 |
| Viral upper respiratory tract infection | | 1 | | | | | | 1 |
| Vision blurred | 11 | 20 | | | 4 | 4 | 7 | 16 |
| Visual brightness | | 1 | | | | 1 | | |
| Visual field defect | 1 | 1 | | | | | 1 | 1 |
| Visual impairment | 4 | 5 | | | | | 4 | 5 |
| Vlth nerve paralysis | 3 | 3 | | | | | 3 | 3 |
| Vitreous floaters | 1 | 2 | | | | 1 | 1 | 1 |
| Vomiting | 80 | 131 | | | 11 | 30 | 69 | 101 |
| Vomiting projectile | 1 | 1 | | | | | 1 | 1 |
| Vulval abscess | 1 | 1 | | | | | 1 | 1 |
| Vulvovaginal candidiasis | 2 | 3 | | | | | 2 | 3 |
| Vulvovaginal pruritus | | 1 | | | | 1 | | |
| Weight decreased | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Wheezing | 8 | 14 | | | 1 | 3 | 7 | 11 |
| White blood cell count decreased | 1 | 1 | | | | | 1 | 1 |
| White blood cell count increased | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Wrong technique in product usage process | 1 | 1 | | | 1 | 1 | | |
| Yellow skin | 1 | 1 | | | | | 1 | 1 |
| | 1 | 1 | | | 1 | 1 | | |
| | 6,586 | 11,253 | 16 | 23 | 982 | 2771 | 5604 | 8482 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 18 | 19 | 2 | 2 | 2 | 2 | 16 | 17 |
| Abdominal distension | 2 | 4 | | | | | 2 | 4 |
| Abdominal pain | 25 | 28 | | | 3 | 3 | 22 | 25 |
| Abdominal pain lower | 3 | 3 | | | | | 3 | 3 |
| Abdominal pain upper | 29 | 34 | | | 4 | 4 | 25 | 30 |
| Abnormal dreams | 2 | 2 | | | | | 2 | 2 |
| Abnormal weight gain | 2 | 2 | | | | | 2 | 2 |
| Abscess oral | 1 | 1 | | | | | 1 | 1 |
| Accidental overdose | | 1 | | | | 1 | | |
| Acne | 1 | 1 | | | | | 1 | 1 |
| Acrochordon | 1 | 1 | | | | | 1 | 1 |
| Acute febrile neutrophilic dermatosis | 1 | 1 | | | | | 1 | 1 |
| Acute kidney injury | 2 | 2 | | | | | 2 | 2 |
| Acute myocardial infarction | 1 | 1 | | | | | 1 | 1 |
| Adverse drug reaction | | 1 | | | | 1 | | |
| Adverse reaction | | | 1 | 1 | | | | |
| Ageusia | 5 | 6 | | | | 1 | 5 | 5 |
| Agitation | | 1 | | | | | | 1 |
| Alanine aminotransferase increased | 1 | 2 | | | | | 1 | 2 |
| Allergic sinusitis | 1 | 1 | | | | | 1 | 1 |
| Allergy to vaccine | 1 | 3 | | | | 1 | 1 | 2 |
| Alopecia | 1 | 1 | | | | | 1 | 1 |
| Amnesia | 1 | 1 | | | 1 | 1 | | |
| Anal haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Anal incontinence | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 |
| Anaphylactic reaction | 10 | 11 | | | | | 10 | 11 |
| Anaphylactic shock | 4 | 4 | | | | | 4 | 4 |
| Angina pectoris | 3 | 4 | | | | | 3 | 4 |
| Angioedema | 5 | 6 | | | | | 5 | 6 |
| Anosmia | 2 | 3 | | | | 1 | 2 | 2 |
| Anxiety | 7 | 9 | | | 2 | 2 | 5 | 7 |
| Apathy | 1 | 1 | | | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Aphasia | | 1 |
| Appetite disorder | 1 | 1 |
| Arrhythmia | 4 | 4 |
| Arrhythmia supraventricular | 2 | 2 |
| Arterial occlusive disease | 1 | 1 |
| Arterial rupture | 1 | 1 |
| Arthralgia | 175 | 175 |
| Arthritis | 6 | 6 |
| Ascites | 1 | 1 |
| Asthenia | 58 | 65 |
| Asthenopia | 3 | 3 |
| Asthma | 7 | 10 |
| Atrial fibrillation | 14 | 15 |
| Atrial flutter | 1 | 1 |
| Atrial tachycardia | 1 | 1 |
| Auditory disorder | 1 | 1 |
| Auricular swelling | 1 | 1 |
| Autoimmune disorder | 2 | 2 |
| Axillary pain | 5 | 7 |
| Back pain | 43 | 44 |
| Balance disorder | 14 | 15 |
| Bedridden | 1 | 1 |
| Bladder disorder | 1 | 1 |
| Blindness | 1 | 1 |
| Blister | 5 | 5 |
| Blood glucose | 1 | 1 |
| Blood glucose decreased | 1 | 1 |
| Blood glucose increased | 1 | 2 |
| Blood pH increased | 1 | 1 |
| Blood pressure abnormal | 1 | 1 |
| Blood pressure decreased | 2 | 2 |
| Blood pressure fluctuation | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 4 | 4 | 16 | 18 | 143 | 157 |
| | | | | 6 | 6 |
| | | | | 1 | 1 |
| 1 | 1 | 15 | 17 | 43 | 48 |
| | | | | 3 | 3 |
| | | | | 7 | 10 |
| | | | | 14 | 15 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 3 | 4 | 2 | 3 |
| 2 | 2 | 4 | 4 | 39 | 40 |
| | | 3 | 3 | 11 | 12 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Blood pressure increased | 18 | 18 |
| Blood urine present | 1 | 1 |
| Body temperature abnormal | 2 | 3 |
| Body temperature decreased | 2 | 2 |
| Body temperature fluctuation | 1 | 1 |
| Body temperature increased | 7 | 10 |
| Bone pain | 4 | 4 |
| Bradycardia | 2 | 4 |
| Brain stem stroke | 1 | 1 |
| Breast enlargement | 1 | 1 |
| Breast pain | 1 | 1 |
| Breast swelling | 1 | 1 |
| Bronchiectasis | 1 | 1 |
| Bundle branch block right | 1 | 2 |
| Burning sensation | 5 | 5 |
| Cardiac arrest | 4 | 8 |
| Cardiac failure | 2 | 2 |
| Cardiac flutter | 2 | 3 |
| Catarrh | 1 | 1 |
| Cellulitis | 6 | 6 |
| Cerebral disorder | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 |
| Cerebral infarction | 1 | 1 |
| Cerebrovascular accident | 9 | 11 |
| Cervicobrachial syndrome | 1 | 1 |
| Chest discomfort | 15 | 17 |
| Chest pain | 25 | 28 |
| Chest X-ray abnormal | 1 | 1 |
| Chills | 140 | 163 |
| Choking | 1 | 1 |
| Chorea | 1 | 1 |
| Chromaturia | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 2 | 2 | 16 | 16 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | 2 | 7 | 8 |
| | | | | 4 | 4 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | 3 | 3 |
| | | | | 4 | 8 |
| | | | | 2 | 2 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 6 | 6 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 9 | 11 |
| | | | | 1 | 1 |
| | | 3 | 3 | 12 | 14 |
| 1 | 1 | 1 | 1 | 24 | 27 |
| | | 1 | 1 | | |
| 1 | 1 | 8 | 13 | 132 | 150 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Circulatory collapse | 1 | 3 |
| Circumstance or information capable of leading to medication error | | 1 |
| Cold sweat | 12 | 12 |
| Colitis | 1 | 1 |
| Colitis ulcerative | 2 | 2 |
| Coma | 1 | 1 |
| Communication disorder | | 1 |
| Condition aggravated | 16 | 16 |
| Confusional state | 20 | 21 |
| Conjunctival haemorrhage | 1 | 1 |
| Conjunctivitis | 2 | 2 |
| Conjunctivitis bacterial | 1 | 1 |
| Constipation | 5 | 5 |
| Contrast media reaction | 1 | 1 |
| Contusion | 10 | 10 |
| Coordination abnormal | 2 | 2 |
| Corneal abrasion | 1 | 1 |
| Costochondritis | 1 | 1 |
| Cough | 25 | 34 |
| COVID-19 | 24 | 31 |
| COVID-19 pneumonia | 1 | 1 |
| C-reactive protein increased | 1 | 1 |
| Creutzfeldt-Jakob disease | 1 | 1 |
| Crying | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 |
| Cyanosis | | 1 |
| Cystitis | 2 | 2 |
| Deafness | 4 | 4 |
| Death | 11 | 19 |
| Decreased appetite | 41 | 46 |
| Deep vein thrombosis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | 1 | 1 | 11 | 11 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 4 | 4 | 12 | 12 |
| | | 9 | 9 | 11 | 12 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 4 |
| | | | | 1 | 1 |
| | | 3 | 3 | 7 | 7 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 10 | 21 | 24 |
| | | 1 | 1 | 23 | 30 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 4 | 4 |
| | | | | 11 | 19 |
| 1 | 1 | 6 | 8 | 35 | 38 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Defaecation urgency | | 1 |
| Dehydration | 6 | 6 |
| Delirium | 6 | 8 |
| Depressed mood | 1 | 2 |
| Depression | 2 | 4 |
| Dermatitis allergic | 3 | 3 |
| Dermatitis bullous | 1 | 1 |
| Diabetes mellitus inadequate control | 1 | 1 |
| Diarrhoea | 115 | 128 |
| Diplopia | 3 | 3 |
| Discharge | 1 | 1 |
| Discomfort | 7 | 8 |
| Disease recurrence | 11 | 11 |
| Disorientation | 8 | 8 |
| Disturbance in attention | 5 | 6 |
| Diverticulitis | 1 | 1 |
| Dizziness | 146 | 166 |
| Dizziness postural | 11 | 13 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 27 | 37 |
| Dry eye | 3 | 3 |
| Dry mouth | 12 | 15 |
| Dry skin | 1 | 2 |
| Dry throat | 3 | 3 |
| Duodenogastric reflux | 1 | 1 |
| Dysarthria | 3 | 3 |
| Dysgeusia | 14 | 15 |
| Dyskinesia | 1 | 1 |
| Dysmenorrhoea | | 1 |
| Dyspepsia | 3 | 3 |
| Dysphagia | 1 | 1 |
| Dysphonia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 1 | 1 | 5 | 5 |
| | | | | 6 | 8 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 8 | 110 | 120 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 4 | 5 | 3 | 3 |
| | | 1 | 1 | 10 | 10 |
| | | | | 8 | 8 |
| | | 1 | 2 | 4 | 4 |
| | | | | 1 | 1 |
| | | 14 | 21 | 132 | 145 |
| | | | 1 | 11 | 12 |
| | | | | 1 | 1 |
| | | | | 27 | 37 |
| | | | | 3 | 3 |
| 1 | 1 | | 2 | 12 | 13 |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 3 | 3 | 11 | 12 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Dyspnoea | 57 | 66 |
| Dyspnoea exertional | 2 | 3 |
| Dysuria | 3 | 3 |
| Ear discomfort | 1 | 1 |
| Ear pain | 9 | 9 |
| Eating disorder | 2 | 3 |
| Eczema | 1 | 1 |
| Eczema nummular | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Emotional distress | 1 | 1 |
| Epilepsy | 1 | 2 |
| Epistaxis | 10 | 12 |
| Erectile dysfunction | 1 | 1 |
| Eructation | 3 | 3 |
| Erythema | 18 | 24 |
| Exertional headache | 1 | 1 |
| Exfoliative rash | 1 | 1 |
| Exposure to SARS-CoV-2 | 1 | 1 |
| External ear pain | 1 | 1 |
| Eye complication associated with device | 1 | 1 |
| Eye contusion | 2 | 2 |
| Eye discharge | 1 | 1 |
| Eye disorder | 1 | 1 |
| Eye infection | 1 | 1 |
| Eye irritation | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eye pain | 16 | 17 |
| Eye pruritus | 2 | 2 |
| Eye swelling | 3 | 4 |
| Face oedema | 2 | 2 |
| Facial discomfort | 1 | 1 |
| Facial neuralgia | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 7 | 52 | 59 |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 3 | 3 | 6 | 6 |
| | | 2 | 2 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 10 | 12 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 4 | 7 | 14 | 17 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 16 | 16 |
| 2 | 2 | | | 2 | 2 |
| 1 | 1 | | | 3 | 4 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Facial pain | 4 | 5 |
| Facial paralysis | 13 | 14 |
| Facial paresis | 2 | 2 |
| Faeces discoloured | 1 | 2 |
| Faeces pale | 1 | 1 |
| Fall | 15 | 16 |
| Fatigue | 346 | 386 |
| Fear of falling | 1 | 1 |
| Feeding disorder | 1 | 1 |
| Feeling abnormal | 20 | 22 |
| Feeling cold | 42 | 45 |
| Feeling hot | 21 | 26 |
| Feeling jittery | 1 | 1 |
| Feeling of body temperature change | 4 | 4 |
| Feeling of despair | 1 | 1 |
| Fibromyalgia | 1 | 2 |
| Flank pain | | 1 |
| Flashback | 1 | 1 |
| Flatulence | 8 | 8 |
| Fluid retention | 2 | 2 |
| Flushing | 11 | 11 |
| Foreign body sensation in eyes | 2 | 2 |
| Formication | 1 | 1 |
| Frequent bowel movements | 1 | 1 |
| Functional gastrointestinal disorder | 1 | 1 |
| Furuncle | 1 | 1 |
| Gait disturbance | 19 | 20 |
| Gait inability | 4 | 5 |
| Gamma-glutamyltransferase increased | | 1 |
| Gastric disorder | 2 | 2 |
| Gastric haemorrhage | 1 | 1 |
| Gastroenteritis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 3 | 4 |
| 1 | 1 | | | 13 | 14 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 4 | 4 | 11 | 12 |
| 16 | 16 | 38 | 47 | 308 | 339 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 2 | 2 | 8 | 8 | 12 | 14 |
| 1 | 1 | 10 | 11 | 32 | 34 |
| | | 5 | 7 | 16 | 19 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 7 | 7 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 10 | 10 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 4 | 15 | 16 |
| 1 | 1 | | | 4 | 5 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Gastrointestinal pain | 7 | 7 |
| Gastroesophageal reflux disease | 3 | 3 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Giant cell arteritis | 1 | 1 |
| Gingival pain | 1 | 1 |
| Gingival swelling | 1 | 1 |
| Glossodynia | 7 | 8 |
| Gout | 5 | 5 |
| Groin pain | 3 | 3 |
| Haematemesis | 1 | 1 |
| Haematochezia | 3 | 3 |
| Haemoglobin decreased | 1 | 1 |
| Haemorrhage | 3 | 3 |
| Haemorrhage urinary tract | 2 | 2 |
| Haemorrhoids | 1 | 1 |
| Hallucination | 3 | 3 |
| Halo vision | 1 | 1 |
| Hangover | 2 | 2 |
| Headache | 360 | 405 |
| Head discomfort | 2 | 2 |
| Head injury | 2 | 2 |
| Heart rate | 1 | 1 |
| Heart rate abnormal | 1 | 1 |
| Heart rate decreased | 3 | 3 |
| Heart rate increased | 18 | 21 |
| Heart rate irregular | 3 | 3 |
| Hemiparesis | | 1 |
| Herpes ophthalmic | 1 | 1 |
| Herpes zoster | 15 | 16 |
| Hiccups | 1 | 1 |
| Hordeolum | 1 | 1 |
| Hot flush | 10 | 12 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 7 | 7 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 3 | 5 | 5 |
| | | | | 5 | 5 |
| 1 | 1 | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 7 | 7 | 32 | 44 | 328 | 361 |
| 1 | 1 | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | 2 | 18 | 19 |
| | | 1 | 1 | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 2 | 3 | 13 | 13 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 9 | 11 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyperacusis | 1 | 1 |
| Hyperaesthesia | 1 | 1 |
| Hyperglycaemia | 1 | 2 |
| Hyperhidrosis | 36 | 40 |
| Hyperkalaemia | 1 | 1 |
| Hypersensitivity | 9 | 10 |
| Hypersomnia | 6 | 7 |
| Hypertension | 15 | 17 |
| Hypertonic bladder | 1 | 1 |
| Hyperventilation | 1 | 1 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 16 | 19 |
| Hypoaesthesia oral | 2 | 3 |
| Hypoglycaemia | 3 | 3 |
| Hyponatraemia | | 1 |
| Hypopnoea | 2 | 2 |
| Hyporeflexia | 1 | 1 |
| Hypotension | 4 | 6 |
| Hypothermia | 1 | 2 |
| Hypothyroidism | 1 | 1 |
| Hypotonia | | 1 |
| Hypoxia | 3 | 3 |
| Illness | 41 | 42 |
| Immobile | 1 | 1 |
| Immune system disorder | 1 | 2 |
| Immune thrombocytopenia | 1 | 1 |
| Inappropriate schedule of product administration | | 1 |
| Incoherent | 1 | 2 |
| Incontinence | 1 | 1 |
| Incorrect route of product administration | 4 | 6 |
| Increased tendency to bruise | 1 | 1 |
| Infection | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| 2 | 2 | 7 | 9 | 29 | 31 |
| | | | | 1 | 1 |
| | | 1 | 1 | 8 | 9 |
| | | 1 | 1 | 5 | 6 |
| | | 1 | 1 | 14 | 16 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 5 | 14 | 14 |
| | | 1 | 2 | 1 | 1 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 5 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 3 | 3 |
| 1 | 1 | 2 | 3 | 39 | 39 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 4 | 6 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Inflammation | 2 | 3 |
| Inflammatory marker increased | | 1 |
| Influenza | 41 | 42 |
| Influenza like illness | 56 | 67 |
| Injection related reaction | 3 | 3 |
| Injection site erythema | | 1 |
| Injection site mass | | 1 |
| Injection site pain | 1 | 3 |
| Injection site pruritus | | 1 |
| Injection site warmth | 1 | 1 |
| Insomnia | 28 | 28 |
| International normalised ratio increased | 1 | 1 |
| Intestinal ischaemia | 1 | 1 |
| Iridocyclitis | 2 | 2 |
| Irritability | 3 | 3 |
| Irritable bowel syndrome | 4 | 4 |
| Ischaemic stroke | 1 | 1 |
| Jaundice | | 1 |
| Joint effusion | 1 | 1 |
| Joint range of motion decreased | 3 | 3 |
| Joint stiffness | 5 | 6 |
| Joint swelling | 13 | 15 |
| Kidney infection | 1 | 1 |
| Labile blood pressure | 1 | 1 |
| Labyrinthitis | 3 | 3 |
| Lacrimation increased | 2 | 3 |
| Laryngitis | 1 | 1 |
| Lethargy | 30 | 33 |
| Limb discomfort | 18 | 19 |
| Limb mass | 1 | 1 |
| Lip swelling | 12 | 14 |
| Listless | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | 3 | 3 | 38 | 39 |
| | | 9 | 11 | 47 | 56 |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 7 | 7 | 21 | 21 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 2 | 2 | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | | 3 | 3 |
| | | | | 5 | 6 |
| | | | 1 | 13 | 14 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| 1 | 1 | 3 | 3 | 27 | 30 |
| 1 | 1 | 4 | 5 | 14 | 14 |
| | | | | 1 | 1 |
| | | 3 | 3 | 9 | 11 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Livedo reticularis | 2 | 2 |
| Liver function test increased | 1 | 1 |
| Liver injury | 1 | 1 |
| Localised oedema | 1 | 1 |
| Local reaction | 1 | 2 |
| Loss of consciousness | 14 | 16 |
| Loss of personal independence in daily activities | 6 | 7 |
| Lower respiratory tract infection | 5 | 7 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 34 | 43 |
| Lymph node pain | 3 | 5 |
| Lymphoedema | 1 | 1 |
| Malaise | 139 | 154 |
| Mallory-Weiss syndrome | 1 | 1 |
| Mastitis | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 1 |
| Memory impairment | 4 | 4 |
| Meniere's disease | 3 | 3 |
| Mental fatigue | 2 | 2 |
| Metamorphopsia | | 1 |
| Micturition urgency | 2 | 2 |
| Middle insomnia | 1 | 1 |
| Migraine | 17 | 20 |
| Migraine with aura | 2 | 2 |
| Mobility decreased | 4 | 7 |
| Monoplegia | 2 | 2 |
| Morning sickness | 1 | 1 |
| Motion sickness | 3 | 3 |
| Mouth ulceration | 3 | 3 |
| Movement disorder | 1 | 1 |
| Multiple allergies | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 14 | 16 |
| | | 1 | 2 | 5 | 5 |
| | | | | 5 | 7 |
| | | | | 1 | 1 |
| | | 2 | 6 | 32 | 37 |
| | | | 1 | 3 | 4 |
| | | | | 1 | 1 |
| 3 | 3 | 19 | 26 | 120 | 128 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 3 | 3 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 2 | 4 | 15 | 16 |
| | | | | 2 | 2 |
| | | 1 | 2 | 3 | 5 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Multiple sclerosis | | 1 |
| Multiple sclerosis relapse | 1 | 1 |
| Muscle contractions involuntary | 1 | 1 |
| Muscle fatigue | 7 | 7 |
| Muscle rigidity | 1 | 2 |
| Muscle spasms | 12 | 13 |
| Muscle strain | 1 | 1 |
| Muscle swelling | 1 | 1 |
| Muscle tightness | 3 | 3 |
| Muscle tone disorder | | 1 |
| Muscle twitching | 2 | 2 |
| Muscular weakness | 21 | 23 |
| Musculoskeletal chest pain | 5 | 5 |
| Musculoskeletal discomfort | 2 | 2 |
| Musculoskeletal pain | | 1 |
| Musculoskeletal stiffness | 23 | 24 |
| Myalgia | 150 | 172 |
| Myelitis transverse | 2 | 2 |
| Myocardial infarction | 6 | 7 |
| Myofascial pain syndrome | 1 | 1 |
| Nasal congestion | 4 | 5 |
| Nasal discomfort | 1 | 1 |
| Nasopharyngitis | 10 | 11 |
| Nausea | 197 | 234 |
| Neck pain | 24 | 27 |
| Needle issue | 1 | 1 |
| Negative thoughts | | 1 |
| Nervousness | 5 | 6 |
| Nervous system disorder | 2 | 2 |
| Neuralgia | 6 | 6 |
| Neurological symptom | 1 | 1 |
| Neuromyopathy | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 6 | 6 |
| | | | | 1 | 2 |
| | | 2 | 2 | 10 | 11 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | 20 | 22 |
| | | | | 5 | 5 |
| | | | | 2 | 2 |
| | | | | | 1 |
| 1 | 1 | 4 | 4 | 19 | 20 |
| 1 | 1 | 8 | 14 | 142 | 158 |
| | | | | 2 | 2 |
| | | | | 6 | 7 |
| | | 1 | 1 | | |
| | | 1 | 1 | 3 | 4 |
| | | | | 1 | 1 |
| | | 2 | 3 | 8 | 8 |
| 2 | 2 | 15 | 28 | 182 | 206 |
| | | 2 | 3 | 22 | 24 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 3 | 3 | 3 |
| | | | | 2 | 2 |
| | | 1 | 1 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Neuropathy peripheral | 2 | 2 |
| Nightmare | 4 | 5 |
| Night sweats | 12 | 12 |
| Nocturnal dyspnoea | 1 | 1 |
| Non-cardiac chest pain | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | 3 | 3 |
| Oedema peripheral | 1 | 1 |
| Off label use | 46 | 49 |
| Oliguria | 1 | 1 |
| Oral candidiasis | 1 | 2 |
| Oral discomfort | 3 | 3 |
| Oral herpes | 3 | 3 |
| Oral pain | 3 | 3 |
| Oral papule | | 1 |
| Oropharyngeal discomfort | 2 | 2 |
| Oropharyngeal pain | 23 | 30 |
| Osteoarthritis | 1 | 1 |
| Overdose | | 3 |
| Oxygen saturation decreased | 4 | 5 |
| Pain | 99 | 111 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 131 | 155 |
| Pain in jaw | 7 | 8 |
| Pain of skin | 5 | 5 |
| Pallor | 4 | 6 |
| Palpitations | 27 | 27 |
| Pancreatitis | 1 | 1 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 27 | 29 |
| Paraesthesia oral | 9 | 9 |
| Paralysis | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 1 | 2 | 3 | 3 |
| 1 | 1 | | | 12 | 12 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 46 | 48 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | 1 | 1 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | 1 | 4 | 22 | 26 |
| | | | | 1 | 1 |
| | | | 3 | | |
| 4 | 4 | 14 | 19 | 4 | 5 |
| | | 1 | 1 | | |
| 14 | 14 | 22 | 31 | 109 | 124 |
| | | 1 | 1 | 6 | 7 |
| | | 1 | 1 | 4 | 4 |
| | | 1 | 1 | 3 | 5 |
| | | 2 | 2 | 25 | 25 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | 25 | 26 |
| 1 | 1 | 1 | 1 | 8 | 8 |
| | | | | 2 | 3 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Paraparesis | 1 | 1 |
| Parkinson's disease | | 1 |
| Parosmia | 5 | 5 |
| Pelvic pain | 1 | 1 |
| Periarthritis | 1 | 1 |
| Periorbital cellulitis | 1 | 1 |
| Periorbital haematoma | 1 | 1 |
| Periorbital oedema | 4 | 4 |
| Periorbital swelling | 4 | 4 |
| Peripheral coldness | 9 | 10 |
| Peripheral swelling | 30 | 33 |
| Peroneal nerve palsy | 1 | 1 |
| Petechiae | 2 | 2 |
| Pharyngeal paraesthesia | 3 | 3 |
| Pharyngeal swelling | 10 | 10 |
| Pharyngeal ulceration | 1 | 1 |
| Pharyngitis | 1 | 1 |
| Photophobia | 3 | 3 |
| Photopsia | 3 | 3 |
| Photosensitivity reaction | 1 | 1 |
| pH urine | 1 | 1 |
| Plantar fasciitis | 1 | 1 |
| Platelet count decreased | 1 | 1 |
| Pleuritic pain | 1 | 1 |
| Pneumonia | 4 | 4 |
| Pollakiuria | 2 | 2 |
| Polymyalgia rheumatica | 1 | 1 |
| Poor peripheral circulation | | 1 |
| Poor quality sleep | 4 | 5 |
| Pre-existing condition improved | | 1 |
| Presyncope | 6 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 4 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 2 | 8 | 8 |
| 1 | 1 | 3 | 4 | 27 | 29 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 10 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 4 | 5 |
| | | | 1 | | |
| | | 2 | 2 | 4 | 5 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Primary headache associated with sexual activity | | 1 |
| Procedural nausea | 2 | 2 |
| Product complaint | 1 | 1 |
| Productive cough | 3 | 3 |
| Product preparation issue | | 2 |
| Product quality issue | 1 | 1 |
| Product use issue | 47 | 50 |
| Prostatomegaly | 1 | 1 |
| Pruritus | 33 | 36 |
| Psoriasis | 1 | 1 |
| Psoriatic arthropathy | 1 | 1 |
| Pulmonary artery thrombosis | 1 | 1 |
| Pulmonary congestion | 1 | 1 |
| Pulmonary embolism | 4 | 4 |
| Pulmonary pain | 1 | 1 |
| Pulmonary thrombosis | | 1 |
| Pulseless electrical activity | | 1 |
| Purpura | 1 | 1 |
| Pyrexia | 181 | 212 |
| Quadrantanopia | 1 | 1 |
| Rash | 25 | 26 |
| Rash erythematous | 22 | 24 |
| Rash macular | 5 | 5 |
| Rash maculo-papular | 1 | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 16 | 18 |
| Rash vesicular | 3 | 3 |
| Raynaud's phenomenon | 1 | 1 |
| Reaction to preservatives | 2 | 2 |
| Reaction to previous exposure to any vaccine | 1 | 1 |
| Rectal haemorrhage | 4 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 47 | 49 | | 1 |
| | | 1 | 1 | | |
| | | 6 | 7 | 27 | 29 |
| 1 | 1 | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | 1 | 1 | | |
| 1 | 1 | | | | 1 |
| 2 | 2 | 7 | 14 | 174 | 198 |
| | | | | 1 | 1 |
| | | 3 | 4 | 22 | 22 |
| 1 | 1 | 5 | 7 | 17 | 17 |
| | | 2 | 2 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 4 | 13 | 14 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Renal pain | 3 | 3 |
| Respiration abnormal | 2 | 3 |
| Respiratory arrest | 1 | 3 |
| Respiratory disorder | 2 | 2 |
| Respiratory distress | 1 | 1 |
| Respiratory rate increased | 3 | 3 |
| Respiratory symptom | | |
| Restlessness | 2 | 3 |
| Retching | 5 | 5 |
| Rheumatoid arthritis | 3 | 3 |
| Rhinitis | 1 | 1 |
| Rhinorrhoea | 11 | 12 |
| Salivary duct obstruction | 1 | 1 |
| Sarcoidosis | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 2 |
| SARS-CoV-2 test | 1 | 1 |
| SARS-CoV-2 test positive | 2 | 2 |
| Sciatica | 1 | 1 |
| Seizure | 10 | 12 |
| Sensation of blood flow | 2 | 2 |
| Sensation of foreign body | 1 | 1 |
| Sensitive skin | 1 | 1 |
| Sensory disturbance | 2 | 2 |
| Sensory loss | 2 | 2 |
| Sepsis | 2 | 2 |
| Serum sickness | 1 | 1 |
| Serum sickness-like reaction | 1 | 1 |
| Shock | 2 | 2 |
| Sialoadenitis | 1 | 1 |
| Sinus congestion | 1 | 1 |
| Sinus disorder | 1 | 1 |
| Sinus headache | 3 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| | | | | 2 | 3 |
| | | | | 1 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| 1 | 1 | | | | |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | 4 | 4 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 11 | 11 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 10 | 12 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Sinusitis | 2 | 3 |
| Sinus node dysfunction | 1 | 1 |
| Skin burning sensation | 1 | 1 |
| Skin erosion | 1 | 1 |
| Skin exfoliation | 3 | 3 |
| Skin irritation | 4 | 4 |
| Skin lesion | 2 | 2 |
| Skin mass | | 1 |
| Skin swelling | 1 | 1 |
| Skin temperature | 1 | 1 |
| Skin warm | 5 | 5 |
| Skull fracture | 1 | 1 |
| Sleep apnoea syndrome | 1 | 1 |
| Sleep disorder | 12 | 13 |
| Sleep disorder due to a general medical condition | 1 | 1 |
| Small intestinal haemorrhage | 1 | 1 |
| Sneezing | 4 | 4 |
| Somnolence | 18 | 18 |
| Speech disorder | 3 | 4 |
| Spinal pain | 3 | 4 |
| Sputum abnormal | 1 | 1 |
| Staring | 1 | 1 |
| Stevens-Johnson syndrome | 2 | 2 |
| Stomatitis | | |
| Subarachnoid haemorrhage | 1 | 1 |
| Sudden death | 2 | 2 |
| Sudden hearing loss | 2 | 2 |
| Suspected COVID-19 | 23 | 26 |
| Sweating fever | 2 | 2 |
| Swelling | 20 | 21 |
| Swelling face | 19 | 20 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 4 |
| | | | | 1 | 1 |
| | | 2 | 3 | 10 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | 2 | 2 | 16 | 16 |
| 1 | 1 | 2 | 2 | 1 | 2 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 1 | 1 | | | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 4 | 4 | 19 | 22 |
| | | | | 2 | 2 |
| 1 | 1 | | | 20 | 21 |
| | | 3 | 3 | 16 | 17 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Swelling of eyelid | 1 | 1 |
| Swollen tongue | 10 | 13 |
| Syncope | 23 | 23 |
| Synovitis | 1 | 1 |
| Systolic hypertension | 1 | 1 |
| Tachycardia | 11 | 12 |
| Taste disorder | 3 | 3 |
| Tenderness | | 1 |
| Tendon injury | 1 | 1 |
| Tendon pain | 1 | 1 |
| Tension headache | 8 | 9 |
| Therapeutic response unexpected | 1 | 2 |
| Thermal burn | 1 | 1 |
| Thinking abnormal | 1 | 1 |
| Thirst | 5 | 6 |
| Throat clearing | 1 | 1 |
| Throat irritation | 3 | 3 |
| Throat tightness | 4 | 5 |
| Thrombocytopenia | 3 | 4 |
| Tinnitus | 15 | 15 |
| Tongue coated | 1 | 1 |
| Tongue discomfort | 1 | 1 |
| Tongue disorder | 3 | 3 |
| Tongue movement disturbance | 1 | 1 |
| Tongue oedema | 2 | 2 |
| Tonic convulsion | 3 | 3 |
| Toothache | 2 | 2 |
| Toxic epidermal necrolysis | 1 | 1 |
| Tracheal pain | 1 | 1 |
| Transient global amnesia | 1 | 1 |
| Transient ischaemic attack | 3 | 3 |
| Traumatic haemorrhage | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 2 | 9 | 11 |
| 1 | 1 | | | 23 | 23 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 11 | 12 |
| | | 1 | 1 | 2 | 2 |
| 1 | 1 | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 8 | 9 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 5 | 6 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 2 | 3 | 3 |
| | | | | 3 | 4 |
| | | 1 | 1 | 14 | 14 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Tremor | 41 | 45 |
| Type 1 diabetes mellitus | 1 | 1 |
| Type IV hypersensitivity reaction | 1 | 1 |
| Ulcerative keratitis | 1 | 1 |
| Unresponsive to stimuli | 2 | 5 |
| Upper-airway cough syndrome | 1 | 1 |
| Upper respiratory tract congestion | 1 | 1 |
| Urinary incontinence | 1 | 1 |
| Urinary retention | 1 | 2 |
| Urinary tract infection | 5 | 5 |
| Urticaria | 10 | 10 |
| Uveitis | 1 | 1 |
| Vaccination site bruising | 4 | 6 |
| Vaccination site coldness | 1 | 1 |
| Vaccination site discolouration | | 1 |
| Vaccination site discomfort | 1 | 1 |
| Vaccination site erythema | 14 | 16 |
| Vaccination site haemorrhage | 3 | 3 |
| Vaccination site induration | 1 | 1 |
| Vaccination site infection | 1 | 2 |
| Vaccination site joint erythema | 1 | 1 |
| Vaccination site joint pain | 1 | 1 |
| Vaccination site mass | 3 | 5 |
| Vaccination site movement impairment | 1 | 2 |
| Vaccination site oedema | 1 | 1 |
| Vaccination site pain | 69 | 87 |
| Vaccination site paraesthesia | 2 | 2 |
| Vaccination site pruritus | 2 | 2 |
| Vaccination site rash | 1 | 1 |
| Vaccination site reaction | 4 | 5 |
| Vaccination site swelling | 16 | 18 |
| Vaccination site warmth | 4 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 2 | 2 | 6 | 8 | 35 | 37 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 5 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | 4 | 4 |
| | | 2 | 2 | 8 | 8 |
| | | | | 1 | 1 |
| | | 1 | 2 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 14 | 16 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 4 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| 1 | 1 | 13 | 20 | 56 | 67 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 4 |
| | | 3 | 5 | 13 | 13 |
| | | | | 4 | 6 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Vascular pain | 1 | 1 |
| Vasculitis | 2 | 2 |
| Vasodilatation | 1 | 1 |
| Venous haemorrhage | 1 | 1 |
| Ventricular fibrillation | | 1 |
| Vertigo | 26 | 28 |
| Vertigo labyrinthine | 1 | 1 |
| Vertigo positional | 2 | 2 |
| Viral infection | 1 | 1 |
| Virologic failure | 1 | 1 |
| Vision blurred | 11 | 12 |
| Visual impairment | 7 | 9 |
| Vomiting | 78 | 91 |
| Vomiting projectile | 3 | 3 |
| Vomiting psychogenic | | 1 |
| Weight bearing difficulty | 1 | 1 |
| Weight decreased | 2 | 2 |
| Weight increased | 2 | 2 |
| Wheezing | 7 | 8 |
| Wound | 3 | 3 |
| Wound secretion | 1 | 1 |
| Writer's cramp | | 1 |
| | 5,168 | 5,869 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|----|---------|-----|------|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | 1 | 1 | | | | |
| | | | | 2 | 2 | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | | | | 1 | | |
| | | 4 | 5 | 22 | 23 | | |
| | | | | 1 | 1 | | |
| | | | | 2 | 2 | | |
| | | | | 1 | 1 | | |
| | | | | 1 | 1 | | |
| | | 2 | 2 | 9 | 10 | | |
| | | 2 | 2 | 5 | 7 | | |
| | | 5 | 10 | 73 | 81 | | |
| | | | | 3 | 3 | | |
| | | | | | 1 | | |
| | | | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 | | |
| | | | | 2 | 2 | | |
| | | | | 7 | 8 | | |
| | | 1 | 1 | 2 | 2 | | |
| | | | | 1 | 1 | | |
| | | | | | 1 | | |
| | | 98 | 98 | 662 | 873 | 4506 | 4996 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal adhesions | | 1 | | | | | 1 | |
| Abdominal discomfort | 4 | 6 | | | | 4 | 6 | |
| Abdominal distension | | 1 | | | | | 1 | |
| Abdominal pain | 10 | 18 | | | | 3 | 10 | 15 |
| Abdominal pain lower | 2 | 4 | | | | | 2 | 4 |
| Abdominal pain upper | 9 | 15 | | | 2 | 5 | 7 | 10 |
| Abdominal tenderness | 1 | 1 | | | | | 1 | 1 |
| Abnormal dreams | 1 | 2 | | | | 1 | 1 | 1 |
| Abnormal weight gain | 1 | 1 | | | | | 1 | 1 |
| Acidosis | | 2 | | | | 1 | | 1 |
| Acute cardiac event | | 1 | | | | | | 1 |
| Acute kidney injury | 2 | 7 | | | | | 2 | 7 |
| Acute myocardial infarction | 3 | 8 | | | | | 3 | 8 |
| Acute pulmonary oedema | | 1 | | | | | | 1 |
| Acute respiratory failure | | 1 | | | | | | 1 |
| Age-related macular degeneration | | 1 | | | | | | 1 |
| Ageusia | 2 | 5 | | | 1 | 2 | 1 | 3 |
| Aggression | 2 | 2 | | | | | 2 | 2 |
| Agitation | 2 | 7 | | | 1 | 3 | 1 | 4 |
| Alanine aminotransferase increased | | 1 | | | | | | 1 |
| Alexia | 1 | 1 | | | 1 | 1 | | |
| Allergy to vaccine | | 2 | | | | 2 | | |
| Altered state of consciousness | | 1 | | | | | | 1 |
| Amnesia | 5 | 5 | | | | | 5 | 5 |
| Anaemia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Anal incontinence | 1 | 2 | | | | | 1 | 2 |
| Anaphylactic reaction | 6 | 11 | | | | | 6 | 11 |
| Angina pectoris | 2 | 2 | | | | | 2 | 2 |
| Angioedema | 2 | 7 | | | | | 2 | 7 |
| Ankylosing spondylitis | | 1 | | | | | | 1 |
| Anosmia | 1 | 2 | | | | 1 | 1 | 1 |
| Anuria | | 1 | | | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------|------------------------------------|--------------------------------------|
| Anxiety | 6 | 7 |
| Aortic aneurysm | 1 | 1 |
| Aortic aneurysm rupture | | 1 |
| Apathy | 1 | 2 |
| Aphasia | 3 | 4 |
| Aphonia | 1 | 2 |
| Appendicitis | 1 | 1 |
| Arrhythmia | 1 | 2 |
| Arthralgia | 43 | 80 |
| Arthritis | 2 | 7 |
| Arthropathy | | 1 |
| Ascites | 1 | 1 |
| Aspiration | 2 | 3 |
| Asthenia | 34 | 67 |
| Asthenopia | 2 | 2 |
| Asthma | 3 | 3 |
| Asymptomatic COVID-19 | | 1 |
| Atelectasis | | 1 |
| Atrial fibrillation | 5 | 18 |
| Axonal neuropathy | 1 | 1 |
| Back pain | 18 | 29 |
| Bacterial infection | 1 | 1 |
| Balance disorder | 15 | 28 |
| Bedridden | 1 | 3 |
| Bile duct stone | | 1 |
| Biliary sepsis | | 1 |
| Bite | | 1 |
| Bladder pain | | 1 |
| Blepharitis | 1 | 1 |
| Blindness | 1 | 3 |
| Blindness transient | 1 | 1 |
| Blister | 4 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 5 | 6 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| 1 | 1 | 5 | 12 | 38 | 68 |
| | | | 1 | 2 | 6 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | 7 | 14 | 27 | 53 |
| | | 1 | 1 | 1 | 1 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 5 | 18 |
| | | | | 1 | 1 |
| | | 3 | 6 | 15 | 23 |
| | | | | 1 | 1 |
| | 1 | 4 | 7 | 11 | 21 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Blood alkaline phosphatase increased | | 1 |
| Blood creatine phosphokinase increased | | 2 |
| Blood creatinine increased | 1 | 1 |
| Blood electrolytes increased | | 1 |
| Blood glucose increased | | 5 |
| Blood lactic acid increased | | 2 |
| Blood magnesium decreased | 1 | 1 |
| Blood pressure decreased | | 2 |
| Blood pressure increased | 5 | 10 |
| Blood pressure orthostatic abnormal | | 1 |
| Blood pressure systolic increased | | 1 |
| Blood sodium decreased | 1 | 2 |
| Blood urea increased | 1 | 2 |
| Blood viscosity increased | 1 | 1 |
| Body temperature | 1 | 1 |
| Body temperature abnormal | | 2 |
| Body temperature decreased | 1 | 2 |
| Body temperature fluctuation | | 1 |
| Body temperature increased | 1 | 3 |
| Bone contusion | 1 | 1 |
| Bone pain | 2 | 3 |
| Bradycardia | | 1 |
| Brain injury | | 1 |
| Brain oedema | 1 | 1 |
| Breast pain | 1 | 1 |
| Breath odour | | 1 |
| Burning sensation | 1 | 3 |
| Cardiac arrest | 6 | 16 |
| Cardiac failure | 1 | 3 |
| Cardiac failure congestive | 1 | 2 |
| Cardiac flutter | | |
| Cardiopulmonary failure | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 2 | | 3 |
| | | | 1 | | 1 |
| | | 1 | 1 | | |
| | | | | | 2 |
| | | | 4 | 5 | 6 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 3 |
| | | | | 6 | 16 |
| | | | | 1 | 3 |
| | | | | 1 | 2 |
| 1 | 1 | | | | |
| | | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Cardio-respiratory arrest | | 1 |
| Carpal tunnel syndrome | 1 | 1 |
| Cellulitis | 8 | 9 |
| Central vision loss | | 1 |
| Cerebellar infarction | | 1 |
| Cerebellar stroke | | 1 |
| Cerebral disorder | 1 | 1 |
| Cerebral haemorrhage | 4 | 6 |
| Cerebral infarction | 3 | 4 |
| Cerebral venous sinus thrombosis | | 1 |
| Cerebrovascular accident | 12 | 28 |
| Chest discomfort | 7 | 12 |
| Chest pain | 16 | 30 |
| Chills | 51 | 107 |
| Choking sensation | 1 | 1 |
| Chromaturia | | 2 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Circulatory collapse | 4 | 12 |
| Clostridium difficile infection | 1 | 1 |
| Cluster headache | 1 | 1 |
| Cognitive disorder | 2 | 5 |
| Cold sweat | 1 | 6 |
| Colitis ulcerative | | 1 |
| Coma scale abnormal | | 2 |
| Communication disorder | 2 | 2 |
| Condition aggravated | 5 | 11 |
| Confusional state | 25 | 47 |
| Conjunctival haemorrhage | 1 | 3 |
| Conjunctivitis | 1 | 1 |
| Conjunctivitis bacterial | 1 | 1 |
| Constipation | 1 | 3 |
| Contraindicated product administered | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 8 | 9 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 6 |
| | | | | 3 | 4 |
| | | | | | 1 |
| | | | | 12 | 28 |
| | | | 2 | 7 | 10 |
| 1 | 1 | | 4 | 16 | 26 |
| 2 | 2 | 5 | 17 | 46 | 90 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 12 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 5 |
| | | | 1 | 1 | 5 |
| | | | | | 1 |
| | | | | | 2 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | 4 | 9 |
| | | 1 | 7 | 24 | 40 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Contusion | 4 | 7 |
| Coordination abnormal | 5 | 5 |
| Coronary artery disease | | 2 |
| Coronary artery occlusion | 1 | 1 |
| Costochondritis | 1 | 1 |
| Cough | 15 | 32 |
| COVID-19 | 23 | 48 |
| COVID-19 pneumonia | 6 | 7 |
| C-reactive protein increased | 2 | 4 |
| Crying | 1 | 2 |
| Crystal arthropathy | 1 | 1 |
| Culture negative | | 1 |
| Cyanosis | | 1 |
| Cystitis | | 1 |
| Deafness | 1 | 3 |
| Deafness unilateral | 2 | 2 |
| Death | 17 | 52 |
| Decreased appetite | 36 | 68 |
| Decreased interest | | 1 |
| Deep vein thrombosis | 2 | 6 |
| Dehydration | 2 | 7 |
| Delirium | 7 | 13 |
| Delusion | 1 | 1 |
| Dementia | 2 | 3 |
| Depressed level of consciousness | | 2 |
| Depressed mood | 1 | 2 |
| Depression | 1 | 2 |
| Dermatitis | 1 | 3 |
| Dermatitis allergic | 1 | 2 |
| Dermatitis bullous | 1 | 2 |
| Dermatitis exfoliative | 1 | 1 |
| Diabetes mellitus | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 3 | 6 |
| | | 1 | 1 | 4 | 4 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 10 | 14 | 22 |
| | | | | 23 | 48 |
| | | | | 6 | 7 |
| | | 2 | 3 | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 3 |
| | | | | 2 | 2 |
| | | | | 17 | 52 |
| 2 | 2 | 4 | 9 | 32 | 59 |
| | | | | | 1 |
| | | | | 2 | 6 |
| | | | 2 | 2 | 5 |
| | | | | 7 | 13 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | | 2 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Diabetes mellitus inadequate control | | 1 |
| Diabetic diet | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 |
| Diarrhoea | 51 | 100 |
| Diplegia | 1 | 1 |
| Diplopia | 2 | 3 |
| Discomfort | 3 | 5 |
| Disease recurrence | 7 | 7 |
| Disorganised speech | 1 | 1 |
| Disorientation | 3 | 5 |
| Disseminated varicella zoster virus infection | 1 | 1 |
| Disturbance in attention | 1 | 3 |
| Dizziness | 55 | 102 |
| Dizziness exertional | 1 | 1 |
| Dizziness postural | 3 | 9 |
| Drug hypersensitivity | 1 | 2 |
| Drug ineffective | 28 | 61 |
| Dry eye | 1 | 2 |
| Dry mouth | 1 | 3 |
| Dry skin | | 1 |
| Dry throat | | 1 |
| Dysarthria | 3 | 10 |
| Dysgeusia | 5 | 8 |
| Dyskinesia | 2 | 2 |
| Dyspepsia | 3 | 3 |
| Dysphagia | 2 | 6 |
| Dysphonia | 2 | 3 |
| Dyspnoea | 40 | 80 |
| Dyspnoea exertional | 1 | 3 |
| Dysstasia | 2 | 5 |
| Dysuria | | 1 |
| Ear discomfort | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 13 | 49 | 87 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | 2 | 4 |
| | | | | 7 | 7 |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | 6 | 17 | 49 | 85 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 8 |
| | | 1 | 2 | | |
| | | 1 | 2 | | |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | | | | 1 |
| | | | 1 | 3 | 9 |
| | | | 3 | 5 | 5 |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | 1 | 2 | 5 |
| | | | 1 | 2 | 2 |
| | | 3 | 11 | 37 | 69 |
| | | 1 | 2 | | 1 |
| | | | 1 | 2 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Ear pain | 2 | 2 |
| Eczema | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Electrocardiogram ST segment abnormal | | 1 |
| Electrocardiogram ST segment elevation | | 1 |
| Emotional disorder | 1 | 1 |
| Emotional distress | 3 | 3 |
| Encephalitis | 1 | 1 |
| Encephalopathy | 1 | 1 |
| Enteritis | | 1 |
| Enuresis | | 1 |
| Epiglottic oedema | 1 | 1 |
| Epilepsy | 1 | 2 |
| Epistaxis | 8 | 12 |
| Eructation | | 2 |
| Erythema | 8 | 20 |
| Expired product administered | | 1 |
| Extrasystoles | 1 | 1 |
| Eye allergy | | 1 |
| Eye disorder | | 2 |
| Eye infection | | 1 |
| Eye pain | 5 | 7 |
| Eye pruritus | 1 | 3 |
| Eye swelling | 3 | 8 |
| Face oedema | 1 | 1 |
| Facial discomfort | | 1 |
| Facial pain | 1 | 3 |
| Facial paralysis | 5 | 12 |
| Facial paresis | | 2 |
| Faeces discoloured | 2 | 3 |
| Faeces pale | | 1 |
| Fall | 19 | 38 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 2 | 8 | 10 |
| | | | | | 2 |
| | | 2 | 7 | 6 | 13 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 2 |
| | | | | | 1 |
| | | | | 5 | 7 |
| | | | 1 | 1 | 2 |
| | | | 2 | 3 | 6 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 3 |
| | | | | 5 | 12 |
| | | | 1 | | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | | | 1 |
| | | 4 | 6 | 15 | 32 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Fatigue | 130 | 230 |
| Fear | | 2 |
| Feeding disorder | 4 | 6 |
| Feeling abnormal | 11 | 18 |
| Feeling cold | 16 | 30 |
| Feeling drunk | | 1 |
| Feeling hot | 8 | 17 |
| Feeling of body temperature change | | 5 |
| Femur fracture | 1 | 1 |
| Fibrin D dimer increased | 1 | 2 |
| Fibromyalgia | 1 | 1 |
| Flank pain | 1 | 1 |
| Flatulence | 2 | 3 |
| Fluid intake reduced | | 1 |
| Fluid retention | 1 | 1 |
| Flushing | 2 | 5 |
| Folliculitis | | 1 |
| Food aversion | 1 | 1 |
| Food refusal | 1 | 1 |
| Frequent bowel movements | 1 | 2 |
| Fungal skin infection | 1 | 1 |
| Furuncle | 1 | 1 |
| Gait disturbance | 12 | 20 |
| Gait inability | 6 | 8 |
| Gastric haemorrhage | 1 | 1 |
| Gastritis | 1 | 2 |
| Gastroenteritis | | 2 |
| Gastroenteritis viral | | 1 |
| Gastrointestinal disorder | | 1 |
| Gastrointestinal pain | 3 | 5 |
| Generalised tonic-clonic seizure | | 1 |
| General physical health deterioration | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 9 | 10 | 19 | 43 | 111 | 187 |
| | | | | | 2 |
| | | 1 | 3 | 3 | 3 |
| | 1 | 3 | 6 | 8 | 12 |
| | | 4 | 8 | 12 | 22 |
| | | | | | 1 |
| | | 1 | 6 | 7 | 11 |
| | | | 1 | | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | 11 | 17 |
| | | 1 | 1 | 5 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 3 | 5 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Giant cell arteritis | 1 | 1 |
| Gingival pain | 1 | 2 |
| Glassy eyes | | 1 |
| Glaucoma | 1 | 1 |
| Gliositis | 1 | 1 |
| Glossodynia | 1 | 2 |
| Gout | 3 | 3 |
| Grip strength decreased | | 1 |
| Groin pain | | 1 |
| Guillain-Barre syndrome | | 1 |
| Haematemesis | 1 | 6 |
| Haematochezia | 1 | 1 |
| Haematoma | 2 | 2 |
| Haemoglobin decreased | | 1 |
| Haemoptysis | 3 | 3 |
| Haemorrhage | 3 | 3 |
| Haemorrhage intracranial | | 2 |
| Haemorrhagic stroke | | 2 |
| Hallucination | 9 | 17 |
| Hallucination, auditory | 1 | 1 |
| Hallucination, visual | | 4 |
| Hand-eye coordination impaired | | 1 |
| Headache | 101 | 170 |
| Head discomfort | 1 | 1 |
| Head injury | 4 | 5 |
| Heart rate abnormal | 1 | 1 |
| Heart rate decreased | | 3 |
| Heart rate increased | | 6 |
| Heart rate irregular | 2 | 2 |
| Hemiparesis | 2 | 10 |
| Hepatic artery embolism | | 1 |
| Hepatic enzyme increased | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 6 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 3 | 3 |
| 1 | 1 | | | 3 | 3 |
| | | | | | 2 |
| | | | | | 2 |
| | | | | 9 | 17 |
| | | | | 1 | 1 |
| | | | | | 4 |
| | | | | | 1 |
| 4 | 4 | 6 | 19 | 95 | 151 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | | 1 | | 5 |
| | | | | 2 | 2 |
| | | | | 2 | 10 |
| | | | | | 1 |
| | | | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Herpes virus infection | 1 | 1 |
| Herpes zoster | 19 | 21 |
| Hot flush | 3 | 4 |
| Hyperacusis | 2 | 3 |
| Hyperglycaemia | 3 | 3 |
| Hyperhidrosis | 9 | 22 |
| Hyperpyrexia | | 1 |
| Hypersensitivity | 5 | 11 |
| Hypersensitivity pneumonitis | | 1 |
| Hypersomnia | 3 | 7 |
| Hypertension | 7 | 11 |
| Hypertonia | 1 | 2 |
| Hyperventilation | 1 | 1 |
| Hypoacusis | | 1 |
| Hypoaesthesia | 5 | 9 |
| Hypoglycaemia | 1 | 3 |
| Hypokinesia | | 1 |
| Hyponatraemia | 1 | 2 |
| Hypophagia | | 2 |
| Hypopnoea | 1 | 2 |
| Hyporeflexia | | 1 |
| Hypotension | 11 | 21 |
| Hypothermia | 1 | 4 |
| Hypotonia | 1 | 1 |
| Hypoxia | | 3 |
| Illness | 21 | 32 |
| Immobile | 1 | 2 |
| Inappropriate schedule of product administration | 2 | 6 |
| Incoherent | | 1 |
| Incomplete course of vaccination | 1 | 1 |
| Incontinence | 2 | 3 |
| Incorrect route of product administration | 2 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | 18 | 20 |
| | | 1 | 1 | 2 | 3 |
| | | | | 2 | 3 |
| | | | | 3 | 3 |
| | | 2 | 4 | 7 | 18 |
| | | | | | 1 |
| | | 1 | 2 | 4 | 9 |
| | | | | | 1 |
| | | 2 | 2 | 1 | 5 |
| 1 | 1 | | | 7 | 11 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | | 5 | 9 |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 3 | 5 | 8 | 16 |
| | | | | 1 | 4 |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | 3 | 7 | 18 | 25 |
| | | | | 1 | 2 |
| | | 2 | 6 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | 2 | 6 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Infarction | | 1 |
| Infection | 3 | 8 |
| Influenza | 13 | 14 |
| Influenza like illness | 23 | 49 |
| Inguinal mass | | 1 |
| Initial insomnia | 1 | 1 |
| Injection site pain | | 1 |
| Injection site rash | 1 | 2 |
| Insomnia | 10 | 22 |
| International normalised ratio decreased | 2 | 2 |
| International normalised ratio increased | 6 | 10 |
| Intestinal obstruction | 1 | 1 |
| Intestinal perforation | 1 | 1 |
| Ischaemic stroke | 2 | 8 |
| Joint effusion | 1 | 2 |
| Joint lock | | 1 |
| Joint range of motion decreased | 2 | 2 |
| Joint stiffness | 1 | 3 |
| Joint swelling | 5 | 8 |
| Lacrimation increased | 1 | 2 |
| Lacunar infarction | | 1 |
| Left ventricular dysfunction | 1 | 1 |
| Left ventricular failure | 1 | 1 |
| Lethargy | 17 | 32 |
| Leukaemia | | 1 |
| Limb discomfort | 6 | 11 |
| Limb immobilisation | 1 | 1 |
| Limb mass | | 1 |
| Lip pain | 1 | 2 |
| Lip swelling | 11 | 18 |
| Listless | 1 | 1 |
| Livedo reticularis | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 3 | 8 |
| | | | | 13 | 14 |
| | | | 6 | 23 | 43 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 6 | 9 | 16 |
| | | | | 2 | 2 |
| | | | | 6 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 8 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 2 |
| | | 1 | 1 | 4 | 7 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 2 | 2 | 3 | 7 | 14 | 25 |
| | | | | | 1 |
| | | 1 | 4 | 5 | 7 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 4 | 10 | 14 |
| | | | | 1 | 1 |
| | | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Liver function test abnormal | 1 | 1 |
| Liver function test increased | | 1 |
| Local reaction | | 1 |
| Logorrhoea | 1 | 1 |
| Loss of consciousness | 14 | 28 |
| Loss of personal independence in daily activities | 1 | 4 |
| Lower limb fracture | 1 | 2 |
| Lower respiratory tract infection | 5 | 12 |
| Lung consolidation | | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 3 | 11 |
| Lymph node pain | 1 | 2 |
| Lymphopenia | 1 | 1 |
| Malaise | 68 | 142 |
| Mastication disorder | | 1 |
| Melaena | 1 | 3 |
| Memory impairment | 5 | 7 |
| Mental fatigue | | 2 |
| Mental impairment | | 1 |
| Micturition disorder | 2 | 2 |
| Middle insomnia | | 1 |
| Migraine | 2 | 3 |
| Migraine with aura | 1 | 2 |
| Miliaria | | 1 |
| Mobility decreased | 10 | 20 |
| Monoparesis | 1 | 1 |
| Monoplegia | | 1 |
| Mood swings | 1 | 1 |
| Motion sickness | | 1 |
| Mouth injury | 1 | 1 |
| Mouth swelling | | 1 |
| Mouth ulceration | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 14 | 28 |
| | | 1 | 1 | | 3 |
| | | | | 1 | 2 |
| | | | | 5 | 12 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 2 | 3 | 9 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| 1 | 1 | 12 | 34 | 56 | 108 |
| | | | | | 1 |
| | | | | 1 | 3 |
| | | | | 5 | 7 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | 5 | 10 | 5 | 10 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Movement disorder | 5 | 6 |
| Mucous stools | 1 | 1 |
| Multiple organ dysfunction syndrome | | 2 |
| Muscle disorder | 1 | 1 |
| Muscle fatigue | 1 | 3 |
| Muscle rigidity | | 2 |
| Muscle spasms | 3 | 5 |
| Muscle strain | | 1 |
| Muscle twitching | 1 | 3 |
| Muscular weakness | 21 | 35 |
| Musculoskeletal chest pain | 3 | 7 |
| Musculoskeletal discomfort | 3 | 4 |
| Musculoskeletal disorder | 2 | 2 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | 8 | 14 |
| Myalgia | 38 | 77 |
| Myelitis | | 1 |
| Myocardial infarction | 3 | 16 |
| Myocardial ischaemia | 1 | 2 |
| Myoclonus | 1 | 1 |
| Narcolepsy | | 1 |
| Nasal congestion | 1 | 1 |
| Nasopharyngitis | 6 | 8 |
| Nausea | 59 | 133 |
| Neck pain | 11 | 18 |
| Necrotising fasciitis | 1 | 1 |
| Nerve compression | 1 | 1 |
| Nervousness | 2 | 3 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 2 | 2 |
| Neurogenic shock | 1 | 1 |
| Neurologic neglect syndrome | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 4 | 5 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | | 2 |
| | | | 1 | 3 | 4 |
| | | | | | 1 |
| | | | 1 | 1 | 2 |
| | | 3 | 5 | 18 | 30 |
| | | | 1 | 3 | 6 |
| | | | 1 | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 3 | 7 | 11 |
| 1 | 1 | 3 | 15 | 35 | 62 |
| | | | | | 1 |
| | | | | 3 | 16 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 6 | 7 |
| 2 | 3 | 6 | 25 | 53 | 108 |
| | | | 3 | 11 | 15 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Neuropathy peripheral | 1 | 1 |
| Neuropsychiatric symptoms | 1 | 1 |
| Neutropenia | 1 | 1 |
| Night sweats | 2 | 4 |
| No adverse event | | 1 |
| Nocturia | | 1 |
| Nodule | | 1 |
| Obsessive-compulsive symptom | | 1 |
| Ocular hyperaemia | 3 | 4 |
| Oedema | | 2 |
| Oedema peripheral | 2 | 3 |
| Off label use | 22 | 30 |
| Ophthalmic herpes zoster | 2 | 2 |
| Optic neuropathy | 1 | 1 |
| Oral candidiasis | 1 | 1 |
| Oral mucosal blistering | | 1 |
| Oral mucosal eruption | | 1 |
| Oral pain | 2 | 2 |
| Orchitis | 1 | 1 |
| Oropharyngeal pain | 5 | 12 |
| Orthopnoea | 1 | 2 |
| Orthostatic hypotension | 2 | 3 |
| Osteoarthritis | 1 | 1 |
| Osteoporosis | 1 | 1 |
| Oversensing | 1 | 1 |
| Oxygen saturation decreased | 1 | 10 |
| Pain | 37 | 62 |
| Painful respiration | 2 | 2 |
| Pain in extremity | 49 | 96 |
| Pain in jaw | 1 | 1 |
| Pallor | 2 | 8 |
| Palpitations | 3 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | | 1 | 2 | 3 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 3 | 4 |
| | | | | | 2 |
| | | 1 | 1 | 1 | 2 |
| | | 22 | 30 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 5 | 11 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 9 |
| 2 | 2 | 5 | 12 | 32 | 50 |
| | | 1 | 1 | 1 | 1 |
| 2 | 2 | 10 | 29 | 39 | 67 |
| | | | | 1 | 1 |
| | | | | 2 | 8 |
| | | | | 3 | 5 |

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Age Range

Greater than or equal to 80 years

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------|--|--|
| Pancytopenia | | 1 |
| Panic attack | 2 | 3 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 4 | 14 |
| Paraesthesia oral | 2 | 6 |
| Paralysis | | 2 |
| Parkinsonism | 2 | 2 |
| Parkinson's disease | 1 | 1 |
| Parotitis | | 2 |
| Pemphigoid | 3 | 3 |
| Pemphigus | 1 | 1 |
| Periarthritis | 1 | 1 |
| Pericarditis | 1 | 2 |
| Periorbital swelling | | 1 |
| Peripheral coldness | | 4 |
| Peripheral ischaemia | | 1 |
| Peripheral swelling | 13 | 26 |
| Personality change | 1 | 1 |
| Petechiae | | 1 |
| Petit mal epilepsy | | 2 |
| Pharyngeal erythema | | 1 |
| Pharyngeal inflammation | | 1 |
| Pharyngeal oedema | | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | | 2 |
| Pharyngeal ulceration | 1 | 1 |
| Phlebitis | 1 | 1 |
| Photophobia | | 1 |
| Photopsia | 1 | 1 |
| pH urine increased | 1 | 1 |
| Platelet count decreased | 1 | 1 |
| Pleural effusion | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | 4 | 4 | 10 |
| | | 1 | 5 | 1 | 1 |
| | | | | | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | | | 4 |
| | | | | | 1 |
| | | 2 | 6 | 11 | 20 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pleuritic pain | | 1 |
| Pneumonia | 3 | 9 |
| Pneumonia aspiration | | 3 |
| Pneumonia staphylococcal | 1 | 1 |
| Pneumonitis | 4 | 5 |
| Pollakiuria | 1 | 2 |
| Polymyalgia rheumatica | 3 | 3 |
| Polyuria | | 1 |
| Poor quality sleep | | 2 |
| Posterior reversible encephalopathy syndrome | | 1 |
| Postoperative ileus | | 1 |
| Post procedural complication | 1 | 1 |
| Posture abnormal | | 1 |
| Presyncope | 2 | 6 |
| Primary cough headache | | 1 |
| Productive cough | 2 | 5 |
| Product use issue | 22 | 30 |
| Prostatomegaly | | 1 |
| Pruritus | 12 | 33 |
| Psoriasis | | 1 |
| Psychiatric symptom | 1 | 1 |
| Psychotic behaviour | | 1 |
| Psychotic disorder | 3 | 3 |
| Psychotic symptom | 1 | 1 |
| Pulmonary congestion | 2 | 2 |
| Pulmonary embolism | 1 | 2 |
| Pulmonary oedema | | 1 |
| Pulmonary thrombosis | 1 | 1 |
| Pulse abnormal | | 1 |
| Pulseless electrical activity | 1 | 1 |
| Purpura | 1 | 2 |
| Pustule | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 3 | 9 |
| | | | | | 3 |
| | | | | 1 | 1 |
| | | | | 4 | 5 |
| | | | 1 | 1 | 1 |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 5 |
| | | | | | 1 |
| | | | | 2 | 5 |
| | | 22 | 30 | | |
| | | | 1 | | |
| | | 2 | 12 | 10 | 21 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Pyrexia | 56 | 126 |
| Rash | 26 | 44 |
| Rash erythematous | 4 | 8 |
| Rash macular | 3 | 10 |
| Rash maculo-papular | 1 | 2 |
| Rash papular | | 1 |
| Rash pruritic | 8 | 12 |
| Rash vesicular | 1 | 3 |
| Reaction to excipient | 1 | 1 |
| Rectal haemorrhage | 5 | 5 |
| Red blood cell sedimentation rate increased | | 1 |
| Red man syndrome | 1 | 1 |
| Regurgitation | | 1 |
| Renal failure | | 1 |
| Renal impairment | 1 | 1 |
| Renal pain | 1 | 2 |
| Repetitive speech | 1 | 1 |
| Respiration abnormal | | 1 |
| Respiratory arrest | | 1 |
| Respiratory failure | 1 | 1 |
| Respiratory rate increased | | 1 |
| Respiratory tract oedema | | 1 |
| Restlessness | 2 | 3 |
| Retching | 5 | 9 |
| Rhabdomyolysis | 1 | 2 |
| Rheumatoid arthritis | 1 | 1 |
| Rhinitis | 1 | 1 |
| Rhinorrhoea | 7 | 7 |
| Right ventricular enlargement | | 1 |
| Road traffic accident | 1 | 1 |
| Rosacea | 1 | 1 |
| Salivary hypersecretion | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 16 | 56 | 110 |
| | | 2 | 14 | 24 | 30 |
| | | | 3 | 4 | 5 |
| | | 1 | 6 | 2 | 4 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | 1 | 4 | 7 | 8 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | 1 | 3 | 4 | 6 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 7 | 7 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Sarcoma | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| SARS-CoV-2 test positive | 4 | 6 |
| Scab | 1 | 1 |
| Sciatica | 1 | 2 |
| Secretion discharge | 1 | 1 |
| Seizure | 7 | 14 |
| Sensory disturbance | 1 | 2 |
| Sepsis | 3 | 7 |
| Sinus headache | | 1 |
| Sinusitis | 2 | 2 |
| Sinus tachycardia | 1 | 1 |
| Skin abrasion | 2 | 2 |
| Skin burning sensation | 3 | 3 |
| Skin cancer | | 1 |
| Skin discolouration | 5 | 8 |
| Skin erosion | | 2 |
| Skin exfoliation | | 4 |
| Skin irritation | 1 | 3 |
| Skin laceration | 1 | 1 |
| Skin mass | 1 | 2 |
| Skin tightness | 1 | 1 |
| Skin ulcer | | 1 |
| Skin warm | | 2 |
| Skin weeping | | 1 |
| Sleep attacks | | 1 |
| Sleep disorder | 5 | 11 |
| Small intestinal obstruction | | 1 |
| Sneezing | 3 | 5 |
| Social avoidant behaviour | 1 | 1 |
| Social fear | 1 | 1 |
| Soft tissue infection | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 4 | 6 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 7 | 14 |
| | | | 1 | 1 | 1 |
| | | | | 3 | 7 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | 1 | 3 | 4 | 5 |
| | | | 1 | | 1 |
| | | | 1 | | 3 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 2 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | 3 | 5 | 2 | 6 |
| | | | | | 1 |
| | | | 1 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Somnolence | 6 | 22 |
| Speech disorder | 2 | 4 |
| Stereotypy | 1 | 1 |
| Stevens-Johnson syndrome | | 1 |
| Stoma site extravasation | | 1 |
| Stoma site haemorrhage | | 1 |
| Stress | | 1 |
| Stridor | | 1 |
| Subarachnoid haemorrhage | | 1 |
| Sudden death | 4 | 11 |
| Supraventricular tachycardia | 1 | 2 |
| Suspected COVID-19 | 6 | 13 |
| Sweating fever | 1 | 2 |
| Swelling | 2 | 3 |
| Swelling face | 7 | 15 |
| Swelling of eyelid | | 1 |
| Swollen tongue | 8 | 13 |
| Syncope | 12 | 28 |
| Synovitis | 1 | 2 |
| Systolic hypertension | 1 | 1 |
| Tachycardia | 1 | 3 |
| Tachypnoea | | 1 |
| Taste disorder | 4 | 5 |
| Temperature regulation disorder | | 1 |
| Tenderness | 1 | 2 |
| Tendonitis | | 1 |
| Tension headache | 1 | 3 |
| Thirst | 4 | 5 |
| Throat irritation | | 1 |
| Throat tightness | 1 | 4 |
| Thrombocytopenia | 1 | 2 |
| Thrombocytosis | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 6 | 4 | 16 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 4 | 11 |
| | | | | 1 | 2 |
| | | 1 | 2 | 5 | 11 |
| | | | | 1 | 2 |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 2 | 6 | 13 |
| | | | | | 1 |
| | | 1 | 3 | 7 | 10 |
| | | | | 12 | 28 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | 1 | 1 | 3 | 4 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 3 |
| | | 1 | 2 | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 4 |
| | | | | 1 | 2 |
| | | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Thrombophlebitis | 1 | 1 |
| Thrombosis | 1 | 4 |
| Tinnitus | 4 | 5 |
| Tongue disorder | 1 | 1 |
| Toothache | | 1 |
| Toxic epidermal necrolysis | | 1 |
| Transient ischaemic attack | 7 | 12 |
| Tremor | 26 | 48 |
| Troponin increased | 1 | 2 |
| Tunnel vision | 1 | 2 |
| Type IV hypersensitivity reaction | 1 | 1 |
| Unresponsive to stimuli | 1 | 8 |
| Upper gastrointestinal haemorrhage | | 2 |
| Upper limb fracture | 2 | 3 |
| Urinary incontinence | 3 | 5 |
| Urinary retention | 2 | 4 |
| Urinary tract disorder | | 1 |
| Urinary tract infection | 8 | 8 |
| Urinary tract infection bacterial | | 1 |
| Urosepsis | | 1 |
| Urticaria | 8 | 18 |
| Urticaria papular | 1 | 1 |
| Uveitis | 1 | 1 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | 1 | 3 |
| Vaccination site cellulitis | | 1 |
| Vaccination site discolouration | | 1 |
| Vaccination site discomfort | 2 | 3 |
| Vaccination site erythema | 6 | 20 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site haemorrhage | | 2 |
| Vaccination site induration | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 4 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | 1 | | |
| 1 | 1 | | | | 1 |
| | | | | 7 | 12 |
| | | 3 | 7 | 23 | 41 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 8 |
| | | | | | 2 |
| | | | | 2 | 3 |
| | | 1 | 1 | 2 | 4 |
| | | | | 2 | 4 |
| | | | | | 1 |
| | | 2 | 2 | 6 | 6 |
| | | | | | 1 |
| | | | | | 1 |
| | | 2 | 9 | 6 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | 2 | 8 | 4 | 12 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|---|------|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Vaccination site infection | | 1 | | | | | | | 1 |
| Vaccination site inflammation | | 2 | | | | | | | 2 |
| Vaccination site joint movement impairment | | 1 | | | | 1 | | | |
| Vaccination site mass | 3 | 4 | | | 2 | 2 | 1 | | 2 |
| Vaccination site movement impairment | 1 | 2 | 1 | 1 | | 1 | 1 | | 1 |
| Vaccination site oedema | | 1 | | | | | | | 1 |
| Vaccination site pain | 25 | 73 | | | 4 | 23 | 21 | | 50 |
| Vaccination site pruritus | | 3 | | | | 3 | | | |
| Vaccination site rash | 2 | 5 | | | | 2 | 2 | | 3 |
| Vaccination site swelling | 4 | 14 | | | 2 | 5 | 2 | | 9 |
| Vaccination site ulcer | | 1 | | | | | | | 1 |
| Vaccination site vesicles | 1 | 2 | | | | | 1 | | 2 |
| Vaccination site warmth | 5 | 11 | | | 1 | 2 | 4 | | 9 |
| Vascular dementia | | 1 | | | | | | | 1 |
| Vasculitic rash | 2 | 2 | | | 1 | 1 | 1 | | 1 |
| Vasculitis | 3 | 4 | | | | | 3 | | 4 |
| Ventricular extrasystoles | 1 | 1 | | | | | 1 | | 1 |
| Ventricular fibrillation | 1 | 2 | | | | | 1 | | 2 |
| Vertigo | 5 | 13 | 1 | 1 | | 2 | 5 | | 11 |
| Vertigo positional | | 1 | | | | | | | 1 |
| Viral infection | 1 | 2 | | | | 1 | 1 | | 1 |
| Viral labyrinthitis | 1 | 1 | | | 1 | 1 | | | |
| Vision blurred | 3 | 14 | | | 1 | 7 | 2 | | 7 |
| Visual acuity reduced | | 1 | | | | 1 | | | |
| Visual impairment | 5 | 8 | | | 1 | 2 | 4 | | 6 |
| Vomiting | 34 | 79 | 2 | 2 | 5 | 20 | 29 | | 59 |
| Weight decreased | 3 | 4 | | | | 1 | 3 | | 3 |
| Weight loss diet | | 1 | | | | | | | 1 |
| Wheezing | 2 | 5 | | | | 1 | 2 | | 4 |
| White blood cell count increased | 1 | 1 | | | | | 1 | | 1 |
| | 1 | 1 | | | 1 | 1 | | | |
| | 2,348 | 4,675 | 40 | 44 | 291 | 857 | 2057 | | 3818 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 5 | 7 | | | 5 | 7 |
| Abdominal distension | 3 | 3 | 2 | 2 | 1 | 1 |
| Abdominal pain | 4 | 9 | 1 | 4 | 3 | 5 |
| Abdominal pain upper | 13 | 19 | 1 | 4 | 12 | 15 |
| Abnormal faeces | | 1 | | 1 | | |
| Accidental overdose | 2 | 2 | 2 | 2 | | |
| Acute respiratory failure | | 1 | | | | 1 |
| Adnexa uteri pain | 2 | 2 | | | 2 | 2 |
| Adverse drug reaction | 2 | 2 | 1 | 1 | 1 | 1 |
| Adverse event | 1 | 1 | | | 1 | 1 |
| African trypanosomiasis | | 1 | | | | 1 |
| Ageusia | 5 | 5 | 2 | 2 | 3 | 3 |
| Agitation | | 1 | | 1 | | |
| Allergy to vaccine | | 2 | | 1 | | 1 |
| Amnesia | | 1 | | 1 | | |
| Anaphylactic reaction | 10 | 13 | | | 10 | 13 |
| Anaphylactoid shock | 1 | 1 | | | 1 | 1 |
| Anger | | 1 | | | | 1 |
| Angina pectoris | 1 | 2 | | | 1 | 2 |
| Angioedema | 1 | 2 | | | 1 | 2 |
| Anosmia | 2 | 4 | 1 | 1 | 1 | 3 |
| Antibody test abnormal | 2 | 2 | 2 | 2 | | |
| Anticoagulation drug level increased | | 1 | | | | 1 |
| Anxiety | 5 | 7 | | | 5 | 7 |
| Apathy | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 35 | 63 | 10 | 22 | 25 | 41 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Arthritis reactive | 1 | 2 | | | 1 | 2 |
| Arthropathy | 1 | 1 | | | 1 | 1 |
| Asthenia | 14 | 21 | 4 | 7 | 10 | 14 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Asthenopia | 2 | 2 |
| Asthma | 1 | 2 |
| Atrial fibrillation | 1 | 2 |
| Autoimmune uveitis | 1 | 1 |
| Axillary pain | 3 | 9 |
| Back pain | 11 | 17 |
| Balance disorder | 2 | 2 |
| Blindness | 1 | 1 |
| Blindness transient | 1 | 1 |
| Blister | 2 | 2 |
| Blood glucose decreased | | 1 |
| Blood growth hormone | | 1 |
| Blood pressure decreased | | 1 |
| Blood pressure fluctuation | 1 | 1 |
| Blood pressure increased | 6 | 10 |
| Body temperature decreased | 1 | 1 |
| Body temperature fluctuation | | 1 |
| Body temperature increased | 5 | 8 |
| Bone pain | 1 | 4 |
| Bradycardia | 1 | 1 |
| Breast cancer | 1 | 1 |
| Breast swelling | 2 | 2 |
| Bundle branch block right | 1 | 1 |
| Burning sensation | 3 | 5 |
| Bursitis | 1 | 1 |
| Cardiac arrest | 1 | 3 |
| Cardiac murmur | 1 | 1 |
| Catarrh | 1 | 1 |
| Cellulitis | 2 | 2 |
| Cerebral infarction | | 1 |
| Cerebrovascular accident | | 1 |
| Chest discomfort | 10 | 13 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| 1 | 2 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| 2 | 5 | 1 | 4 |
| 3 | 6 | 8 | 11 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | | 1 |
| | 1 | | |
| | | | 1 |
| 1 | 4 | 5 | 6 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 2 | 4 | 6 |
| | 2 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 5 |
| | | 1 | 1 |
| | | 1 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | | 1 |
| | | | 1 |
| 2 | 2 | 8 | 11 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Chest pain | 4 | 13 |
| Chills | 51 | 93 |
| Choking | | 1 |
| Circulatory collapse | 1 | 3 |
| Circumstance or information capable of leading to medication error | 1 | 4 |
| Cluster headache | 1 | 1 |
| Cold sweat | 2 | 2 |
| Communication disorder | 1 | 1 |
| Condition aggravated | 3 | 3 |
| Confusional state | 4 | 4 |
| Consciousness fluctuating | | 1 |
| Constipation | 3 | 3 |
| Contraindicated product administered | | 1 |
| Contusion | 1 | 2 |
| Coronary artery disease | 1 | 1 |
| Coronavirus infection | | 1 |
| Cough | 11 | 18 |
| COVID-19 | 16 | 93 |
| COVID-19 pneumonia | 1 | 1 |
| C-reactive protein increased | 1 | 1 |
| CT hypotension complex | 1 | 1 |
| Deafness | 1 | 1 |
| Death | 4 | 7 |
| Decreased appetite | 7 | 11 |
| Dehydration | 1 | 1 |
| Delirium | | 1 |
| Depression | 1 | 1 |
| Dermatitis | 1 | 2 |
| Dermatitis allergic | | 1 |
| Diarrhoea | 17 | 33 |
| Diplopia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 5 | 3 | 8 |
| 15 | 36 | 36 | 57 |
| | | | 1 |
| | | 1 | 3 |
| 1 | 4 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 1 | 3 | 3 |
| | | | 1 |
| | | 3 | 3 |
| | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 2 | 8 | 9 | 10 |
| 1 | 2 | 15 | 91 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 7 |
| 2 | 3 | 5 | 8 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | | |
| 3 | 12 | 14 | 21 |
| | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Discomfort | 4 | 5 |
| Disease recurrence | | 2 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 45 | 80 |
| Dizziness postural | | 3 |
| Drug eruption | | 2 |
| Drug ineffective | 19 | 105 |
| Dry mouth | 2 | 4 |
| Dry throat | 1 | 1 |
| Dysgeusia | 4 | 12 |
| Dyspepsia | 2 | 2 |
| Dysphagia | 2 | 3 |
| Dyspnoea | 18 | 35 |
| Dysstasia | 1 | 1 |
| Dysuria | 1 | 1 |
| Ear discomfort | | 1 |
| Ear haemorrhage | 1 | 1 |
| Ear infection | | 1 |
| Ear pain | 3 | 6 |
| Eating disorder | 1 | 1 |
| Eczema | 1 | 1 |
| Epilepsy | 1 | 2 |
| Epistaxis | 1 | 6 |
| Erythema | 9 | 15 |
| Euphoric mood | | 1 |
| Excessive granulation tissue | 1 | 1 |
| Exposure via breast milk | 3 | 5 |
| Extrasystoles | | 1 |
| Eye abscess | 1 | 1 |
| Eye disorder | | 1 |
| Eye haemorrhage | 1 | 1 |
| Eye irritation | 1 | 2 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 3 | 2 | 2 |
| | 1 | | 1 |
| | | 1 | 1 |
| 10 | 25 | 35 | 55 |
| | 1 | | 2 |
| | | | 2 |
| | | 19 | 105 |
| | 2 | 2 | 2 |
| | | 1 | 1 |
| 1 | 7 | 3 | 5 |
| | | 2 | 2 |
| | | 2 | 3 |
| 1 | 7 | 17 | 28 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 2 | 3 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 2 |
| 1 | 2 | | 4 |
| 3 | 6 | 6 | 9 |
| | | | 1 |
| | | 1 | 1 |
| 2 | 4 | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eyelid irritation | | 1 |
| Eye pain | 3 | 3 |
| Eye pruritus | 1 | 1 |
| Eye swelling | 1 | 1 |
| Facial discomfort | | 1 |
| Facial pain | 1 | 3 |
| Facial paralysis | 3 | 3 |
| Faeces soft | 1 | 1 |
| Fall | 1 | 2 |
| Fatigue | 92 | 152 |
| Feeding disorder | 1 | 1 |
| Feeling abnormal | 11 | 18 |
| Feeling cold | 12 | 17 |
| Feeling drunk | | 1 |
| Feeling hot | 3 | 10 |
| Feeling of body temperature change | 1 | 2 |
| Flushing | 3 | 7 |
| Formication | | 1 |
| Gait disturbance | 5 | 5 |
| Gait inability | 3 | 3 |
| Gastric antral vascular ectasia | 1 | 1 |
| Gastritis | 1 | 1 |
| Gastroenteritis | 3 | 3 |
| Gastroenteritis viral | 1 | 1 |
| Gastrointestinal pain | 1 | 1 |
| Gastrointestinal sounds abnormal | 1 | 1 |
| Gastrooesophageal reflux disease | 1 | 1 |
| Generalised tonic-clonic seizure | | 1 |
| Gingival pain | | 2 |
| Gonorrhoea | 1 | 1 |
| Groin pain | 1 | 1 |
| Haematemesis | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 2 | | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 2 | | |
| 27 | 60 | 65 | 92 |
| 1 | 1 | | |
| 3 | 5 | 8 | 13 |
| 3 | 6 | 9 | 11 |
| | 1 | | |
| | 7 | 3 | 3 |
| | 1 | 1 | 1 |
| | 2 | 3 | 5 |
| | | | 1 |
| | | 5 | 5 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Haematoma | 1 | 1 |
| Haemoptysis | 1 | 2 |
| Haemorrhage | 1 | 2 |
| Haemorrhage subcutaneous | 1 | 1 |
| Hair colour changes | | 1 |
| Hallucination, visual | 1 | 1 |
| Headache | 107 | 199 |
| Head discomfort | 4 | 4 |
| Head injury | 1 | 2 |
| Heart rate increased | 4 | 9 |
| Heart rate irregular | 3 | 3 |
| Herpes zoster | 3 | 6 |
| Hot flush | 4 | 7 |
| Hyperacusis | | 1 |
| Hyperaesthesia | 2 | 3 |
| Hyperchlorhydria | | 1 |
| Hyperglycaemia | | 1 |
| Hyperhidrosis | 12 | 18 |
| Hypersensitivity | 7 | 12 |
| Hypertension | 4 | 8 |
| Hyperventilation | | 1 |
| Hypoaesthesia | 8 | 14 |
| Hypoaesthesia oral | 4 | 9 |
| Hypoglycaemia | 2 | 2 |
| Hyporesponsive to stimuli | | 1 |
| Hypotension | 1 | 3 |
| Hypothermia | 1 | 1 |
| Illness | 13 | 18 |
| Immobile | 1 | 1 |
| Impaired healing | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 5 |
| Incontinence | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 34 | 83 | 73 | 116 |
| 3 | 3 | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 5 | 3 | 4 |
| | | 3 | 3 |
| | 3 | 3 | 3 |
| 1 | 2 | 3 | 5 |
| | 1 | | |
| 2 | 2 | | 1 |
| | 1 | | |
| | | | 1 |
| 4 | 8 | 8 | 10 |
| 2 | 6 | 5 | 6 |
| 1 | 2 | 3 | 6 |
| | | | 1 |
| 4 | 5 | 4 | 9 |
| 2 | 5 | 2 | 4 |
| | | 2 | 2 |
| | | | 1 |
| 1 | 1 | | 2 |
| | | 1 | 1 |
| 3 | 5 | 10 | 13 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 5 | | |
| 1 | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Incorrect route of product administration | 2 | 2 |
| Increased insulin requirement | 1 | 1 |
| Increased upper airway secretion | | 1 |
| Induration | | 1 |
| Inflammation | 2 | 4 |
| Inflammatory marker increased | 1 | 1 |
| Influenza | 4 | 9 |
| Influenza like illness | 13 | 24 |
| Infusion related reaction | 1 | 1 |
| Injection related reaction | 2 | 3 |
| Injection site mass | | 1 |
| Injection site pain | 1 | 5 |
| Injection site swelling | | 1 |
| Injury associated with device | | 1 |
| Insomnia | 9 | 10 |
| Joint range of motion decreased | 3 | 3 |
| Joint swelling | 4 | 5 |
| Lacrimation increased | 1 | 2 |
| Lacunar stroke | | 1 |
| Lethargy | 11 | 20 |
| Limb discomfort | 5 | 6 |
| Limb mass | 1 | 1 |
| Lip erythema | 1 | 1 |
| Lip swelling | 5 | 7 |
| Liquid product physical issue | | 2 |
| Localised infection | | 1 |
| Localised oedema | 2 | 2 |
| Loss of consciousness | 9 | 11 |
| Loss of control of legs | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lower respiratory tract infection | 1 | 2 |
| Lymphadenopathy | 23 | 43 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | | 2 | 4 |
| | | 1 | 1 |
| | 2 | 4 | 7 |
| 2 | 11 | 11 | 13 |
| | | 1 | 1 |
| | 1 | | |
| | 4 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 2 | 8 | 8 |
| 1 | 1 | 2 | 2 |
| 2 | 3 | 2 | 2 |
| | | 1 | 2 |
| | | | 1 |
| 3 | 11 | 8 | 9 |
| 1 | 2 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 4 | 5 |
| | 2 | | |
| | | | 1 |
| | | 2 | 2 |
| | | 9 | 11 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 7 | 20 | 16 | 23 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Lymph node pain | 3 | 6 |
| Lymphoma | 1 | 1 |
| Malaise | 32 | 64 |
| Mast cell activation syndrome | | 1 |
| Maternal exposure during pregnancy | 2 | 3 |
| Mean cell volume decreased | 1 | 1 |
| Medication error | 1 | 1 |
| Memory impairment | | 1 |
| Menorrhagia | 1 | 1 |
| Mental fatigue | 2 | 2 |
| Mental impairment | | 1 |
| Metastases to lymph nodes | 3 | 3 |
| Metrorrhagia | 1 | 1 |
| Middle insomnia | 2 | 2 |
| Migraine | 12 | 19 |
| Miliaria | 1 | 1 |
| Mobility decreased | 4 | 5 |
| Monoparesis | 1 | 1 |
| Monoplegia | 3 | 3 |
| Mood swings | 1 | 1 |
| Morning sickness | | 1 |
| Motion sickness | 1 | 1 |
| Mouth swelling | | 2 |
| Mouth ulceration | 1 | 1 |
| Muscle atrophy | 1 | 1 |
| Muscle spasms | 7 | 8 |
| Muscular weakness | 9 | 13 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal disorder | 2 | 3 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | 8 | 10 |
| Myalgia | 56 | 93 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 3 | 3 | 3 |
| | | 1 | 1 |
| 10 | 28 | 22 | 36 |
| | | | 1 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 2 | 2 | | |
| 2 | 8 | 10 | 11 |
| | | 1 | 1 |
| 3 | 4 | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 5 | 6 |
| 2 | 2 | 7 | 11 |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | | |
| 2 | 3 | 6 | 7 |
| 20 | 42 | 36 | 51 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Myelitis transverse | 1 | 1 |
| Myelosuppression | 1 | 1 |
| Nasal congestion | 3 | 5 |
| Nasal discomfort | | 1 |
| Nasal dryness | | 1 |
| Nasopharyngitis | 4 | 7 |
| Nausea | 66 | 107 |
| Neck pain | 8 | 20 |
| Nervousness | 5 | 6 |
| Neurogenic shock | 2 | 3 |
| Night sweats | 5 | 6 |
| No adverse event | 4 | 5 |
| Occupational exposure to product | | 1 |
| Ocular hyperaemia | 1 | 2 |
| Off label use | 17 | 22 |
| Oral discomfort | | 1 |
| Oral pain | 1 | 2 |
| Oral pruritus | 1 | 2 |
| Oropharyngeal pain | 10 | 20 |
| Osteoarthritis | 1 | 1 |
| Overdose | | 1 |
| Oxygen saturation decreased | 1 | 2 |
| Pain | 29 | 58 |
| Pain in extremity | 48 | 84 |
| Pain in jaw | 3 | 3 |
| Pain of skin | 2 | 3 |
| Pallor | 1 | 3 |
| Palpitations | 5 | 8 |
| Papule | | 1 |
| Paraesthesia | 12 | 29 |
| Paraesthesia oral | 7 | 22 |
| Paralysis | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | 1 | 2 |
| | | | 1 |
| | | | 1 |
| 1 | 3 | 3 | 4 |
| 18 | 41 | 48 | 66 |
| 2 | 10 | 6 | 10 |
| | | 5 | 6 |
| | | 2 | 3 |
| 3 | 3 | 2 | 3 |
| 4 | 5 | | |
| | 1 | | |
| | | 1 | 2 |
| 17 | 21 | | 1 |
| | | | 1 |
| | | 1 | 2 |
| | 1 | 1 | 1 |
| 1 | 10 | 9 | 10 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | 1 |
| 10 | 25 | 19 | 33 |
| 21 | 44 | 27 | 40 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 1 | 2 |
| | 1 | 1 | 2 |
| 1 | 2 | 4 | 6 |
| | | | 1 |
| 2 | 10 | 10 | 19 |
| 3 | 16 | 4 | 6 |
| | | 2 | 2 |

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* I=Interval, C=Cumulative
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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Parosmia | 1 | 2 |
| Peau d'orange | | 1 |
| Pelvic discomfort | 1 | 1 |
| Periorbital swelling | 3 | 3 |
| Peripheral coldness | | 2 |
| Peripheral sensory neuropathy | 1 | 1 |
| Peripheral swelling | 10 | 16 |
| Peroneal nerve palsy | 1 | 1 |
| Petit mal epilepsy | 1 | 1 |
| Pharyngeal swelling | 3 | 5 |
| Photophobia | 1 | 3 |
| Plasma cell myeloma | 1 | 1 |
| Poor quality product administered | 1 | 10 |
| Poor quality sleep | 2 | 2 |
| Premature baby | 1 | 1 |
| Presyncope | 5 | 11 |
| Product administered at inappropriate site | 1 | 1 |
| Productive cough | 5 | 6 |
| Product label confusion | | 1 |
| Product packaging quantity issue | | 4 |
| Product preparation error | | 3 |
| Product quality issue | 1 | 1 |
| Product temperature excursion issue | | 3 |
| Product use issue | 17 | 19 |
| Pruritus | 17 | 33 |
| Pulmonary embolism | 1 | 1 |
| Pulmonary pain | 1 | 2 |
| Pulmonary thrombosis | | 1 |
| Puncture site discharge | 1 | 1 |
| Pyrexia | 67 | 135 |
| Q fever | 1 | 1 |
| Rash | 16 | 33 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | 2 | | |
| | | 1 | 1 |
| 3 | 5 | 7 | 11 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | 3 | 3 |
| 1 | 2 | | 1 |
| | | 1 | 1 |
| 1 | 10 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 2 | 5 | 3 | 6 |
| | | 1 | 1 |
| 2 | 3 | 3 | 3 |
| | 1 | | |
| | 4 | | |
| | 3 | | |
| 1 | 1 | | |
| | 3 | | |
| 17 | 18 | | 1 |
| 5 | 14 | 12 | 19 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 17 | 46 | 50 | 89 |
| | | 1 | 1 |
| 3 | 16 | 13 | 17 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Rash erythematous | 3 | 9 |
| Rash papular | 1 | 1 |
| Rash pruritic | 3 | 7 |
| Rash vesicular | 1 | 1 |
| Renal pain | 1 | 3 |
| Respiratory arrest | | 1 |
| Respiratory rate increased | 1 | 1 |
| Retching | | 1 |
| Rheumatoid arthritis | 2 | 2 |
| Rhinorrhoea | 2 | 3 |
| Salivary hypersecretion | | 1 |
| SARS-CoV-2 ant body test negative | 9 | 9 |
| SARS-CoV-2 test positive | 2 | 10 |
| Second primary malignancy | 1 | 1 |
| Seizure | 1 | 2 |
| Sensory loss | 1 | 1 |
| Serotonin syndrome | | 1 |
| Shock | 1 | 1 |
| Sinus disorder | | 1 |
| Sinus headache | 1 | 2 |
| Sinus pain | | 1 |
| Sinus tachycardia | 1 | 1 |
| Skin abrasion | 1 | 1 |
| Skin burning sensation | 1 | 1 |
| Skin exfoliation | 1 | 1 |
| Skin tightness | 1 | 1 |
| Skin warm | | 3 |
| Sleep disorder | 1 | 5 |
| Sleep terror | | 1 |
| Sneezing | 1 | 3 |
| Somnolence | 5 | 7 |
| Stridor | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 4 | 2 | 5 |
| | | 1 | 1 |
| 2 | 4 | 1 | 3 |
| | | 1 | 1 |
| | 1 | 1 | 2 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| 8 | 8 | 1 | 1 |
| 1 | 3 | 1 | 7 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 2 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | 2 |
| 1 | 3 | | 2 |
| | | | 1 |
| | 1 | 1 | 2 |
| 1 | 2 | 4 | 5 |
| | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Suspected COVID-19 | 10 | 15 |
| Sweating fever | 2 | 3 |
| Swelling | 4 | 9 |
| Swelling face | 7 | 10 |
| Swollen tongue | 2 | 5 |
| Symphysiolysis | | 1 |
| Syncope | 26 | 34 |
| Synovial rupture | | 1 |
| Tachycardia | 5 | 12 |
| Tachypnoea | | 2 |
| Taste disorder | 1 | 3 |
| Tenderness | | 1 |
| Tension headache | 1 | 2 |
| Therapeutic response unexpected | | 1 |
| Thirst | 1 | 1 |
| Throat clearing | 1 | 1 |
| Throat irritation | 2 | 3 |
| Throat tightness | 2 | 4 |
| Thrombocytopenia | 1 | 2 |
| Thrombosis | 1 | 1 |
| Tinnitus | 4 | 6 |
| Tongue erythema | 1 | 1 |
| Tongue pruritus | 1 | 1 |
| Tonsillar hypertrophy | 1 | 2 |
| Tonsillitis | | 1 |
| Transient ischaemic attack | 2 | 2 |
| Tremor | 16 | 23 |
| Trismus | | 1 |
| Type I hypersensitivity | 1 | 1 |
| Ulnar nerve injury | 1 | 1 |
| Underdose | | 3 |
| Unresponsive to stimuli | 1 | 3 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | 7 | 12 |
| | | 2 | 3 |
| 1 | 4 | 3 | 5 |
| 3 | 4 | 4 | 6 |
| | 1 | 2 | 4 |
| | | 26 | 34 |
| | 1 | | |
| 2 | 5 | 3 | 7 |
| | | | 2 |
| | 2 | 1 | 1 |
| | 1 | | |
| | 1 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | 1 | 2 | 3 |
| | | 1 | 2 |
| | | 1 | 1 |
| 2 | 2 | 2 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| 3 | 7 | 13 | 16 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 3 | | |
| | | 1 | 3 |

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 * AE=Adverse Event
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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Upper-airway cough syndrome | 1 | 1 |
| Urinary incontinence | 3 | 4 |
| Urinary retention | 2 | 3 |
| Urinary tract infection | 4 | 5 |
| Urticaria | 4 | 14 |
| Urticaria chronic | 1 | 1 |
| Vaccination site bruising | 1 | 4 |
| Vaccination site cellulitis | | 2 |
| Vaccination site discomfort | | 1 |
| Vaccination site erythema | 5 | 17 |
| Vaccination site haemorrhage | | 1 |
| Vaccination site hypoaesthesia | | 1 |
| Vaccination site induration | | 1 |
| Vaccination site inflammation | 1 | 1 |
| Vaccination site joint movement impairment | | 1 |
| Vaccination site mass | 5 | 11 |
| Vaccination site movement impairment | 1 | 2 |
| Vaccination site nodule | 1 | 1 |
| Vaccination site pain | 22 | 58 |
| Vaccination site paraesthesia | | 3 |
| Vaccination site pruritus | 4 | 7 |
| Vaccination site rash | 2 | 2 |
| Vaccination site scab | 1 | 1 |
| Vaccination site swelling | 5 | 21 |
| Vaccination site vesicles | 1 | 1 |
| Vaccination site warmth | 2 | 10 |
| Ventricular arrhythmia | 1 | 1 |
| Vertigo | 2 | 6 |
| Viral tonsillitis | | 1 |
| Vision blurred | 5 | 10 |
| Visual acuity reduced | 1 | 1 |
| Visual impairment | 1 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 3 | 4 |
| | | 2 | 3 |
| | | 4 | 5 |
| | 4 | 4 | 10 |
| | | 1 | 1 |
| 1 | 2 | | 2 |
| | 1 | | 1 |
| | 1 | | |
| 2 | 9 | 3 | 8 |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 5 | 4 | 6 |
| | | 1 | 2 |
| | | 1 | 1 |
| 8 | 36 | 14 | 22 |
| | 2 | | 1 |
| 1 | 4 | 3 | 3 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 4 | 13 | 1 | 8 |
| 1 | 1 | | |
| | 4 | 2 | 6 |
| | | 1 | 1 |
| | 1 | 2 | 5 |
| | | | 1 |
| 1 | 4 | 4 | 6 |
| | | 1 | 1 |
| | | 1 | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 14 | 28 | 5 | 9 | 9 | 19 |
| Wheezing | 3 | 5 | | 2 | 3 | 3 |
| White blood cell count decreased | 1 | 1 | | | 1 | 1 |
| Wrong product administered | | 1 | | 1 | | |
| | | 2 | | 2 | | |
| | 1,673 | 3,115 | 459 | 1138 | 1214 | 1977 |

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Country Where Event Occurred
UNITED STATES

Age Range

Less than or equal to 17 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | | 1 | | 1 | | |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | 6 | 36 | 6 | 36 | | |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye swelling | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Increased appetite | | 1 | | 1 | | |
| Infantile vomiting | | 2 | | 2 | | |
| Infant irritability | | 3 | | 3 | | |
| Insomnia | | 1 | | 1 | | |
| Lethargy | | 1 | | 1 | | |
| Loss of consciousness | 3 | 3 | | | 3 | 3 |
| Malaise | 1 | 1 | | | 1 | 1 |
| Nausea | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 3 | 1 | 3 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Periorbital swelling | 1 | 1 | 1 | 1 | | |
| Poor feeding infant | | 1 | | 1 | | |
| Product administered to patient of inappropriate age | 3 | 9 | 3 | 9 | | |
| Product use issue | | 1 | | 1 | | |
| Pyrexia | 2 | 5 | 2 | 5 | | |
| Rash | | 2 | | 2 | | |
| Vaginal infection | | 1 | | 1 | | |
| | 27 | 82 | 18 | 73 | 9 | 9 |

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- * AE=Adverse Event
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 4 | 10 | 4 | 10 | | |
| Abdominal distension | | 1 | | 1 | | |
| Abdominal pain | 2 | 18 | 1 | 17 | 1 | 1 |
| Abdominal pain upper | 3 | 18 | 3 | 17 | | 1 |
| Abdominal rigidity | 1 | 1 | 1 | 1 | | |
| Abnormal dreams | | 1 | | 1 | | |
| Abortion spontaneous | 3 | 4 | | | 3 | 4 |
| Accidental exposure to product | | 1 | | 1 | | |
| Accidental overdose | 1 | 3 | | 2 | 1 | 1 |
| Acne | | 1 | | 1 | | |
| Ageusia | 2 | 13 | 1 | 10 | 1 | 3 |
| Agitation | | 1 | | 1 | | |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | | 6 | | 5 | | 1 |
| Alopecia | | 2 | | 2 | | |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 20 | 1 | 1 | 3 | 19 |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Anger | 1 | 1 | 1 | 1 | | |
| Angioedema | 1 | 3 | | | 1 | 3 |
| Anosmia | 2 | 15 | 2 | 13 | | 2 |
| Anxiety | 3 | 11 | 3 | 9 | | 2 |
| Aphasia | 1 | 2 | | 1 | 1 | 1 |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 2 | 3 | | | 2 | 3 |
| Arthralgia | 27 | 112 | 27 | 110 | | 2 |
| Arthritis | 2 | 3 | 2 | 3 | | |
| Aspartate aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Asthenia | 16 | 65 | 15 | 59 | 1 | 6 |
| Asthenopia | 1 | 1 | 1 | 1 | | |
| Asymptomatic COVID-19 | | 1 | | | | 1 |
| Autoscopy | 1 | 1 | 1 | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Axillary mass | 1 | 1 |
| Axillary pain | 5 | 14 |
| Back pain | 8 | 40 |
| Balance disorder | | 4 |
| Blepharospasm | 1 | 2 |
| Blister | 2 | 2 |
| Blood bilirubin increased | 1 | 1 |
| Blood glucose increased | | 1 |
| Blood potassium decreased | | 1 |
| Blood potassium increased | 1 | 1 |
| Blood pressure abnormal | | 1 |
| Blood pressure decreased | 3 | 5 |
| Blood pressure increased | 3 | 9 |
| Blood pressure systolic increased | 1 | 1 |
| Blood sodium decreased | | 1 |
| Body temperature abnormal | 1 | 1 |
| Body temperature decreased | | 1 |
| Body temperature fluctuation | 1 | 1 |
| Body temperature increased | 3 | 7 |
| Bone pain | | 2 |
| Breast mass | 1 | 1 |
| Breast pain | | 1 |
| Burning sensation | 6 | 6 |
| Cardiac disorder | 1 | 3 |
| Cardiomyopathy | 1 | 1 |
| Cerebrovascular accident | 2 | 3 |
| Chest discomfort | 6 | 21 |
| Chest pain | 13 | 35 |
| Chills | 95 | 366 |
| Choking sensation | 1 | 1 |
| Chromaturia | | 2 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 5 | 14 | | |
| 7 | 37 | 1 | 3 |
| | 3 | | 1 |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 3 | 5 | | |
| 2 | 5 | 1 | 4 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 3 | 7 | | |
| | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 5 | 5 | 1 | 1 |
| | 1 | 1 | 2 |
| | | 1 | 1 |
| | | 2 | 3 |
| 3 | 13 | 3 | 8 |
| 11 | 28 | 2 | 7 |
| 93 | 356 | 2 | 10 |
| | | 1 | 1 |
| | 2 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Circumstance or information capable of leading to medication error | | 1 |
| Cold sweat | | 8 |
| Condition aggravated | 6 | 11 |
| Confusional state | 3 | 5 |
| Constipation | | 2 |
| Contusion | 4 | 4 |
| Costochondritis | 1 | 1 |
| Costovertebral angle tenderness | | 1 |
| Cough | 8 | 44 |
| COVID-19 | 9 | 35 |
| C-reactive protein increased | | 1 |
| Crying | | 3 |
| Cyanosis | | 2 |
| Death | 3 | 3 |
| Decreased appetite | 4 | 13 |
| Deep vein thrombosis | | 2 |
| Dehydration | 3 | 9 |
| Delirium | 1 | 1 |
| Depressed mood | | 1 |
| Depression | | 1 |
| Device breakage | | 1 |
| Diabetes mellitus | 1 | 1 |
| Diaphragmatic paralysis | 1 | 1 |
| Diarrhoea | 14 | 55 |
| Discomfort | 5 | 13 |
| Disease recurrence | | 2 |
| Disorientation | 3 | 3 |
| Disturbance in attention | 1 | 2 |
| Dizziness | 40 | 158 |
| Dizziness postural | | 3 |
| Drug hypersensitivity | 1 | 2 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 7 | | 1 |
| 4 | 9 | 2 | 2 |
| 3 | 5 | | |
| | 2 | | |
| 4 | 4 | | |
| 1 | 1 | | |
| | 1 | | |
| 7 | 36 | 1 | 8 |
| 1 | 6 | 8 | 29 |
| | | | 1 |
| | 2 | | 1 |
| | 1 | | 1 |
| | | 3 | 3 |
| 4 | 12 | | 1 |
| | | | 2 |
| 2 | 7 | 1 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 13 | 52 | 1 | 3 |
| 4 | 10 | 1 | 3 |
| | 2 | | |
| 3 | 3 | | |
| 1 | 2 | | |
| 32 | 136 | 8 | 22 |
| | 1 | | 2 |
| | 1 | 1 | 1 |

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 * AE=Adverse Event
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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Drug ineffective | 11 | 58 |
| Dry mouth | 3 | 6 |
| Dry skin | 1 | 2 |
| Dry throat | | 9 |
| Dysarthria | 2 | 2 |
| Dysgeusia | 3 | 7 |
| Dyskinesia | | 1 |
| Dyspepsia | 1 | 3 |
| Dysphagia | 6 | 14 |
| Dysphemia | | 1 |
| Dysphonia | 1 | 6 |
| Dyspnoea | 21 | 70 |
| Dysstasia | 2 | 2 |
| Dysuria | 1 | 2 |
| Ear discomfort | | 6 |
| Ear disorder | | 1 |
| Ear pain | 1 | 5 |
| Ear swelling | 1 | 3 |
| Ejection fraction abnormal | | 1 |
| Electrocardiogram QT prolonged | 1 | 1 |
| Electrocardiogram T wave peaked | 1 | 1 |
| Emotional disorder | | 1 |
| Enlarged uvula | | 1 |
| Eosinophil count increased | | 1 |
| Epistaxis | | 2 |
| Eructation | | 1 |
| Erythema | 7 | 23 |
| Exposure during pregnancy | 2 | 4 |
| Exposure to SARS-CoV-2 | 2 | 4 |
| Eye discharge | 1 | 1 |
| Eye disorder | | 2 |
| Eyelid ptosis | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 11 | 57 |
| 3 | 6 | | |
| 1 | 2 | | |
| | 7 | | 2 |
| 1 | 1 | 1 | 1 |
| 3 | 7 | | |
| | | | 1 |
| 1 | 3 | | |
| 3 | 6 | 3 | 8 |
| | 1 | | |
| 1 | 5 | | 1 |
| 15 | 45 | 6 | 25 |
| 1 | 1 | 1 | 1 |
| 1 | 2 | | |
| | 6 | | |
| | 1 | | |
| 1 | 5 | | |
| | 2 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| | 2 | | |
| | 1 | | |
| 7 | 21 | | 2 |
| 2 | 3 | | 1 |
| 1 | 3 | 1 | 1 |
| 1 | 1 | | |
| | 2 | | |
| | | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eye movement disorder | 1 | 1 |
| Eye pain | | 6 |
| Eye pruritus | 3 | 3 |
| Eye swelling | 4 | 7 |
| Face injury | | 1 |
| Face oedema | | 1 |
| Facial neuralgia | 1 | 1 |
| Facial pain | | 4 |
| Facial paralysis | 6 | 12 |
| Facial paresis | | 2 |
| Facial spasm | 1 | 1 |
| Fall | 1 | 3 |
| Fatigue | 81 | 312 |
| Fear | | 1 |
| Feeding disorder | | 1 |
| Feeling abnormal | 6 | 26 |
| Feeling cold | 5 | 13 |
| Feeling drunk | 1 | 1 |
| Feeling hot | 8 | 27 |
| Feeling jittery | 1 | 2 |
| Feeling of body temperature change | 1 | 2 |
| Flank pain | 1 | 1 |
| Fluid imbalance | | 1 |
| Flushing | 5 | 22 |
| Foetal death | 1 | 1 |
| Formication | | 1 |
| Gait disturbance | 2 | 3 |
| Gait inability | 1 | 1 |
| Gastrointestinal disorder | | 1 |
| Gastrointestinal inflammation | 1 | 1 |
| Gastrooesophageal reflux disease | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 5 | | 1 |
| 2 | 2 | 1 | 1 |
| 3 | 6 | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | 4 | | |
| | | 6 | 12 |
| | | | 2 |
| | | 1 | 1 |
| | 2 | 1 | 1 |
| 81 | 309 | | 3 |
| | | | 1 |
| | 1 | | |
| 5 | 22 | 1 | 4 |
| 4 | 12 | 1 | 1 |
| 1 | 1 | | |
| 8 | 25 | | 2 |
| 1 | 2 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | | | 1 |
| 5 | 15 | | 7 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------|------------------------------------|--------------------------------------|
| Gingival blister | | 1 |
| Gingival discolouration | | 1 |
| Gingival discomfort | | 1 |
| Gingival pain | | 2 |
| Glassy eyes | | 1 |
| Haematochezia | | 1 |
| Haemorrhage | 1 | 1 |
| Hallucination | 1 | 1 |
| Hallucination, visual | 1 | 1 |
| Hangover | 1 | 1 |
| Headache | 98 | 406 |
| Head injury | 1 | 2 |
| Heart rate increased | 12 | 51 |
| Heart rate irregular | 1 | 2 |
| Hemiparesis | | 1 |
| Herpes zoster | | 4 |
| Hot flush | 3 | 14 |
| Hyperacusis | | 1 |
| Hyperaemia | | 1 |
| Hyperaesthesia | | 2 |
| Hyperglycaemia | 1 | 1 |
| Hyperhidrosis | 16 | 47 |
| Hyperpyrexia | 1 | 2 |
| Hypersensitivity | | 9 |
| Hypersomnia | 2 | 5 |
| Hypertension | 2 | 10 |
| Hyperthermia | | 1 |
| Hyperventilation | 1 | 3 |
| Hypoaesthesia | 19 | 52 |
| Hypoaesthesia oral | | 4 |
| Hypoglycaemia | 1 | 1 |
| Hypopnoea | | 2 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| | | | 2 |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 94 | 393 | 4 | 13 |
| | 1 | 1 | 1 |
| 7 | 39 | 5 | 12 |
| | 1 | 1 | 1 |
| | | | 1 |
| | 4 | | |
| 3 | 12 | | 2 |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| 1 | 1 | | |
| 16 | 46 | | 1 |
| | | 1 | 2 |
| | 6 | | 3 |
| 2 | 5 | | |
| | 5 | 2 | 5 |
| | 1 | | |
| 1 | 2 | | 1 |
| 17 | 43 | 2 | 9 |
| | 4 | | |
| 1 | 1 | | |
| | 2 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyporesponsive to stimuli | 1 | 1 |
| Hypotension | 3 | 10 |
| Illness | 2 | 10 |
| Immune thrombocytopenia | 1 | 2 |
| Impaired work ability | | 1 |
| Inappropriate schedule of product administration | 13 | 58 |
| Incorrect dose administered | | 1 |
| Incorrect route of product administration | 1 | 3 |
| Induration | | 1 |
| Infection | | 1 |
| Inflammation | | 1 |
| Influenza | 2 | 5 |
| Influenza like illness | 3 | 19 |
| Injection site erythema | 1 | 3 |
| Injection site pain | | 2 |
| Injection site rash | 1 | 3 |
| Injection site swelling | | 1 |
| Injection site urticaria | | 1 |
| Injury | | 1 |
| Insomnia | 3 | 11 |
| Inspiratory capacity decreased | 1 | 1 |
| Intracranial aneurysm | 1 | 1 |
| Intranasal paraesthesia | | 1 |
| Irritability | 1 | 1 |
| Irritable bowel syndrome | | 1 |
| Joint dislocation | 1 | 1 |
| Joint instability | | 1 |
| Joint range of motion decreased | 2 | 9 |
| Joint stiffness | | 2 |
| Joint swelling | | 2 |
| Kidney infection | | 1 |
| Lacrimation decreased | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 2 | 6 | 1 | 4 |
| 2 | 9 | | 1 |
| | | 1 | 2 |
| | 1 | | |
| 13 | 58 | | |
| | 1 | | |
| 1 | 2 | | 1 |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| 1 | 4 | 1 | 1 |
| 3 | 19 | | |
| 1 | 3 | | |
| | 2 | | |
| 1 | 3 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 3 | 10 | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| 2 | 7 | | 2 |
| | 2 | | |
| | 1 | | 1 |
| | | | 1 |
| | | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Lacrimation increased | | 1 |
| Laryngeal oedema | | 1 |
| Lethargy | 3 | 9 |
| Ligament injury | | 1 |
| Limb discomfort | 2 | 4 |
| Lip erythema | | 1 |
| Lip oedema | | 2 |
| Lip swelling | | 9 |
| Loss of consciousness | 10 | 18 |
| Loss of personal independence in daily activities | 1 | 4 |
| Lung disorder | | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 32 | 111 |
| Lymph node pain | 9 | 18 |
| Lymph node palpable | | 1 |
| Macule | | 1 |
| Malaise | 17 | 77 |
| Mass | 1 | 2 |
| Maternal exposure during pregnancy | 3 | 14 |
| Meningism | | 1 |
| Meningitis noninfective | 1 | 1 |
| Menstrual disorder | 1 | 2 |
| Mental impairment | 2 | 5 |
| Micturition disorder | 1 | 1 |
| Micturition urgency | 1 | 1 |
| Middle insomnia | 1 | 1 |
| Migraine | 7 | 27 |
| Migraine with aura | 1 | 1 |
| Mobility decreased | 2 | 4 |
| Monoplegia | 1 | 1 |
| Mood swings | 1 | 1 |
| Mouth swelling | 1 | 3 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | | 1 |
| 3 | 9 | | |
| | 1 | | |
| 2 | 4 | | |
| | 1 | | |
| | 1 | | 1 |
| | 6 | | 3 |
| | | 10 | 18 |
| | 3 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 31 | 107 | 1 | 4 |
| 9 | 18 | | |
| | 1 | | |
| 17 | 73 | | 4 |
| 1 | 2 | | |
| 3 | 14 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 2 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 7 | 26 | | 1 |
| 1 | 1 | | |
| 1 | 3 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Movement disorder | 1 | 2 |
| Mucosal disorder | | 1 |
| Muscle discomfort | | 1 |
| Muscle disorder | | 2 |
| Muscle fatigue | | 2 |
| Muscle spasms | 3 | 9 |
| Muscle tightness | 1 | 7 |
| Muscle twitching | 2 | 3 |
| Muscular weakness | 9 | 14 |
| Musculoskeletal chest pain | | 2 |
| Musculoskeletal discomfort | 1 | 2 |
| Musculoskeletal disorder | | 2 |
| Musculoskeletal pain | 1 | 2 |
| Musculoskeletal stiffness | 4 | 14 |
| Myalgia | 41 | 179 |
| Myocardial infarction | | 1 |
| Myocardial necrosis marker increased | | 1 |
| Myoclonus | 1 | 1 |
| Narcolepsy | 1 | 1 |
| Nasal congestion | 4 | 25 |
| Nasal discomfort | | 2 |
| Nasal dryness | | 2 |
| Nasal injury | | 2 |
| Nasal oedema | 2 | 3 |
| Nasal pruritus | 1 | 1 |
| Nasopharyngitis | 4 | 10 |
| Nausea | 53 | 245 |
| Neck mass | | 1 |
| Neck pain | 7 | 26 |
| Nephropathy | 1 | 1 |
| Nervousness | 3 | 7 |
| Neuralgia | 1 | 5 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 2 | | |
| 3 | 9 | | |
| 1 | 7 | | |
| 2 | 3 | | |
| 6 | 11 | 3 | 3 |
| | 2 | | |
| 1 | 2 | | |
| | 2 | | |
| 1 | 2 | | |
| 3 | 13 | 1 | 1 |
| 40 | 174 | 1 | 5 |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 23 | | 2 |
| | 2 | | |
| | 2 | | |
| | 2 | | |
| 1 | 1 | 1 | 2 |
| 1 | 1 | | |
| 4 | 10 | | |
| 53 | 237 | | 8 |
| | 1 | | |
| 3 | 20 | 4 | 6 |
| 1 | 1 | | |
| 3 | 7 | | |
| 1 | 5 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Neuralgic amyotrophy | 1 | 1 |
| Neurological symptom | 1 | 1 |
| Neutrophil count increased | | 1 |
| Nightmare | | 2 |
| Night sweats | 2 | 12 |
| No adverse event | 1 | 1 |
| Noninfective encephalitis | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | | 1 |
| Odynophagia | 1 | 1 |
| Oedema mouth | 1 | 1 |
| Off label use | 15 | 41 |
| Oral discomfort | 1 | 2 |
| Oral disorder | | 3 |
| Oral herpes | | 2 |
| Oral mucosal eruption | | 1 |
| Oral pain | | 2 |
| Oral pruritus | | 1 |
| Oropharyngeal discomfort | | 3 |
| Oropharyngeal pain | 4 | 35 |
| Overdose | 2 | 7 |
| Pain | 73 | 270 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 42 | 141 |
| Pain in jaw | 2 | 4 |
| Pain of skin | | 2 |
| Palatal swelling | | 1 |
| Pallor | 2 | 3 |
| Palpitations | 7 | 32 |
| Panic attack | | 1 |
| Panic reaction | | 1 |
| Paraesthesia | 19 | 52 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 2 | | |
| 2 | 11 | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 13 | 39 | 2 | 2 |
| 1 | 2 | | |
| | 3 | | |
| | 2 | | |
| | 1 | | |
| | 1 | | 1 |
| | 2 | | |
| 3 | 30 | 1 | 5 |
| 2 | 7 | | |
| 70 | 260 | 3 | 10 |
| 1 | 1 | | |
| 41 | 140 | 1 | 1 |
| 2 | 4 | | |
| | 2 | | |
| | 1 | | |
| 1 | 2 | 1 | 1 |
| 7 | 26 | | 6 |
| | 1 | | |
| | 1 | | |
| 14 | 42 | 5 | 10 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Paraesthesia oral | 2 | 8 |
| Paralysis | | 2 |
| Paranasal sinus discomfort | | 3 |
| Parosmia | | 1 |
| Periarthritis | | 1 |
| Periorbital swelling | 1 | 2 |
| Peripheral coldness | 2 | 3 |
| Peripheral swelling | 5 | 16 |
| Petechiae | | 1 |
| Pharyngeal enanthema | 1 | 1 |
| Pharyngeal hypoaesthesia | | 2 |
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal paraesthesia | | 3 |
| Pharyngeal swelling | 5 | 14 |
| Photophobia | | 2 |
| Photopsia | | 1 |
| Photosensitivity reaction | 1 | 3 |
| Phrenic nerve injury | 1 | 1 |
| Piloerection | | 3 |
| Pityriasis | 1 | 1 |
| Platelet count decreased | 1 | 1 |
| Platelet count increased | | 2 |
| Pleuritic pain | | 1 |
| Pollakiuria | 1 | 3 |
| Polyuria | | 1 |
| Poor quality product administered | | 1 |
| Poor quality sleep | | 2 |
| Postictal state | | 1 |
| Premature rupture of membranes | | 1 |
| Presyncope | 6 | 13 |
| Procedural pain | | 1 |
| Product administered at inappropriate site | 2 | 6 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 7 | | 1 |
| | | | 2 |
| | 3 | | |
| | 1 | | |
| | | | 1 |
| 1 | 2 | | |
| 2 | 3 | | |
| 5 | 15 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| | | 1 | 1 |
| | 3 | | |
| 4 | 9 | 1 | 5 |
| | 2 | | |
| | 1 | | |
| 1 | 3 | | |
| | | 1 | 1 |
| | 3 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 2 |
| | 1 | | |
| 1 | 3 | | |
| | 1 | | |
| | 2 | | |
| | 1 | | |
| | | | 1 |
| 6 | 12 | | 1 |
| | | | 1 |
| 2 | 5 | | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Product administration error | 1 | 2 |
| Product formulation issue | | 1 |
| Productive cough | 1 | 1 |
| Product preparation error | 1 | 4 |
| Product preparation issue | | 1 |
| Product prescribing error | 1 | 1 |
| Product temperature excursion issue | | 1 |
| Product use issue | 12 | 35 |
| Pruritus | 13 | 47 |
| Pulmonary embolism | | 1 |
| Pulmonary pain | 1 | 1 |
| Pulse absent | 1 | 1 |
| Pyrexia | 93 | 377 |
| Rash | 24 | 63 |
| Rash erythematous | 3 | 9 |
| Rash macular | 1 | 4 |
| Rash maculo-papular | 1 | 2 |
| Rash papular | 1 | 5 |
| Rash pruritic | 2 | 11 |
| Reaction to excipient | | 1 |
| Renal pain | | 1 |
| Respiration abnormal | 1 | 1 |
| Respiratory disorder | 2 | 2 |
| Respiratory distress | 2 | 3 |
| Respiratory symptom | 1 | 1 |
| Respiratory tract congestion | 1 | 2 |
| Restlessness | 1 | 4 |
| Retching | | 3 |
| Rhinalgia | | 1 |
| Rhinorrhoea | 6 | 16 |
| Ruptured cerebral aneurysm | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 4 | | |
| 1 | 1 | | 1 |
| | 1 | | |
| 10 | 33 | 2 | 2 |
| 12 | 41 | 1 | 6 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 90 | 361 | 3 | 16 |
| 21 | 55 | 3 | 8 |
| 3 | 7 | | 2 |
| 1 | 4 | | |
| 1 | 2 | | |
| 1 | 5 | | |
| 2 | 10 | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 2 |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 3 | | 1 |
| | 3 | | |
| | 1 | | |
| 6 | 15 | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| SARS-CoV-2 test false positive | | 1 |
| SARS-CoV-2 test positive | 5 | 30 |
| Scar | | 1 |
| Seasonal allergy | | 1 |
| Seizure | 2 | 4 |
| Sensation of blood flow | 1 | 1 |
| Sensation of foreign body | | 5 |
| Sensitive skin | | 2 |
| Shock symptom | | 1 |
| Sinus congestion | 1 | 4 |
| Sinus headache | 1 | 1 |
| Sinusitis | 1 | 2 |
| Sinus rhythm | | 1 |
| Sinus tachycardia | | 1 |
| Skin burning sensation | 1 | 4 |
| Skin discolouration | | 1 |
| Skin disorder | 2 | 5 |
| Skin exfoliation | 1 | 1 |
| Skin irritation | 1 | 1 |
| Skin lesion | 1 | 1 |
| Skin tightness | | 1 |
| Sleep disorder | 1 | 4 |
| Slow response to stimuli | | 1 |
| Sneezing | 1 | 4 |
| Snoring | | 1 |
| Somnolence | 2 | 6 |
| Speech disorder | 4 | 6 |
| Spinal pain | | 2 |
| Stomatitis | | 3 |
| Stomatitis haemorrhagic | 1 | 1 |
| Strabismus | 1 | 1 |
| Stress | | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 2 | 4 | 3 | 26 |
| | 1 | | |
| | 1 | | |
| | | 2 | 4 |
| | | 1 | 1 |
| | 2 | | 3 |
| | 2 | | |
| | | | 1 |
| 1 | 4 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | | | 1 |
| 1 | 4 | | |
| | 1 | | |
| 2 | 5 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 4 | | |
| | 1 | | |
| 1 | 4 | | |
| | | | 1 |
| 2 | 6 | | |
| 2 | 3 | 2 | 3 |
| | 2 | | |
| | 3 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Subarachnoid haemorrhage | 1 | 1 |
| Suspected COVID-19 | | 1 |
| Suture related complication | | 1 |
| Swelling | 1 | 12 |
| Swelling face | 3 | 14 |
| Swelling of eyelid | | 3 |
| Swollen tongue | | 5 |
| Syncope | 13 | 32 |
| Tachycardia | 4 | 37 |
| Tachypnoea | 1 | 3 |
| Taste disorder | | 3 |
| Temperature intolerance | 1 | 1 |
| Temperature regulation disorder | 1 | 1 |
| Tenderness | | 2 |
| Tension headache | 2 | 3 |
| Thirst | 1 | 3 |
| Throat irritation | 3 | 13 |
| Throat tightness | 4 | 18 |
| Thrombocytopenia | | 1 |
| Thrombotic thrombocytopenic purpura | 1 | 2 |
| Tinnitus | 1 | 4 |
| Tongue discomfort | 1 | 2 |
| Tongue disorder | | 1 |
| Tongue pruritus | | 1 |
| Tonsillar hypertrophy | 1 | 2 |
| Tonsillolith | | 1 |
| Toothache | | 1 |
| Torsade de pointes | 1 | 1 |
| Tremor | 7 | 23 |
| Trigeminal neuralgia | 1 | 1 |
| Trismus | | 1 |
| Tuberculin test positive | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | | 1 |
| | | | 1 |
| 1 | 12 | | |
| 2 | 13 | 1 | 1 |
| | 3 | | |
| | 3 | | 2 |
| | | 13 | 32 |
| 3 | 24 | 1 | 13 |
| 1 | 2 | | 1 |
| | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| 2 | 3 | | |
| 1 | 3 | | |
| 3 | 10 | | 3 |
| 1 | 3 | 3 | 15 |
| | | | 1 |
| | | 1 | 2 |
| | 3 | 1 | 1 |
| 1 | 2 | | |
| | | | 1 |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| 7 | 22 | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |

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

Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Tunnel vision | | 1 |
| Underdose | | 5 |
| Upper-airway cough syndrome | | 3 |
| Upper respiratory tract congestion | | 1 |
| Urethral disorder | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urine abnormality | 1 | 1 |
| Urine odour abnormal | 1 | 1 |
| Urticaria | 11 | 51 |
| Use of accessory respiratory muscles | 1 | 1 |
| Uterine haemorrhage | | 1 |
| Vaccination site bruising | 1 | 3 |
| Vaccination site cellulitis | | 1 |
| Vaccination site discomfort | | 2 |
| Vaccination site erythema | 9 | 49 |
| Vaccination site haemorrhage | 2 | 4 |
| Vaccination site hypersensitivity | | 1 |
| Vaccination site hypoaesthesia | 1 | 4 |
| Vaccination site induration | 2 | 9 |
| Vaccination site infection | | 1 |
| Vaccination site inflammation | 1 | 4 |
| Vaccination site injury | | 1 |
| Vaccination site joint movement impairment | | 1 |
| Vaccination site lymphadenopathy | 2 | 4 |
| Vaccination site macule | | 1 |
| Vaccination site mass | 3 | 7 |
| Vaccination site movement impairment | 1 | 2 |
| Vaccination site nodule | | 1 |
| Vaccination site pain | 64 | 227 |
| Vaccination site papule | 1 | 2 |
| Vaccination site paraesthesia | 1 | 5 |
| Vaccination site pruritus | 3 | 17 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | 5 | | |
| | 3 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 9 | 39 | 2 | 12 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 3 | | |
| | | | 1 |
| | 2 | | |
| 9 | 48 | | 1 |
| 2 | 4 | | |
| | 1 | | |
| 1 | 4 | | |
| 2 | 9 | | |
| | 1 | | |
| 1 | 3 | | 1 |
| | 1 | | |
| | | | 1 |
| 2 | 4 | | |
| | 1 | | |
| 3 | 7 | | |
| 1 | 2 | | |
| | 1 | | |
| 64 | 226 | | 1 |
| 1 | 2 | | |
| 1 | 5 | | |
| 2 | 16 | 1 | 1 |

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Age Range

18 - 30 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site rash | 6 | 13 | 5 | 12 | 1 | 1 |
| Vaccination site scab | | 1 | | 1 | | |
| Vaccination site swelling | 11 | 51 | 11 | 49 | | 2 |
| Vaccination site vesicles | | 2 | | 2 | | |
| Vaccination site warmth | 2 | 16 | 2 | 16 | | |
| Vaginal lesion | 1 | 1 | 1 | 1 | | |
| Ventricular tachycardia | | 1 | | | | 1 |
| Vertigo | 3 | 8 | 2 | 6 | 1 | 2 |
| Viral rash | | 1 | | 1 | | |
| Vision blurred | 1 | 4 | 1 | 3 | | 1 |
| Visual field defect | 1 | 1 | 1 | 1 | | |
| Visual impairment | 2 | 4 | 2 | 3 | | 1 |
| Vomiting | 21 | 79 | 19 | 75 | 2 | 4 |
| Vulval disorder | 1 | 1 | 1 | 1 | | |
| Wheezing | | 4 | | 1 | | 3 |
| White blood cell count increased | 1 | 3 | 1 | 1 | | 2 |
| Wrong product administered | 1 | 1 | 1 | 1 | | |
| Wrong technique in product usage process | 1 | 2 | | 1 | 1 | 1 |
| Yellow skin | 1 | 1 | 1 | 1 | | |
| | 1,602 | 5,876 | 1368 | 5128 | 234 | 748 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 8 | 30 | 8 | 28 | | 2 |
| Abdominal distension | | 5 | | 5 | | |
| Abdominal pain | 11 | 30 | 9 | 27 | 2 | 3 |
| Abdominal pain lower | 1 | 5 | 1 | 3 | | 2 |
| Abdominal pain upper | 13 | 36 | 12 | 33 | 1 | 3 |
| Abdominal rigidity | | 1 | | 1 | | |
| Abnormal dreams | 1 | 7 | 1 | 7 | | |
| Abnormal sensation in eye | | 2 | | 2 | | |
| Abnormal withdrawal bleeding | 1 | 1 | 1 | 1 | | |
| Abortion spontaneous | 3 | 6 | | | 3 | 6 |
| Accidental exposure to product | | 2 | | 2 | | |
| Accidental overdose | | 9 | | 8 | | 1 |
| Accidental underdose | | 1 | | 1 | | |
| Acetonaemia | | 1 | | 1 | | |
| Acne | 3 | 5 | 3 | 5 | | |
| Acute disseminated encephalomyelitis | | 1 | | | | 1 |
| Acute myocardial infarction | | 1 | | | | 1 |
| Adrenocortical insufficiency acute | 1 | 1 | | | 1 | 1 |
| Ageusia | 13 | 36 | 12 | 32 | 1 | 4 |
| Agitation | 1 | 2 | 1 | 2 | | |
| Alanine aminotransferase increased | | 1 | | | | 1 |
| Allergy to vaccine | 5 | 20 | 4 | 13 | 1 | 7 |
| Alopecia | | 1 | | 1 | | |
| Amnesia | 3 | 4 | 2 | 2 | 1 | 2 |
| Anaesthesia | | 1 | | 1 | | |
| Anal incontinence | | 1 | | 1 | | |
| Anaphylactic reaction | 18 | 55 | | 1 | 18 | 54 |
| Anaphylactic shock | | 3 | | 1 | | 2 |
| Anaphylactoid reaction | | 2 | | | | 2 |
| Aneurysm ruptured | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 9 | | | 1 | 9 |
| Angiopathy | 2 | 2 | 2 | 2 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Anosmia | 12 | 36 |
| Anxiety | 15 | 48 |
| Apathy | 1 | 1 |
| Aphasia | | 2 |
| Aphonia | 1 | 1 |
| Appendicitis | 2 | 6 |
| Arrhythmia | 3 | 6 |
| Arteriospasm coronary | | 1 |
| Arthralgia | 95 | 359 |
| Arthritis | | 5 |
| Arthropathy | 2 | 2 |
| Arthropod bite | 1 | 1 |
| Aspartate aminotransferase increased | | 1 |
| Asthenia | 40 | 160 |
| Asthenopia | 1 | 7 |
| Asthma | 3 | 13 |
| Asymptomatic COVID-19 | 2 | 4 |
| Atrial fibrillation | 1 | 2 |
| Aura | | 1 |
| Autoimmune disorder | 1 | 4 |
| Autonomic nervous system imbalance | 1 | 2 |
| Axillary mass | 1 | 8 |
| Axillary pain | 17 | 46 |
| Back pain | 29 | 88 |
| Balance disorder | 3 | 17 |
| Bedridden | | 1 |
| Behaviour disorder | 1 | 1 |
| Bilirubin urine present | | 1 |
| Blepharospasm | | 3 |
| Blindness | | 1 |
| Blindness transient | | 1 |
| Blister | | 8 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 11 | 30 | 1 | 6 |
| 15 | 46 | | 2 |
| 1 | 1 | | |
| | 1 | | 1 |
| | | 1 | 1 |
| | | 2 | 6 |
| | | 3 | 6 |
| | | | 1 |
| 93 | 340 | 2 | 19 |
| | 5 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 33 | 138 | 7 | 22 |
| 1 | 6 | | 1 |
| 3 | 11 | | 2 |
| | | 2 | 4 |
| | | 1 | 2 |
| | 1 | | |
| | | 1 | 4 |
| 1 | 1 | | 1 |
| 1 | 6 | | 2 |
| 17 | 45 | | 1 |
| 22 | 75 | 7 | 13 |
| 3 | 15 | | 2 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 3 | | |
| | | | 1 |
| | | | 1 |
| | 8 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood chloride increased | | 1 | | 1 | | |
| Blood cholesterol increased | 1 | 1 | 1 | 1 | | |
| Blood count abnormal | | 1 | | 1 | | |
| Blood glucose abnormal | | 1 | | 1 | | |
| Blood glucose decreased | 3 | 4 | 3 | 4 | | |
| Blood glucose increased | 1 | 1 | | | 1 | 1 |
| Blood iron decreased | 1 | 2 | 1 | 2 | | |
| Blood ketone body increased | 1 | 1 | | | 1 | 1 |
| Blood potassium decreased | | 1 | | | | 1 |
| Blood pressure abnormal | | 2 | | 2 | | |
| Blood pressure decreased | 5 | 9 | 5 | 7 | | 2 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure diastolic increased | | 2 | | 2 | | |
| Blood pressure fluctuation | 1 | 2 | 1 | 2 | | |
| Blood pressure increased | 20 | 72 | 12 | 45 | 8 | 27 |
| Blood pressure systolic increased | 1 | 3 | | 1 | 1 | 2 |
| Blood thyroid stimulating hormone increased | | 1 | | 1 | | |
| Blood urine present | | 2 | | 2 | | |
| Body temperature abnormal | 2 | 5 | 2 | 5 | | |
| Body temperature decreased | 1 | 2 | 1 | 2 | | |
| Body temperature fluctuation | | 1 | | 1 | | |
| Body temperature increased | 9 | 22 | 8 | 21 | 1 | 1 |
| Bone pain | 9 | 25 | 7 | 19 | 2 | 6 |
| Bone swelling | | 1 | | 1 | | |
| Booster dose missed | | 1 | | 1 | | |
| Brachial plexopathy | | 2 | | 1 | | 1 |
| Bradykinesia | | 1 | | 1 | | |
| Brain injury | | 2 | | | | 2 |
| Brain stem syndrome | 1 | 1 | | | 1 | 1 |
| Breast discharge | 1 | 1 | 1 | 1 | | |
| Breast discomfort | | 1 | | 1 | | |
| Breast pain | 4 | 9 | 4 | 9 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Breast swelling | | 2 |
| Breast tenderness | 1 | 3 |
| Breath odour | | 2 |
| Bronchospasm | | 3 |
| Bruxism | 1 | 1 |
| Burning sensation | 14 | 50 |
| Bursitis | | 1 |
| Butterfly rash | 1 | 1 |
| Capillary nail refill test abnormal | | 1 |
| Cardiac arrest | 1 | 3 |
| Cardiac disorder | | 2 |
| Cardiac flutter | 2 | 5 |
| Cardiac neoplasm unspecified | | 1 |
| Cardiac valve sclerosis | | 1 |
| Cardio-respiratory arrest | | 1 |
| Cellulitis | 3 | 5 |
| Central nervous system lesion | | 1 |
| Cerebral haemorrhage | | 2 |
| Cerebrovascular accident | 3 | 12 |
| Cheilitis | 1 | 2 |
| Chest discomfort | 27 | 108 |
| Chest pain | 25 | 90 |
| Chills | 198 | 819 |
| Choking | 1 | 2 |
| Choking sensation | | 1 |
| Chromaturia | 2 | 4 |
| Ciliary muscle spasm | 1 | 1 |
| Circulatory collapse | | 2 |
| Circumstance or information capable of leading to medication error | | 2 |
| Claustrophobia | | 1 |
| Clumsiness | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| 1 | 2 | | 1 |
| | 2 | | |
| | 2 | | 1 |
| 1 | 1 | | |
| 11 | 41 | 3 | 9 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 3 |
| | 2 | | |
| | | 2 | 5 |
| | | | 1 |
| | | | 1 |
| | | 3 | 5 |
| | 1 | | |
| | | | 2 |
| | | 3 | 12 |
| 1 | 2 | | |
| 17 | 77 | 10 | 31 |
| 19 | 64 | 6 | 26 |
| 188 | 785 | 10 | 34 |
| | | 1 | 2 |
| | | | 1 |
| 2 | 4 | | |
| 1 | 1 | | |
| | | | 2 |
| | 2 | | |
| | 1 | | |
| | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Cluster headache | 1 | 1 |
| Coccidioidomycosis | 1 | 1 |
| Cognitive disorder | 2 | 4 |
| Cold sweat | 5 | 22 |
| Coma | 1 | 1 |
| Condition aggravated | 8 | 27 |
| Confusional state | 6 | 17 |
| Conjunctival irritation | | 1 |
| Conjunctival oedema | | 1 |
| Conjunctivitis | 1 | 3 |
| Constipation | 2 | 4 |
| Contusion | 2 | 12 |
| Coordination abnormal | | 1 |
| Corneal oedema | | 1 |
| Corneal reflex decreased | 1 | 1 |
| Cough | 32 | 118 |
| COVID-19 | 38 | 150 |
| COVID-19 pneumonia | | 1 |
| Cranial nerve disorder | 1 | 1 |
| C-reactive protein increased | | 1 |
| Crying | 4 | 10 |
| Cyanosis | 1 | 3 |
| Cyst | | 1 |
| Cystitis | 1 | 1 |
| Deafness | 4 | 8 |
| Deafness neurosensory | 1 | 3 |
| Deafness unilateral | | 2 |
| Death | 3 | 3 |
| Decreased appetite | 13 | 55 |
| Decreased interest | 1 | 1 |
| Deep vein thrombosis | 1 | 1 |
| Defaecation urgency | | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | 1 | 2 |
| 5 | 19 | | 3 |
| | | 1 | 1 |
| 5 | 20 | 3 | 7 |
| 4 | 14 | 2 | 3 |
| | 1 | | |
| | 1 | | |
| 1 | 3 | | |
| 2 | 4 | | |
| 2 | 12 | | |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| 25 | 94 | 7 | 24 |
| 1 | 9 | 37 | 141 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| 4 | 10 | | |
| | 1 | 1 | 2 |
| | 1 | | |
| 1 | 1 | | |
| | | 4 | 8 |
| | | 1 | 3 |
| | | | 2 |
| | | 3 | 3 |
| 13 | 54 | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Dehydration | 2 | 13 |
| Delirium | 2 | 2 |
| Demyelinating polyneuropathy | | 1 |
| Dental paraesthesia | | 1 |
| Depressed level of consciousness | | 3 |
| Depressed mood | | 2 |
| Depression | | 2 |
| Dermatitis | 1 | 3 |
| Dermatitis acneiform | 1 | 1 |
| Dermatitis allergic | | 3 |
| Dermatitis exfoliative | | 1 |
| Diabetes mellitus | 1 | 2 |
| Diarrhoea | 36 | 170 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Dilatation ventricular | | 1 |
| Diplopia | 1 | 1 |
| Discomfort | 9 | 28 |
| Disease recurrence | 6 | 16 |
| Disorientation | 3 | 7 |
| Dissociation | | 1 |
| Disturbance in attention | 5 | 17 |
| Dizziness | 116 | 423 |
| Dizziness exertional | | 2 |
| Dizziness postural | 2 | 7 |
| Drooling | | 1 |
| Drug eruption | | 1 |
| Drug hypersensitivity | | 3 |
| Drug ineffective | 39 | 192 |
| Drug interaction | 1 | 6 |
| Drug intolerance | 1 | 1 |
| Dry eye | 1 | 3 |
| Dry mouth | 4 | 24 |

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 11 | | 2 |
| | | 2 | 2 |
| | | | 1 |
| | 1 | | |
| | | | 3 |
| | 1 | | 1 |
| | 2 | | |
| 1 | 3 | | |
| 1 | 1 | | |
| | 2 | | 1 |
| | | | 1 |
| | | 1 | 2 |
| 35 | 162 | 1 | 8 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 9 | 27 | | 1 |
| 5 | 14 | 1 | 2 |
| 3 | 5 | | 2 |
| | 1 | | |
| 5 | 14 | | 3 |
| 98 | 363 | 18 | 60 |
| | 2 | | |
| 2 | 7 | | |
| | 1 | | |
| | 1 | | |
| | 3 | | |
| | 4 | 39 | 188 |
| | 5 | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | | |
| 4 | 21 | | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Dry skin | 2 | 3 |
| Dry throat | 1 | 12 |
| Duodenogastric reflux | 1 | 1 |
| Dysaesthesia | 3 | 3 |
| Dysarthria | 3 | 9 |
| Dyschromatopsia | 1 | 1 |
| Dysgeusia | 15 | 64 |
| Dyskinesia | | 2 |
| Dysmenorrhoea | 1 | 5 |
| Dyspepsia | 2 | 8 |
| Dysphagia | 15 | 32 |
| Dysphemia | 1 | 1 |
| Dysphonia | 5 | 16 |
| Dyspnoea | 62 | 200 |
| Dyspnoea exertional | 3 | 11 |
| Dysstasia | 3 | 7 |
| Dysuria | 1 | 1 |
| Ear congestion | | 1 |
| Ear discomfort | 1 | 9 |
| Ear disorder | | 2 |
| Ear pain | 4 | 29 |
| Ear pruritus | | 1 |
| Ear swelling | 1 | 2 |
| Eating disorder | 1 | 4 |
| Eczema | 1 | 2 |
| Electrocardiogram abnormal | 1 | 4 |
| Electrocardiogram QT prolonged | | 1 |
| Emotional disorder | | 1 |
| Emotional distress | 1 | 1 |
| Enanthema | | 1 |
| Encephalitis | 1 | 1 |
| Enlarged uvula | 1 | 3 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 3 | | |
| 1 | 9 | | 3 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| 1 | 5 | 2 | 4 |
| 1 | 1 | | |
| 14 | 61 | 1 | 3 |
| | 1 | | 1 |
| 1 | 5 | | |
| 1 | 7 | 1 | 1 |
| 11 | 19 | 4 | 13 |
| | | 1 | 1 |
| 4 | 9 | 1 | 7 |
| 41 | 129 | 21 | 71 |
| 3 | 10 | | 1 |
| 1 | 4 | 2 | 3 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 9 | | |
| | 2 | | |
| 2 | 26 | 2 | 3 |
| | 1 | | |
| 1 | 2 | | |
| | 3 | 1 | 1 |
| 1 | 2 | | |
| 1 | 4 | | |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | 1 |

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 * AE=Adverse Event
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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Epicondylitis | | 2 |
| Epinephrine increased | | 1 |
| Epistaxis | 1 | 10 |
| Erectile dysfunction | 3 | 3 |
| Eructation | 1 | 1 |
| Erythema | 20 | 79 |
| Erythema of eyelid | 1 | 4 |
| Euphoric mood | 1 | 1 |
| Exercise lack of | | 1 |
| Exposure during pregnancy | 3 | 9 |
| Exposure to SARS-CoV-2 | 2 | 7 |
| Exposure via skin contact | | 1 |
| Extensive swelling of vaccinated limb | | 1 |
| Extrasystoles | 2 | 3 |
| Extremity contracture | | 1 |
| Eye contusion | | 1 |
| Eye discharge | | 1 |
| Eye disorder | | 9 |
| Eye haemorrhage | | 3 |
| Eye infection | | 1 |
| Eye inflammation | | 2 |
| Eye irritation | 2 | 11 |
| Eyelid irritation | | 1 |
| Eyelid pain | 1 | 3 |
| Eyelid ptosis | 1 | 2 |
| Eyelid sensory disorder | | 1 |
| Eyelids pruritus | | 3 |
| Eye movement disorder | 1 | 3 |
| Eye oedema | 1 | 3 |
| Eye pain | 6 | 31 |
| Eye paraesthesia | | 1 |
| Eye pruritus | 2 | 12 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| | 1 | | |
| | 9 | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | | |
| 14 | 57 | 6 | 22 |
| | 3 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 3 | 9 | | |
| 2 | 5 | | 2 |
| | 1 | | |
| | 1 | | |
| 2 | 3 | | |
| | 1 | | |
| | 1 | | |
| | 8 | | 1 |
| | | | 3 |
| | 1 | | |
| | 1 | | 1 |
| 2 | 11 | | |
| | 1 | | |
| | 2 | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | | |
| | 3 | | |
| 1 | 2 | | 1 |
| 1 | 3 | | |
| 6 | 27 | | 4 |
| | | | 1 |
| 2 | 10 | | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eye swelling | 2 | 33 |
| Face injury | | 1 |
| Face oedema | | 1 |
| Facet joint syndrome | | 1 |
| Facial discomfort | | 1 |
| Facial nerve disorder | 1 | 1 |
| Facial pain | 2 | 15 |
| Facial paralysis | 21 | 48 |
| Facial paresis | 1 | 4 |
| Fall | 5 | 9 |
| Fasciitis | 1 | 1 |
| Fatigue | 223 | 855 |
| Fear | | 1 |
| Febrile convulsion | 1 | 1 |
| Feeding disorder | 2 | 3 |
| Feeling abnormal | 42 | 144 |
| Feeling cold | 13 | 44 |
| Feeling drunk | | 3 |
| Feeling hot | 27 | 119 |
| Feeling jittery | 2 | 7 |
| Feeling of body temperature change | 3 | 11 |
| Fibrin D dimer increased | 1 | 2 |
| Fibromyalgia | 1 | 1 |
| Fine motor skill dysfunction | 1 | 4 |
| Flank pain | 4 | 5 |
| Flatulence | | 4 |
| Flushing | 11 | 91 |
| Folliculitis | 2 | 2 |
| Formication | 2 | 4 |
| Frequent bowel movements | | 1 |
| Fungal infection | | 1 |
| Gait disturbance | 11 | 26 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 29 | 2 | 4 |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 11 | 1 | 4 |
| | | 21 | 48 |
| | 2 | 1 | 2 |
| 4 | 6 | 1 | 3 |
| | | 1 | 1 |
| 212 | 822 | 11 | 33 |
| | 1 | | |
| | | 1 | 1 |
| 2 | 3 | | |
| 38 | 133 | 4 | 11 |
| 13 | 42 | | 2 |
| | 2 | | 1 |
| 22 | 99 | 5 | 20 |
| 2 | 6 | | 1 |
| 3 | 10 | | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 4 | | |
| 4 | 5 | | |
| | 4 | | |
| 11 | 68 | | 23 |
| 2 | 2 | | |
| 2 | 4 | | |
| | 1 | | |
| | 1 | | |
| 9 | 22 | 2 | 4 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Gait inability | 4 | 9 |
| Gal bladder disorder | | 1 |
| Gal bladder polyp | | 1 |
| Gastric disorder | | 1 |
| Gastric pH decreased | | 1 |
| Gastritis | | 3 |
| Gastroenteritis viral | 1 | 1 |
| Gastrointestinal disorder | 2 | 7 |
| Gastrointestinal infection | 1 | 1 |
| Gastrointestinal pain | | 2 |
| Gastrointestinal sounds abnormal | 1 | 2 |
| Gastrointestinal viral infection | | 1 |
| Gastrooesophageal reflux disease | | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Genital herpes | 1 | 1 |
| Genital lesion | 1 | 1 |
| Genital ulceration | 1 | 1 |
| Gingival bleeding | | 1 |
| Gingival erythema | 1 | 1 |
| Gingival pain | 1 | 2 |
| Gingival swelling | 2 | 2 |
| Glossitis | | 1 |
| Glossodynia | 1 | 4 |
| Glycosylated haemoglobin increased | | 1 |
| Gout | | 3 |
| Grip strength decreased | | 2 |
| Groin pain | 1 | 2 |
| Grunting | | 1 |
| Guillain-Barre syndrome | 3 | 6 |
| Haematochezia | | 1 |
| Haematocrit decreased | | 1 |
| Haematuria | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 6 | 2 | 3 |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 3 | | |
| 1 | 1 | | |
| 2 | 7 | | |
| 1 | 1 | | |
| | 2 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| | 3 | | |
| | 2 | | |
| 1 | 2 | | |
| | | | 1 |
| | | 3 | 6 |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Haemoglobin decreased | | 2 |
| Haemoglobin increased | | 1 |
| Haemolytic anaemia | 1 | 2 |
| Haemoptysis | | 1 |
| Haemorrhage | 2 | 4 |
| Hallucination | 4 | 5 |
| Hallucination, auditory | | 2 |
| Hallucination, visual | 1 | 2 |
| Hand-eye coordination impaired | | 1 |
| Hangover | 1 | 4 |
| Headache | 309 | 1,164 |
| Head discomfort | 5 | 22 |
| Heart rate abnormal | 1 | 3 |
| Heart rate decreased | 2 | 5 |
| Heart rate increased | 33 | 150 |
| Heart rate irregular | 2 | 6 |
| Hemiparesis | | 1 |
| Hemiplegia | 2 | 3 |
| Hepatic pain | | 1 |
| Hepatomegaly | 1 | 1 |
| Herpes simplex | 2 | 3 |
| Herpes simplex reactivation | 1 | 1 |
| Herpes virus infection | | 3 |
| Herpes zoster | 5 | 17 |
| Hidradenitis | | 1 |
| Histamine level increased | | 1 |
| Hordeolum | | 1 |
| Hormone level abnormal | 2 | 2 |
| Hot flush | 12 | 41 |
| Hunger | | 1 |
| Hydrophobia | | 1 |
| Hyperacusis | | 3 |

| Spontaneous | | | |
|-------------|------|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | 1 |
| | 1 | | |
| | | 1 | 2 |
| | | | 1 |
| | | 2 | 4 |
| | | 4 | 5 |
| | | | 2 |
| | | 1 | 2 |
| | | | 1 |
| 1 | 4 | | |
| 289 | 1101 | 20 | 63 |
| 5 | 21 | | 1 |
| 1 | 3 | | |
| 2 | 4 | | 1 |
| 27 | 117 | 6 | 33 |
| 2 | 5 | | 1 |
| | | | 1 |
| | | 2 | 3 |
| | 1 | | |
| | | 1 | 1 |
| 2 | 3 | | |
| 1 | 1 | | |
| | 3 | | |
| 2 | 13 | 3 | 4 |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 9 | 34 | 3 | 7 |
| | 1 | | |
| | 1 | | |
| | 3 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Hyperaesthesia | 1 | 11 |
| Hyperaesthesia teeth | 1 | 2 |
| Hyperhidrosis | 37 | 127 |
| Hypersensitivity | 14 | 52 |
| Hypersomnia | 2 | 10 |
| Hypertension | 15 | 48 |
| Hypertensive crisis | | 2 |
| Hypertensive emergency | | 1 |
| Hyperventilation | 3 | 6 |
| Hypervigilance | | 1 |
| Hypoacusis | | 1 |
| Hypoaesthesia | 51 | 208 |
| Hypoaesthesia eye | | 1 |
| Hypoaesthesia oral | 16 | 63 |
| Hypocalcaemia | | 1 |
| Hypogeusia | | 1 |
| Hypoglycaemia | | 3 |
| Hypokalaemia | | 1 |
| Hypokinesia | 1 | 2 |
| Hypomagnesaemia | | 1 |
| Hypopnoea | 1 | 1 |
| Hyporeflexia | 1 | 1 |
| Hyposmia | | 2 |
| Hypotension | 3 | 9 |
| Hypothermia | | 1 |
| Hypothyroidism | | 1 |
| Hypotonia | | 1 |
| Hypoxia | | 1 |
| Illness | 6 | 28 |
| Immune-mediated arthritis | | 1 |
| Immune system disorder | 1 | 3 |
| Immune thrombocytopenia | 3 | 3 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 10 | | 1 |
| 1 | 2 | | |
| 34 | 113 | 3 | 14 |
| 8 | 31 | 6 | 21 |
| 2 | 10 | | |
| 12 | 34 | 3 | 14 |
| | | | 2 |
| | | | 1 |
| 2 | 3 | 1 | 3 |
| | 1 | | |
| | 1 | | |
| 43 | 175 | 8 | 33 |
| | 1 | | |
| 14 | 50 | 2 | 13 |
| | | | 1 |
| | 1 | | |
| | 3 | | |
| | | | 1 |
| 1 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| 2 | 7 | 1 | 2 |
| | | | 1 |
| | | | 1 |
| | 1 | | |
| | | | 1 |
| 6 | 26 | | 2 |
| | | | 1 |
| | | 1 | 3 |
| | | 3 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Immunodeficiency | | 1 |
| Impaired driving ability | 3 | 5 |
| Impaired work ability | | 2 |
| Impulsive behaviour | | 1 |
| Inappropriate schedule of product administration | 49 | 136 |
| Incomplete course of vaccination | 1 | 2 |
| Incorrect dosage administered | 1 | 1 |
| Incorrect dose administered | | 3 |
| Incorrect route of product administration | 2 | 26 |
| Increased appetite | | 1 |
| Increased upper airway secretion | | 3 |
| Increased viscosity of bronchial secretion | 1 | 1 |
| Induration | | 1 |
| Infection | 1 | 2 |
| Inflammation | 3 | 12 |
| Influenza | 3 | 11 |
| Influenza like illness | 7 | 58 |
| Inhibitory drug interaction | | 1 |
| Initial insomnia | 1 | 2 |
| Injected limb mobility decreased | 1 | 2 |
| Injection site bruising | | 1 |
| Injection site erythema | | 1 |
| Injection site extravasation | | 2 |
| Injection site indentation | 1 | 1 |
| Injection site pain | 1 | 9 |
| Injection site warmth | 1 | 2 |
| Insomnia | 16 | 62 |
| Intestinal obstruction | 1 | 1 |
| Intracranial pressure increased | | 1 |
| Irregular breathing | 1 | 1 |
| Irritability | 1 | 8 |
| Jaundice | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 3 | 5 | | |
| | 2 | | |
| | 1 | | |
| 49 | 136 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | 3 | | |
| 2 | 26 | | |
| | 1 | | |
| | 3 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | 1 | 1 |
| 3 | 11 | | 1 |
| 3 | 11 | | |
| 7 | 55 | | 3 |
| | 1 | | |
| 1 | 2 | | |
| 1 | 2 | | |
| | 1 | | |
| | 2 | | |
| 1 | 1 | | |
| 1 | 9 | | |
| 1 | 2 | | |
| 15 | 59 | 1 | 3 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 7 | | 1 |
| | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Jaw disorder | 1 | 1 |
| Joint dislocation | | 1 |
| Joint effusion | 1 | 1 |
| Joint instability | | 1 |
| Joint noise | | 1 |
| Joint range of motion decreased | 4 | 16 |
| Joint stiffness | 3 | 11 |
| Joint swelling | 3 | 14 |
| Laboratory test abnormal | | 1 |
| Labyrinthitis | | 1 |
| Lacrimation increased | | 5 |
| Laryngeal oedema | | 1 |
| Laryngitis | 1 | 2 |
| Laryngospasm | | 3 |
| Laziness | | 1 |
| Lethargy | 16 | 41 |
| Ligament injury | | 1 |
| Ligament sprain | 1 | 1 |
| Limb discomfort | 5 | 43 |
| Limb injury | 1 | 4 |
| Limb mass | | 1 |
| Lip blister | | 1 |
| Lip disorder | | 3 |
| Lip erythema | | 1 |
| Lip exfoliation | | 1 |
| Lip infection | | 1 |
| Lip injury | | 1 |
| Lip oedema | | 1 |
| Lip pain | | 1 |
| Lip pruritus | 1 | 5 |
| Lip swelling | 6 | 32 |
| Livedo reticularis | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| 4 | 15 | | 1 |
| 3 | 10 | | 1 |
| 3 | 13 | | 1 |
| | | | 1 |
| | | | 1 |
| | 5 | | |
| | | | 1 |
| 1 | 2 | | |
| | | | 3 |
| | 1 | | |
| 15 | 39 | 1 | 2 |
| | 1 | | |
| 1 | 1 | | |
| 5 | 37 | | 6 |
| 1 | 4 | | |
| | 1 | | |
| | 3 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 3 | 1 | 2 |
| 4 | 20 | 2 | 12 |
| | | | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Liver injury | | 1 |
| Liver tenderness | 1 | 1 |
| Local reaction | | 1 |
| Loss of consciousness | 13 | 24 |
| Loss of personal independence in daily activities | 3 | 16 |
| Loss of proprioception | | 1 |
| Lower respiratory tract infection | | 1 |
| Lung disorder | 1 | 2 |
| Lung infiltration | | 1 |
| Lymphadenitis | 2 | 6 |
| Lymphadenopathy | 84 | 291 |
| Lymphangitis | 1 | 1 |
| Lymph gland infection | 1 | 2 |
| Lymph node pain | 12 | 62 |
| Lymphoedema | 1 | 5 |
| Lymphoma | 1 | 1 |
| Macroglossia | 1 | 1 |
| Major depression | 1 | 1 |
| Malaise | 51 | 213 |
| Malignant hypertension | 1 | 1 |
| Malnutrition | | 1 |
| Mania | 1 | 2 |
| Mass | | 3 |
| Mastitis | | 1 |
| Mastoid disorder | 1 | 1 |
| Maternal exposure during pregnancy | 3 | 31 |
| Maternal exposure timing unspecified | | 1 |
| Memory impairment | 5 | 10 |
| Meningeal disorder | 1 | 1 |
| Meningitis | | 1 |
| Menopausal symptoms | 1 | 1 |
| Menorrhagia | 3 | 6 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 13 | 24 |
| 2 | 12 | 1 | 4 |
| | | | 1 |
| | | | 1 |
| | 1 | 1 | 1 |
| | | | 1 |
| 2 | 6 | | |
| 83 | 276 | 1 | 15 |
| | | 1 | 1 |
| 1 | 2 | | |
| 12 | 59 | | 3 |
| 1 | 5 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 50 | 203 | 1 | 10 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | 1 |
| | 3 | | |
| | | | 1 |
| | | 1 | 1 |
| 3 | 30 | | 1 |
| | 1 | | |
| 4 | 6 | 1 | 4 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 3 | 6 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Menstrual disorder | 2 | 5 |
| Menstruation delayed | 2 | 2 |
| Menstruation irregular | 1 | 8 |
| Mental disorder | 1 | 4 |
| Mental fatigue | 1 | 1 |
| Mental impairment | 7 | 14 |
| Metrorrhagia | 2 | 5 |
| Middle insomnia | 2 | 10 |
| Migraine | 27 | 73 |
| Migraine with aura | | 2 |
| Miliaria | 2 | 2 |
| Mobility decreased | 2 | 18 |
| Mononeuropathy | | 1 |
| Monoplegia | 2 | 2 |
| Motion sickness | | 2 |
| Motor dysfunction | 1 | 1 |
| Mouth swelling | 2 | 4 |
| Mouth ulceration | | 2 |
| Movement disorder | 4 | 12 |
| Muscle atrophy | | 1 |
| Muscle contractions involuntary | | 1 |
| Muscle discomfort | | 2 |
| Muscle fatigue | 3 | 7 |
| Muscle rigidity | 1 | 1 |
| Muscle spasms | 10 | 47 |
| Muscle strain | | 3 |
| Muscle swelling | | 2 |
| Muscle tightness | 1 | 18 |
| Muscle twitching | 3 | 11 |
| Muscular weakness | 15 | 52 |
| Musculoskeletal chest pain | 6 | 12 |
| Musculoskeletal discomfort | 3 | 8 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 5 | | |
| 1 | 1 | 1 | 1 |
| 1 | 8 | | |
| 1 | 4 | | |
| 1 | 1 | | |
| | | 7 | 14 |
| 2 | 5 | | |
| 2 | 9 | | 1 |
| 26 | 68 | 1 | 5 |
| | 2 | | |
| 2 | 2 | | |
| 2 | 16 | | 2 |
| | | | 1 |
| | | 2 | 2 |
| | 2 | | |
| 1 | 1 | | |
| 1 | 2 | 1 | 2 |
| | 2 | | |
| 4 | 11 | | 1 |
| | 1 | | |
| | 2 | | 1 |
| 3 | 7 | | |
| | | 1 | 1 |
| 8 | 39 | 2 | 8 |
| | 3 | | |
| | 2 | | |
| 1 | 17 | | 1 |
| 2 | 9 | 1 | 2 |
| 12 | 39 | 3 | 13 |
| 6 | 12 | | |
| 3 | 8 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Musculoskeletal disorder | 1 | 2 |
| Musculoskeletal pain | 2 | 7 |
| Musculoskeletal stiffness | 13 | 44 |
| Myalgia | 100 | 455 |
| Myelitis transverse | | 1 |
| Myocardial infarction | 1 | 3 |
| Myocardial necrosis marker increased | | 1 |
| Myocarditis | | 1 |
| Myopia | | 1 |
| Myositis | | 2 |
| Nasal congestion | 8 | 58 |
| Nasal discomfort | | 2 |
| Nasal disorder | 1 | 2 |
| Nasal dryness | | 1 |
| Nasal oedema | | 4 |
| Nasopharyngitis | 10 | 22 |
| Nausea | 138 | 538 |
| Neck injury | | 1 |
| Neck mass | 1 | 1 |
| Neck pain | 35 | 110 |
| Needle issue | | 3 |
| Neoplasm skin | 1 | 2 |
| Nerve compression | | 2 |
| Nerve injury | 1 | 1 |
| Nervousness | 7 | 18 |
| Nervous system disorder | 2 | 2 |
| Neuralgia | 4 | 20 |
| Neuralgic amyotrophy | 2 | 2 |
| Neurological symptom | 1 | 2 |
| Neuropathy peripheral | 5 | 12 |
| Neutrophil count decreased | 1 | 1 |
| Neutrophil count increased | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | 1 |
| 2 | 5 | | 2 |
| 12 | 41 | 1 | 3 |
| 95 | 432 | 5 | 23 |
| | | | 1 |
| | | 1 | 3 |
| | | | 1 |
| | 1 | | |
| | | | 2 |
| 7 | 52 | 1 | 6 |
| | 1 | | 1 |
| 1 | 2 | | |
| | | | 1 |
| | 3 | | 1 |
| 10 | 20 | | 2 |
| 129 | 497 | 9 | 41 |
| | 1 | | |
| 1 | 1 | | |
| 30 | 99 | 5 | 11 |
| | 3 | | |
| 1 | 2 | | |
| | 2 | | |
| 1 | 1 | | |
| 7 | 17 | | 1 |
| 2 | 2 | | |
| 2 | 17 | 2 | 3 |
| 2 | 2 | | |
| 1 | 1 | | 1 |
| | | 5 | 12 |
| | | 1 | 1 |
| 1 | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Nightmare | 3 | 4 |
| Night sweats | 12 | 35 |
| Nipple pain | 1 | 2 |
| Nipple swelling | | 1 |
| Nodule | | 1 |
| Noninfective encephalitis | 1 | 2 |
| Noninfective gingivitis | | 1 |
| Nuchal rigidity | 1 | 2 |
| Nystagmus | | 2 |
| Obstructive airways disorder | | 3 |
| Occupational exposure to SARS-CoV-2 | 1 | 3 |
| Ocular discomfort | 1 | 8 |
| Ocular hyperaemia | 1 | 11 |
| Odynophagia | 2 | 5 |
| Oedema | 1 | 4 |
| Oedema peripheral | | 5 |
| Off label use | 29 | 127 |
| Ophthalmic herpes simplex | 1 | 1 |
| Optic neuritis | | 1 |
| Oral blood blister | 1 | 1 |
| Oral discomfort | 2 | 7 |
| Oral disorder | | 3 |
| Oral herpes | 3 | 6 |
| Oral mucosal blistering | 1 | 3 |
| Oral mucosal eruption | | 2 |
| Oral pain | 1 | 3 |
| Oral pruritus | 1 | 4 |
| Orchitis | | 1 |
| Oropharyngeal discomfort | 1 | 9 |
| Oropharyngeal pain | 30 | 128 |
| Oropharyngeal spasm | | 1 |
| Oropharyngeal swelling | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 4 | | |
| 12 | 32 | | 3 |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 2 |
| | 1 | | |
| | 1 | 1 | 1 |
| | 1 | | 1 |
| | 1 | | 2 |
| | 2 | 1 | 1 |
| 1 | 5 | | 3 |
| 1 | 10 | | 1 |
| 1 | 3 | 1 | 2 |
| 1 | 3 | | 1 |
| | 4 | | 1 |
| 27 | 124 | 2 | 3 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 2 | 6 | | 1 |
| | 3 | | |
| 3 | 6 | | |
| 1 | 3 | | |
| | 2 | | |
| 1 | 3 | | |
| | 3 | 1 | 1 |
| | 1 | | |
| 1 | 5 | | 4 |
| 29 | 121 | 1 | 7 |
| | | | 1 |
| | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Orthopnoea | | 1 |
| Orthostatic hypotension | 1 | 1 |
| Osteochondritis | | 1 |
| Overdose | 3 | 11 |
| Overweight | 1 | 1 |
| Oxygen saturation decreased | 3 | 5 |
| Pain | 158 | 678 |
| Painful respiration | 1 | 4 |
| Pain in extremity | 126 | 455 |
| Pain in jaw | 1 | 17 |
| Pain of skin | 5 | 12 |
| Pallor | 8 | 19 |
| Palmar erythema | | 3 |
| Palpitations | 25 | 108 |
| Pancreatitis | 1 | 2 |
| Pancreatitis acute | | 1 |
| Pancytopenia | 1 | 1 |
| Panic attack | 3 | 7 |
| Panic disorder | 1 | 1 |
| Panic reaction | 2 | 5 |
| Paraesthesia | 61 | 232 |
| Paraesthesia ear | | 1 |
| Paraesthesia mucosal | | 1 |
| Paraesthesia oral | 20 | 89 |
| Paralysis | 1 | 2 |
| Paranasal sinus discomfort | 2 | 7 |
| Paranoia | | 1 |
| Parosmia | 4 | 10 |
| Pelvic pain | 1 | 2 |
| Periarthritis | | 2 |
| Pericardial disease | | 1 |
| Pericarditis | 1 | 4 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| 3 | 10 | | 1 |
| 1 | 1 | | |
| 1 | 3 | 2 | 2 |
| 152 | 645 | 6 | 33 |
| 1 | 4 | | |
| 122 | 441 | 4 | 14 |
| | 15 | 1 | 2 |
| 5 | 12 | | |
| 6 | 13 | 2 | 6 |
| | 2 | | 1 |
| 22 | 79 | 3 | 29 |
| | | 1 | 2 |
| | | | 1 |
| | | 1 | 1 |
| 3 | 5 | | 2 |
| 1 | 1 | | |
| 2 | 4 | | 1 |
| 55 | 202 | 6 | 30 |
| | 1 | | |
| | 1 | | |
| 15 | 68 | 5 | 21 |
| | | 1 | 2 |
| 2 | 7 | | |
| | 1 | | |
| 4 | 9 | | 1 |
| 1 | 2 | | |
| | 2 | | |
| | | | 1 |
| | | 1 | 4 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Periorbital swelling | 2 | 7 |
| Peripheral coldness | 4 | 24 |
| Peripheral nerve injury | 2 | 2 |
| Peripheral swelling | 23 | 77 |
| Peripheral vascular disorder | 1 | 1 |
| Peroneal nerve palsy | | 1 |
| Petechiae | 3 | 10 |
| Pharyngeal disorder | | 2 |
| Pharyngeal erythema | 1 | 5 |
| Pharyngeal hypoaesthesia | 2 | 7 |
| Pharyngeal mass | 3 | 3 |
| Pharyngeal oedema | 1 | 2 |
| Pharyngeal paraesthesia | 1 | 10 |
| Pharyngeal swelling | 10 | 42 |
| Pharyngitis | 1 | 2 |
| Pharyngitis streptococcal | | 1 |
| Photophobia | | 9 |
| Photopsia | | 1 |
| Photosensitivity reaction | 2 | 6 |
| Physical examination abnormal | 1 | 1 |
| Pigmentation disorder | 1 | 1 |
| Piloerection | | 2 |
| Platelet count decreased | 1 | 2 |
| Platelet count increased | 1 | 1 |
| Pleural effusion | | 1 |
| Pleuritic pain | 1 | 2 |
| Pneumonia | 1 | 3 |
| PO2 decreased | | 1 |
| Pollakiuria | | 2 |
| Polyarthrits | 1 | 1 |
| Polymenorrhoea | 1 | 1 |
| Polyneuropathy | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 6 | | 1 |
| 3 | 22 | 1 | 2 |
| | | 2 | 2 |
| 21 | 74 | 2 | 3 |
| 1 | 1 | | |
| | | | 1 |
| 3 | 8 | | 2 |
| | 2 | | |
| 1 | 4 | | 1 |
| 2 | 4 | | 3 |
| 2 | 2 | 1 | 1 |
| | | 1 | 2 |
| 1 | 7 | | 3 |
| 7 | 20 | 3 | 22 |
| | 1 | 1 | 1 |
| | 1 | | |
| | 8 | | 1 |
| | 1 | | |
| 2 | 6 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 2 | | |
| | | 1 | 3 |
| | 1 | | |
| | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Polyuria | | 1 |
| Poor peripheral circulation | | 2 |
| Poor quality product administered | 2 | 4 |
| Poor quality sleep | 2 | 8 |
| Post-traumatic stress disorder | | 1 |
| Postural orthostatic tachycardia syndrome | 3 | 3 |
| Premenstrual syndrome | 2 | 2 |
| Pressure of speech | 1 | 2 |
| Presyncope | 14 | 38 |
| Procedural site reaction | 1 | 1 |
| Product administered at inappropriate site | 2 | 11 |
| Product administration error | | 2 |
| Product confusion | | 1 |
| Productive cough | 2 | 6 |
| Product leakage | | 1 |
| Product preparation error | 1 | 9 |
| Product preparation issue | 1 | 3 |
| Product storage error | 1 | 1 |
| Product use issue | 27 | 120 |
| Prothrombin time prolonged | 1 | 1 |
| Pruritus | 36 | 162 |
| Psychomotor hyperactivity | | 1 |
| Pulmonary congestion | 1 | 1 |
| Pulmonary pain | 3 | 5 |
| Pulmonary thrombosis | 1 | 1 |
| Pulse abnormal | | 4 |
| Purpura | 1 | 2 |
| Pyrexia | 198 | 826 |
| Radiculitis brachial | | 1 |
| Rash | 45 | 171 |
| Rash erythematous | 10 | 31 |
| Rash macular | 3 | 22 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 1 | | 1 |
| 2 | 4 | | |
| 2 | 8 | | |
| | 1 | | |
| | | 3 | 3 |
| 2 | 2 | | |
| 1 | 1 | | 1 |
| 10 | 29 | 4 | 9 |
| | | 1 | 1 |
| 2 | 11 | | |
| | 2 | | |
| | 1 | | |
| 2 | 6 | | |
| | 1 | | |
| 1 | 8 | | 1 |
| 1 | 3 | | |
| 1 | 1 | | |
| 25 | 117 | 2 | 3 |
| | | 1 | 1 |
| 31 | 143 | 5 | 19 |
| | 1 | | |
| | | 1 | 1 |
| 3 | 4 | | 1 |
| | | 1 | 1 |
| | 2 | | 2 |
| 1 | 2 | | |
| 183 | 776 | 15 | 50 |
| | | | 1 |
| 34 | 135 | 11 | 36 |
| 8 | 23 | 2 | 8 |
| 2 | 19 | 1 | 3 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Rash maculo-papular | | 5 |
| Rash papular | 2 | 9 |
| Rash pruritic | 5 | 28 |
| Rash pustular | | 1 |
| Rash vesicular | 3 | 5 |
| Raynaud's phenomenon | | 2 |
| Reaction to excipient | | 1 |
| Rectal haemorrhage | | 1 |
| Red blood cell count decreased | | 1 |
| Red blood cells urine positive | | 1 |
| Red ear syndrome | 1 | 1 |
| Reduced facial expression | | 1 |
| Renal disorder | | 1 |
| Renal pain | 1 | 5 |
| Respiratory disorder | | 2 |
| Respiratory distress | | 4 |
| Respiratory failure | | 1 |
| Respiratory rate increased | 3 | 7 |
| Respiratory tract congestion | 2 | 6 |
| Respiratory tract oedema | | 1 |
| Restless legs syndrome | | 1 |
| Restlessness | 3 | 9 |
| Retching | | 4 |
| Rheumatoid arthritis | 1 | 2 |
| Rhinalgia | | 2 |
| Rhinitis | 1 | 2 |
| Rhinitis allergic | | 1 |
| Rhinorrhoea | 10 | 55 |
| Right ventricular dysfunction | | 1 |
| Salivary hypersecretion | 1 | 2 |
| SARS-CoV-2 ant body test negative | 2 | 5 |
| SARS-CoV-2 test positive | 3 | 49 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 5 | | |
| 2 | 9 | | |
| 5 | 26 | | 2 |
| | 1 | | |
| 2 | 3 | 1 | 2 |
| | 2 | | |
| | 1 | | |
| | 1 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 5 | | |
| | 1 | | 1 |
| | 1 | | 3 |
| | 1 | | |
| 2 | 5 | 1 | 2 |
| 2 | 6 | | |
| | | | 1 |
| | 1 | | |
| 3 | 8 | | 1 |
| | 4 | | |
| | | 1 | 2 |
| | 2 | | |
| 1 | 2 | | |
| | 1 | | |
| 10 | 49 | | 6 |
| | | | 1 |
| 1 | 2 | | |
| | 3 | 2 | 2 |
| 1 | 7 | 2 | 42 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Scab | | 1 | | 1 | | |
| Sciatica | 1 | 1 | 1 | 1 | | |
| Scleritis | | 1 | | | | 1 |
| Scratch | | 2 | | 2 | | |
| Screaming | 1 | 2 | 1 | 1 | | 1 |
| Secretion discharge | | 1 | | 1 | | |
| Sedation | | 1 | | 1 | | |
| Seizure | 4 | 9 | | | 4 | 9 |
| Seizure like phenomena | | 1 | | | | 1 |
| Sensation of foreign body | 3 | 13 | 2 | 7 | 1 | 6 |
| Sensitive skin | 2 | 5 | 2 | 5 | | |
| Sensorimotor disorder | | 1 | | | | 1 |
| Sensory disturbance | 1 | 5 | 1 | 4 | | 1 |
| Sensory loss | 1 | 3 | | 2 | 1 | 1 |
| Sepsis | | 2 | | | | 2 |
| Serum sickness | | 1 | | | | 1 |
| Shock symptom | 1 | 1 | | | 1 | 1 |
| Sialoadenitis | 1 | 1 | | | 1 | 1 |
| Sinus congestion | | 4 | | 4 | | |
| Sinus disorder | 1 | 5 | 1 | 5 | | |
| Sinus headache | 1 | 4 | 1 | 4 | | |
| Sinusitis | 1 | 8 | 1 | 8 | | |
| Sinus pain | 1 | 4 | 1 | 4 | | |
| Sinus tachycardia | | 4 | | 2 | | 2 |
| Sitting disability | 1 | 1 | 1 | 1 | | |
| Sjogren's syndrome | 1 | 1 | | | 1 | 1 |
| Skin burning sensation | 2 | 6 | 1 | 5 | 1 | 1 |
| Skin depigmentation | 1 | 1 | 1 | 1 | | |
| Skin discolouration | 2 | 9 | 2 | 9 | | |
| Skin discomfort | 1 | 1 | 1 | 1 | | |
| Skin disorder | | 4 | | 3 | | 1 |
| Skin exfoliation | 2 | 5 | 2 | 4 | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Skin indentation | | 1 |
| Skin injury | | 2 |
| Skin irritation | 1 | 4 |
| Skin laceration | 1 | 2 |
| Skin lesion | 2 | 3 |
| Skin odour abnormal | | 1 |
| Skin oedema | 1 | 1 |
| Skin reaction | 1 | 3 |
| Skin swelling | | 2 |
| Skin tightness | | 2 |
| Skin ulcer | 1 | 1 |
| Skin warm | | 2 |
| Sleep disorder | 1 | 6 |
| Sleep disorder due to a general medical condition | | 1 |
| Sleep disorder due to general medical condition, insomnia type | 1 | 2 |
| Sleep paralysis | 1 | 2 |
| Sluggishness | 2 | 5 |
| Sneezing | 1 | 6 |
| Snoring | 1 | 1 |
| Somnolence | 11 | 47 |
| Speech disorder | 6 | 14 |
| Spinal cord disorder | 1 | 1 |
| Spinal disorder | 1 | 1 |
| Spinal pain | 4 | 10 |
| Splenomegaly | 2 | 2 |
| Sputum discoloured | | 1 |
| Staring | 1 | 2 |
| Stevens-Johnson syndrome | | 1 |
| Stomatitis | 1 | 5 |
| Strawberry tongue | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 2 | | |
| 1 | 4 | | |
| 1 | 2 | | |
| 2 | 3 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | 1 |
| | 2 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| | 2 | | |
| 1 | 6 | | |
| | 1 | | |
| 1 | 2 | | |
| 1 | 2 | | |
| 2 | 5 | | |
| 1 | 6 | | |
| 1 | 1 | | |
| 10 | 43 | 1 | 4 |
| 1 | 6 | 5 | 8 |
| | | 1 | 1 |
| 1 | 1 | | |
| 4 | 9 | | 1 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | 1 |
| | | | 1 |
| 1 | 4 | | 1 |
| | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Streptococcal infection | | 1 |
| Stress | 3 | 4 |
| Stridor | 1 | 2 |
| Substance abuse | | 1 |
| Sudden hearing loss | | 1 |
| Suicidal ideation | 1 | 1 |
| Supraventricular tachycardia | | 1 |
| Suspected COVID-19 | 1 | 11 |
| Swelling | 18 | 66 |
| Swelling face | 19 | 57 |
| Swelling of eyelid | 1 | 10 |
| Swollen tongue | 13 | 38 |
| Syncope | 22 | 34 |
| Synovial cyst | 1 | 1 |
| Syringe issue | | 1 |
| Systemic immune activation | 1 | 1 |
| Systemic inflammatory response syndrome | | 1 |
| Systemic lupus erythematosus | | 1 |
| Systemic scleroderma | | 1 |
| Tachycardia | 14 | 108 |
| Tachyphrenia | | 3 |
| Tachypnoea | | 2 |
| Taste disorder | 5 | 16 |
| Temperature intolerance | 4 | 4 |
| Tenderness | 1 | 11 |
| Tendonitis | | 2 |
| Tendon pain | | 1 |
| Tension | 2 | 2 |
| Tension headache | | 3 |
| Terminal insomnia | | 2 |
| Testicular swelling | | 1 |
| Tetany | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 3 | 4 | | |
| | | 1 | 2 |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | 1 | 10 |
| 15 | 60 | 3 | 6 |
| 13 | 43 | 6 | 14 |
| 1 | 10 | | |
| 9 | 21 | 4 | 17 |
| | | 22 | 34 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | | 1 |
| | | | 1 |
| 7 | 75 | 7 | 33 |
| | 3 | | |
| | | | 2 |
| 4 | 14 | 1 | 2 |
| 4 | 4 | | |
| 1 | 11 | | |
| | 2 | | |
| | 1 | | |
| 2 | 2 | | |
| | 3 | | |
| | 2 | | |
| | 1 | | |
| | | | 2 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Therapeutic response unexpected | 1 | 1 |
| Thinking abnormal | 1 | 2 |
| Thirst | 2 | 10 |
| Throat clearing | 3 | 5 |
| Throat irritation | 12 | 61 |
| Throat tightness | 11 | 51 |
| Thrombocytopenia | | 2 |
| Thrombosis | 1 | 2 |
| Thyroid disorder | | 1 |
| Tinnitus | 8 | 35 |
| Tongue discolouration | | 1 |
| Tongue discomfort | 1 | 6 |
| Tongue disorder | 1 | 6 |
| Tongue dry | 1 | 1 |
| Tongue erythema | | 1 |
| Tongue haemorrhage | | 1 |
| Tongue movement disturbance | | 1 |
| Tongue pruritus | 1 | 3 |
| Tongue ulceration | 1 | 1 |
| Tonsillar disorder | 1 | 1 |
| Tonsillar hypertrophy | | 1 |
| Tonsillitis | | 1 |
| Toothache | 2 | 8 |
| Tooth disorder | 1 | 1 |
| Transient ischaemic attack | | 1 |
| Tremor | 17 | 67 |
| Trigeminal neuralgia | 2 | 4 |
| Trigeminal neuritis | | 1 |
| Trismus | 1 | 2 |
| Troponin increased | 1 | 2 |
| Tryptase decreased | | 1 |
| Tryptase increased | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 2 | | |
| 2 | 10 | | |
| 2 | 3 | 1 | 2 |
| 10 | 49 | 2 | 12 |
| 6 | 26 | 5 | 25 |
| | | | 2 |
| | | 1 | 2 |
| | 1 | | |
| 5 | 26 | 3 | 9 |
| | 1 | | |
| | 4 | 1 | 2 |
| 1 | 5 | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 2 | 8 | | |
| 1 | 1 | | |
| | | | 1 |
| 12 | 52 | 5 | 15 |
| 2 | 3 | | 1 |
| | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 2 |
| | 1 | | |
| | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tunnel vision | 2 | 4 | | | 2 | 4 |
| Type IV hypersensitivity reaction | | 2 | | 2 | | |
| Underdose | 5 | 14 | 5 | 14 | | |
| Undifferentiated connective tissue disease | | 1 | | | | 1 |
| Unresponsive to stimuli | 1 | 2 | | | 1 | 2 |
| Upper-airway cough syndrome | 1 | 2 | 1 | 2 | | |
| Upper respiratory tract congestion | | 5 | | 4 | | 1 |
| Upper respiratory tract infection | | 3 | | 3 | | |
| Urinary incontinence | 1 | 2 | 1 | 2 | | |
| Urinary tract disorder | 1 | 1 | 1 | 1 | | |
| Urinary tract infection | | 2 | | 2 | | |
| Urine output increased | | 1 | | 1 | | |
| Urticaria | 27 | 143 | 18 | 113 | 9 | 30 |
| Uterine contractions during pregnancy | | 1 | | 1 | | |
| Uvulitis | | 1 | | 1 | | |
| Vaccination failure | 2 | 3 | | | 2 | 3 |
| Vaccination site bruising | 3 | 14 | 3 | 14 | | |
| Vaccination site cellulitis | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site coldness | 1 | 3 | 1 | 3 | | |
| Vaccination site discolouration | 1 | 6 | 1 | 6 | | |
| Vaccination site discomfort | 1 | 6 | 1 | 5 | | 1 |
| Vaccination site erythema | 30 | 115 | 30 | 112 | | 3 |
| Vaccination site haemorrhage | 1 | 5 | 1 | 5 | | |
| Vaccination site hyperaesthesia | | 1 | | 1 | | |
| Vaccination site hypersensitivity | | 1 | | 1 | | |
| Vaccination site hypoaesthesia | | 6 | | 6 | | |
| Vaccination site induration | 1 | 12 | 1 | 12 | | |
| Vaccination site infection | | 1 | | 1 | | |
| Vaccination site inflammation | 2 | 3 | 2 | 3 | | |
| Vaccination site irritation | | 1 | | 1 | | |
| Vaccination site joint erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site joint movement impairment | 1 | 5 | 1 | 4 | | 1 |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Vaccination site joint pain | 2 | 4 |
| Vaccination site lymphadenopathy | 2 | 6 |
| Vaccination site mass | 1 | 14 |
| Vaccination site movement impairment | 1 | 13 |
| Vaccination site nodule | | 5 |
| Vaccination site oedema | | 1 |
| Vaccination site pain | 140 | 579 |
| Vaccination site paraesthesia | | 7 |
| Vaccination site pruritus | 13 | 55 |
| Vaccination site rash | 9 | 23 |
| Vaccination site reaction | 1 | 4 |
| Vaccination site scab | | 1 |
| Vaccination site swelling | 36 | 120 |
| Vaccination site ulcer | | 1 |
| Vaccination site urticaria | 3 | 15 |
| Vaccination site vesicles | 2 | 5 |
| Vaccination site warmth | 12 | 54 |
| Vaginal haemorrhage | 1 | 4 |
| Vein discolouration | 2 | 2 |
| Ventricular arrhythmia | 1 | 1 |
| Ventricular extrasystoles | 2 | 5 |
| Ventricular fibrillation | 1 | 1 |
| Ventricular tachycardia | | 1 |
| Vertigo | 13 | 39 |
| Vertigo positional | | 2 |
| Viral infection | | 1 |
| Vision blurred | 9 | 27 |
| Visual impairment | 5 | 16 |
| Vitamin B12 decreased | 1 | 1 |
| Vitamin D decreased | 1 | 1 |
| Vocal cord disorder | 1 | 1 |
| Vocal cord paralysis | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 3 | | 1 |
| 1 | 5 | 1 | 1 |
| 1 | 14 | | |
| 1 | 13 | | |
| | 5 | | |
| | 1 | | |
| 138 | 564 | 2 | 15 |
| | 6 | | 1 |
| 13 | 54 | | 1 |
| 8 | 22 | 1 | 1 |
| 1 | 4 | | |
| | 1 | | |
| 35 | 117 | 1 | 3 |
| | 1 | | |
| 3 | 15 | | |
| 2 | 5 | | |
| 12 | 53 | | 1 |
| 1 | 3 | | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 4 | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 10 | 33 | 3 | 6 |
| | 1 | | 1 |
| | 1 | | |
| 7 | 22 | 2 | 5 |
| 2 | 12 | 3 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |

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Age Range

31 - 50 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 44 | 151 | 35 | 134 | 9 | 17 |
| Vomiting projectile | 1 | 2 | 1 | 2 | | |
| Vulvovaginal mycotic infection | | 1 | | 1 | | |
| Walking disability | 1 | 1 | | | 1 | 1 |
| Weight decreased | | 2 | | 2 | | |
| Weight increased | | 2 | | 2 | | |
| Wheezing | 3 | 11 | 3 | 9 | | 2 |
| White blood cell count decreased | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 3 | 1 | 1 | | 2 |
| Winged scapula | 1 | 1 | 1 | 1 | | |
| Withdrawal bleed | 1 | 1 | 1 | 1 | | |
| Wound closure | 1 | 1 | 1 | 1 | | |
| Wrong product administered | | 2 | | 2 | | |
| Wrong technique in product usage process | 1 | 6 | 1 | 5 | | 1 |
| Xanthopsia | 1 | 1 | 1 | 1 | | |
| | 4,537 | 17,381 | 3788 | 14781 | 749 | 2600 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 6 | 25 | 6 | 24 | | 1 |
| Abdominal distension | 4 | 7 | 4 | 6 | | 1 |
| Abdominal pain | 5 | 31 | 4 | 26 | 1 | 5 |
| Abdominal pain lower | 1 | 4 | 1 | 3 | | 1 |
| Abdominal pain upper | 11 | 26 | 10 | 23 | 1 | 3 |
| Abdominal rigidity | 1 | 2 | 1 | 1 | | 1 |
| Abnormal dreams | 3 | 4 | 3 | 4 | | |
| Abnormal faeces | | 1 | | 1 | | |
| Abnormal sensation in eye | | 1 | | 1 | | |
| Accidental exposure to product | 1 | 2 | 1 | 2 | | |
| Accidental overdose | 1 | 3 | 1 | 3 | | |
| Acute kidney injury | | 1 | | | | 1 |
| Acute myocardial infarction | | 1 | | | | 1 |
| Acute pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Acute respiratory distress syndrome | | 1 | | | | 1 |
| Administration site warmth | 1 | 1 | 1 | 1 | | |
| Adrenal disorder | 1 | 1 | | | 1 | 1 |
| Ageusia | 6 | 31 | 6 | 29 | | 2 |
| Agitation | 1 | 5 | 1 | 5 | | |
| Allergy to vaccine | 2 | 9 | 1 | 5 | 1 | 4 |
| Alopecia | 1 | 1 | 1 | 1 | | |
| Amnesia | 1 | 5 | 1 | 4 | | 1 |
| Anal skin tags | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 5 | 25 | | 1 | 5 | 24 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anger | | 2 | | 2 | | |
| Angioedema | 3 | 4 | | | 3 | 4 |
| Anion gap abnormal | 1 | 1 | 1 | 1 | | |
| Anosmia | 6 | 25 | 5 | 22 | 1 | 3 |
| Anterior chamber cell | 1 | 1 | | | 1 | 1 |
| Anxiety | 8 | 24 | 6 | 22 | 2 | 2 |
| Apathy | 1 | 1 | 1 | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Aphasia | 1 | 4 |
| Aphonia | | 1 |
| Apthous ulcer | | 1 |
| Application site pruritus | 1 | 1 |
| Aptyalism | | 1 |
| Arrhythmia | | 1 |
| Arthralgia | 61 | 226 |
| Arthritis | | 5 |
| Arthropathy | | 5 |
| Asthenia | 27 | 104 |
| Asthenopia | 1 | 1 |
| Asthma | 3 | 3 |
| Asymptomatic COVID-19 | | 1 |
| Ataxia | 1 | 1 |
| Atelectasis | 1 | 1 |
| Atrial fibrillation | 3 | 5 |
| Auricular swelling | | 1 |
| Autoimmune disorder | 1 | 1 |
| Axillary mass | | 1 |
| Axillary pain | 9 | 18 |
| Back injury | 1 | 1 |
| Back pain | 19 | 66 |
| Balance disorder | 3 | 10 |
| Basal ganglia haemorrhage | | 2 |
| Basal ganglia stroke | 1 | 1 |
| Bedridden | | 3 |
| Blepharitis | 1 | 1 |
| Blepharochalasis | | 1 |
| Blindness | 1 | 2 |
| Blindness transient | 1 | 1 |
| Blindness unilateral | 1 | 1 |
| Blister | 2 | 5 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | 2 |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| 60 | 219 | 1 | 7 |
| | 4 | | 1 |
| | 5 | | |
| 24 | 96 | 3 | 8 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 5 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 9 | 18 | | |
| 1 | 1 | | |
| 18 | 63 | 1 | 3 |
| 2 | 8 | 1 | 2 |
| | | | 2 |
| | | 1 | 1 |
| | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 4 | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Blood creatine increased | | 1 |
| Blood glucose decreased | 1 | 1 |
| Blood glucose fluctuation | | 1 |
| Blood glucose increased | 2 | 6 |
| Blood iron decreased | 1 | 1 |
| Blood lactic acid increased | 1 | 1 |
| Blood potassium decreased | | 2 |
| Blood pressure decreased | 1 | 2 |
| Blood pressure diastolic increased | | 1 |
| Blood pressure fluctuation | 1 | 2 |
| Blood pressure increased | 7 | 35 |
| Blood pressure systolic increased | | 3 |
| Blood sodium decreased | | 1 |
| Blood thyroid stimulating hormone increased | | 2 |
| Blood triglycerides increased | | 1 |
| Blood urine present | 1 | 1 |
| Body temperature abnormal | | 1 |
| Body temperature decreased | 1 | 2 |
| Body temperature increased | 3 | 15 |
| Bone pain | 1 | 9 |
| Bone swelling | 1 | 1 |
| Bradyphrenia | 1 | 2 |
| Brain oedema | | 1 |
| Brain stem haemorrhage | 1 | 1 |
| Brain stem syndrome | 1 | 1 |
| Breast discharge | 2 | 2 |
| Breast discomfort | 1 | 1 |
| Breast pain | 1 | 1 |
| Breast tenderness | 1 | 2 |
| Bronchitis | 1 | 1 |
| Bronchospasm | | 2 |
| Burning sensation | 10 | 25 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 2 | 5 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| 1 | 1 | | 1 |
| | | | 1 |
| 1 | 1 | | 1 |
| 3 | 20 | 4 | 15 |
| | | | 3 |
| | 1 | | |
| | 1 | | 1 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| 3 | 15 | | |
| 1 | 9 | | |
| 1 | 1 | | |
| | | 1 | 2 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | 2 | | |
| 8 | 21 | 2 | 4 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Candida infection | 1 | 1 |
| Cardiac arrest | | 1 |
| Cardiac disorder | | 1 |
| Cardiac failure congestive | | 1 |
| Cardiac fibrillation | 1 | 1 |
| Cardiac flutter | | 1 |
| Cardiovascular disorder | 1 | 1 |
| Cartilage injury | | 1 |
| Cellulitis | 1 | 2 |
| Cerebral disorder | | 1 |
| Cerebral haemorrhage | 1 | 2 |
| Cerebrovascular accident | 1 | 3 |
| Chest discomfort | 12 | 47 |
| Chest pain | 12 | 26 |
| Chest X-ray abnormal | 1 | 1 |
| Chills | 128 | 482 |
| Choking sensation | | 1 |
| Circumoral swelling | | 1 |
| Circumstance or information capable of leading to medication error | | 3 |
| Cognitive disorder | | 2 |
| Cold sweat | 5 | 9 |
| Colitis | 1 | 1 |
| Coma | | 1 |
| Condition aggravated | 6 | 19 |
| Confusional state | 2 | 6 |
| Conjunctival haemorrhage | | 1 |
| Conjunctivitis | 1 | 2 |
| Conjunctivitis viral | | 1 |
| Constipation | 1 | 1 |
| Contusion | 5 | 9 |
| Coordination abnormal | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 2 |
| | 1 | | |
| | | 1 | 2 |
| | | 1 | 3 |
| 7 | 30 | 5 | 17 |
| 8 | 19 | 4 | 7 |
| | | 1 | 1 |
| 120 | 455 | 8 | 27 |
| | | | 1 |
| | 1 | | |
| | 3 | | |
| | 1 | | 1 |
| 5 | 9 | | |
| | | 1 | 1 |
| | | | 1 |
| 3 | 14 | 3 | 5 |
| 2 | 5 | | 1 |
| | | | 1 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 5 | 9 | | |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Corneal disorder | 1 | 1 |
| Corneal graft rejection | 1 | 1 |
| Corneal infiltrates | 1 | 1 |
| Costochondritis | | 1 |
| Cough | 13 | 80 |
| COVID-19 | 22 | 104 |
| COVID-19 pneumonia | 2 | 3 |
| C-reactive protein increased | | 3 |
| Crohn's disease | 1 | 1 |
| Crying | 1 | 2 |
| Crystal urine | | 1 |
| Cyanosis | | 1 |
| Cyst | | 1 |
| Deafness | 2 | 5 |
| Deafness neurosensory | 1 | 2 |
| Deafness unilateral | 1 | 2 |
| Death | 1 | 5 |
| Decreased appetite | 13 | 34 |
| Deep vein thrombosis | | 2 |
| Dehydration | 2 | 4 |
| Delirium | | 1 |
| Depersonalisation/derealisation disorder | | 1 |
| Depressed mood | | 2 |
| Depression | 1 | 3 |
| Dermatitis | 1 | 2 |
| Dermatitis allergic | | 1 |
| Dermatitis contact | | 1 |
| Diabetes mellitus | | 1 |
| Diabetes mellitus inadequate control | 2 | 2 |
| Diarrhoea | 24 | 99 |
| Diarrhoea haemorrhagic | | 1 |
| Diplopia | 1 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 10 | 67 | 3 | 13 |
| 4 | 12 | 18 | 92 |
| | | 2 | 3 |
| | 3 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 2 | 5 |
| | | 1 | 2 |
| | | 1 | 2 |
| | | 1 | 5 |
| 13 | 32 | | 2 |
| | | | 2 |
| 1 | 2 | 1 | 2 |
| | | | 1 |
| | 1 | | |
| | 2 | | |
| 1 | 2 | | 1 |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | | 2 | 2 |
| 21 | 93 | 3 | 6 |
| | | | 1 |
| | | 1 | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Discomfort | 4 | 17 | 3 | 15 | 1 | 2 |
| Disease progression | | 1 | | 1 | | |
| Disease recurrence | 6 | 16 | 5 | 14 | 1 | 2 |
| Disorientation | 1 | 2 | 1 | 2 | | |
| Dissociation | 1 | 2 | 1 | 1 | | 1 |
| Disturbance in attention | 5 | 11 | 2 | 7 | 3 | 4 |
| Dizziness | 66 | 234 | 59 | 205 | 7 | 29 |
| Dizziness postural | 2 | 5 | 2 | 5 | | |
| Drug hypersensitivity | 2 | 4 | 1 | 3 | 1 | 1 |
| Drug ineffective | 24 | 121 | | 4 | 24 | 117 |
| Drug interaction | 1 | 2 | 1 | 2 | | |
| Dry eye | 3 | 4 | 2 | 3 | 1 | 1 |
| Dry mouth | 3 | 16 | 3 | 14 | | 2 |
| Dry skin | 2 | 2 | 2 | 2 | | |
| Dry throat | 1 | 2 | 1 | 2 | | |
| Dysaesthesia | | 2 | | 2 | | |
| Dysarthria | | 1 | | 1 | | |
| Dysgeusia | 9 | 43 | 9 | 41 | | 2 |
| Dyslexia | | 1 | | 1 | | |
| Dyspepsia | 2 | 9 | 2 | 9 | | |
| Dysphagia | 6 | 12 | 5 | 10 | 1 | 2 |
| Dysphonia | 4 | 9 | 3 | 6 | 1 | 3 |
| Dyspnoea | 22 | 83 | 10 | 49 | 12 | 34 |
| Dyspnoea exertional | | 2 | | 1 | | 1 |
| Dysstasia | 1 | 2 | 1 | 2 | | |
| Dystonia | | 1 | | | | 1 |
| Dysuria | 1 | 2 | 1 | 2 | | |
| Ear congestion | | 1 | | 1 | | |
| Ear discomfort | 4 | 5 | 4 | 5 | | |
| Ear disorder | 4 | 4 | 2 | 2 | 2 | 2 |
| Ear pain | 7 | 18 | 7 | 18 | | |
| Ear pruritus | 1 | 3 | 1 | 3 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Ear swelling | | 2 |
| Eating disorder | 2 | 5 |
| Eczema | | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Emotional disorder | | 2 |
| Emotional distress | | 1 |
| Encephalopathy | | 1 |
| Endodontic procedure | 1 | 1 |
| Energy increased | 1 | 2 |
| Enlarged uvula | | 1 |
| Eosinophilia | | 1 |
| Episcleritis | | 2 |
| Epistaxis | 3 | 8 |
| Eructation | 1 | 1 |
| Erythema | 22 | 67 |
| Erythema of eyelid | 1 | 1 |
| Exposure to SARS-CoV-2 | 1 | 10 |
| Exposure via skin contact | 1 | 2 |
| External ear pain | | 1 |
| Eye contusion | | 1 |
| Eye discharge | 2 | 3 |
| Eye disorder | | 3 |
| Eye haemorrhage | | 2 |
| Eye inflammation | | 3 |
| Eye irritation | 2 | 6 |
| Eyelid disorder | 1 | 2 |
| Eyelid irritation | 1 | 1 |
| Eyelids pruritus | | 1 |
| Eye movement disorder | | 1 |
| Eye oedema | 1 | 1 |
| Eye pain | 5 | 17 |
| Eye pruritus | 4 | 7 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| 2 | 4 | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| | | | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| | | | 1 |
| | 1 | | |
| | 2 | | |
| 3 | 8 | | |
| 1 | 1 | | |
| 19 | 60 | 3 | 7 |
| | | 1 | 1 |
| 1 | 8 | | 2 |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| 2 | 3 | | |
| | 2 | | 1 |
| | | | 2 |
| | 2 | | 1 |
| 2 | 5 | | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 5 | 17 | | |
| 4 | 5 | | 2 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eye swelling | 6 | 13 |
| Face injury | 1 | 2 |
| Face oedema | 1 | 1 |
| Facial discomfort | 2 | 4 |
| Facial nerve disorder | | 1 |
| Facial pain | 6 | 8 |
| Facial paralysis | 6 | 16 |
| Faeces discoloured | | 1 |
| Faeces soft | 1 | 1 |
| Fall | | 5 |
| Fatigue | 142 | 492 |
| Fear | 1 | 4 |
| Febrile convulsion | | 1 |
| Feeding disorder | 1 | 3 |
| Feeling abnormal | 29 | 86 |
| Feeling cold | 7 | 32 |
| Feeling drunk | 3 | 4 |
| Feeling hot | 14 | 48 |
| Feeling jittery | 1 | 4 |
| Feeling of body temperature change | 4 | 7 |
| Fibrin D dimer increased | | 1 |
| Fine motor skill dysfunction | | 1 |
| Flank pain | | 3 |
| Flatulence | 1 | 3 |
| Fluid intake reduced | | 1 |
| Fluid retention | 1 | 1 |
| Flushing | 10 | 53 |
| Food aversion | | 1 |
| Foot deformity | 1 | 1 |
| Foreign body aspiration | | 1 |
| Freezing phenomenon | | 1 |
| Frequent bowel movements | | 3 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 8 | 3 | 5 |
| 1 | 2 | | |
| 1 | 1 | | |
| 2 | 4 | | |
| | 1 | | |
| 6 | 8 | | |
| | | 6 | 16 |
| | 1 | | |
| 1 | 1 | | |
| | 4 | | 1 |
| 134 | 470 | 8 | 22 |
| 1 | 4 | | |
| | | | 1 |
| 1 | 2 | | 1 |
| 26 | 78 | 3 | 8 |
| 6 | 28 | 1 | 4 |
| 3 | 4 | | |
| 13 | 45 | 1 | 3 |
| | 2 | 1 | 2 |
| 4 | 7 | | |
| | 1 | | |
| | 3 | | |
| 1 | 3 | | |
| | 1 | | |
| 1 | 1 | | |
| 7 | 43 | 3 | 10 |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| | 3 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Frostbite | | 1 |
| Frustration tolerance decreased | | 1 |
| Fungal infection | 1 | 1 |
| Gait disturbance | 6 | 21 |
| Gait inability | 5 | 9 |
| Gal bladder disorder | | 1 |
| Gastric disorder | | 1 |
| Gastrointestinal disorder | | 6 |
| Gastrointestinal haemorrhage | 1 | 1 |
| Gastrointestinal motility disorder | | 1 |
| Gastrointestinal pain | 1 | 3 |
| Gastrooesophageal reflux disease | 2 | 2 |
| Gastrooesophageal sphincter insufficiency | | 1 |
| Gingival bleeding | | 3 |
| Gingival blister | 1 | 1 |
| Gingival disorder | | 1 |
| Gingival erythema | | 2 |
| Gingival pain | | 2 |
| Gingival recession | | 1 |
| Gingival swelling | | 3 |
| Glossitis | | 1 |
| Glossodynia | 3 | 4 |
| Good syndrome | 1 | 1 |
| Groin pain | | 2 |
| Grunting | | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematochezia | 2 | 2 |
| Haematocrit increased | | 1 |
| Haemoptysis | | 1 |
| Haemorrhage | 3 | 4 |
| Haemorrhage intracranial | | 1 |
| Haemorrhagic stroke | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 6 | 18 | | 3 |
| 3 | 7 | 2 | 2 |
| | 1 | | |
| | 1 | | |
| | 5 | | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 3 | | |
| 2 | 2 | | |
| | | | 1 |
| | 3 | | |
| | | 1 | 1 |
| | 1 | | |
| | 2 | | |
| | 2 | | |
| | 1 | | |
| | 3 | | |
| | 1 | | |
| 3 | 4 | | |
| | | 1 | 1 |
| | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | | |
| | 1 | | |
| | | 3 | 4 |
| | | | 1 |
| | | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------|------------------------------------|--------------------------------------|
| Haemorrhoids | | 1 |
| Hallucination | | 1 |
| Headache | 156 | 636 |
| Head discomfort | 8 | 20 |
| Head injury | | 2 |
| Head titubation | | 1 |
| Heart rate decreased | 1 | 2 |
| Heart rate increased | 20 | 66 |
| Heart rate irregular | | 1 |
| Helicobacter infection | 1 | 1 |
| Hemiparesis | | 1 |
| Hepatitis acute | 1 | 1 |
| Herpes simplex | | 1 |
| Herpes virus infection | | 1 |
| Herpes zoster | 7 | 18 |
| Hidradenitis | | 1 |
| Hordeolum | | 2 |
| Hot flush | 4 | 16 |
| Hunger | | 3 |
| Hyperaesthesia | | 3 |
| Hyperaesthesia teeth | | 1 |
| Hyperglycaemia | | 2 |
| Hyperhidrosis | 18 | 59 |
| Hypersensitivity | 10 | 27 |
| Hypersomnia | 4 | 13 |
| Hypertension | 11 | 28 |
| Hypertensive emergency | | 1 |
| Hypertonia | | 1 |
| Hyperventilation | 1 | 3 |
| Hypoacusis | 4 | 9 |
| Hypoaesthesia | 23 | 81 |
| Hypoaesthesia eye | 1 | 2 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | | 1 |
| 145 | 594 | 11 | 42 |
| 8 | 18 | | 2 |
| | 2 | | |
| | 1 | | |
| 1 | 2 | | |
| 16 | 53 | 4 | 13 |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 4 | 15 | 3 | 3 |
| | 1 | | |
| | 2 | | |
| 3 | 15 | 1 | 1 |
| | 3 | | |
| | 3 | | |
| | 1 | | 1 |
| 17 | 55 | 1 | 4 |
| 8 | 21 | 2 | 6 |
| 4 | 12 | | 1 |
| 7 | 14 | 4 | 14 |
| | | | 1 |
| | 1 | | |
| 1 | 3 | | |
| 2 | 7 | 2 | 2 |
| 19 | 66 | 4 | 15 |
| 1 | 2 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypoaesthesia oral | 7 | 28 |
| Hypoaesthesia teeth | 1 | 1 |
| Hypogeusia | 2 | 4 |
| Hypokinesia | 2 | 4 |
| Hypophagia | | 2 |
| Hypopnoea | 1 | 1 |
| Hyposmia | | 2 |
| Hypotension | 2 | 2 |
| Hypothermia | 1 | 1 |
| Hypothyroidism | | 1 |
| Idiosyncratic drug reaction | | 1 |
| Illness | 8 | 31 |
| Illness anxiety disorder | | 1 |
| Immune system disorder | 1 | 3 |
| Immune thrombocytopenia | 1 | 2 |
| Immunodeficiency | 2 | 3 |
| Immunosuppression | 1 | 1 |
| Impaired driving ability | | 1 |
| Impaired work ability | 1 | 7 |
| Inappropriate schedule of product administration | 26 | 64 |
| Incoherent | | 1 |
| Incorrect dosage administered | 1 | 1 |
| Incorrect dose administered | 1 | 3 |
| Incorrect route of product administration | 1 | 6 |
| Increased tendency to bruise | 1 | 1 |
| Increased upper airway secretion | | 1 |
| Inflammation | 2 | 5 |
| Inflammatory pain | | 1 |
| Influenza | 3 | 11 |
| Influenza B virus test positive | | 1 |
| Influenza like illness | 9 | 47 |
| Initial insomnia | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 21 | 3 | 7 |
| 1 | 1 | | |
| 2 | 4 | | |
| 2 | 4 | | |
| | 2 | | |
| 1 | 1 | | |
| | 2 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| 7 | 29 | 1 | 2 |
| | 1 | | |
| 1 | 3 | | |
| | | 1 | 2 |
| | | 2 | 3 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 7 | | |
| 26 | 64 | | |
| | | | 1 |
| 1 | 1 | | |
| | 2 | 1 | 1 |
| 1 | 5 | | 1 |
| 1 | 1 | | |
| | | | 1 |
| 2 | 4 | | 1 |
| | 1 | | |
| 3 | 11 | | |
| | 1 | | |
| 9 | 46 | | 1 |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Injection site erythema | 1 | 1 |
| Injection site pain | 1 | 6 |
| Insomnia | 16 | 32 |
| International normalised ratio increased | | 1 |
| Intervertebral disc protrusion | 1 | 2 |
| Intestinal obstruction | | 1 |
| Intrusive thoughts | | 1 |
| Irregular sleep wake rhythm disorder | 1 | 2 |
| Irritability | | 2 |
| Jaundice | | 1 |
| Joint dislocation | 1 | 2 |
| Joint effusion | | 1 |
| Joint injury | 1 | 1 |
| Joint range of motion decreased | 2 | 4 |
| Joint stiffness | | 1 |
| Joint swelling | 4 | 14 |
| Joint warmth | 1 | 1 |
| Keratic precipitates | 1 | 1 |
| Labile hypertension | | 1 |
| Lacrimation increased | 7 | 9 |
| Laryngitis | | 1 |
| Lethargy | 2 | 14 |
| Limb discomfort | 4 | 17 |
| Limb injury | | 1 |
| Limb mass | 2 | 2 |
| Lip blister | 2 | 3 |
| Lip erythema | | 1 |
| Lipids increased | | 1 |
| Lip injury | | 1 |
| Lip pain | 1 | 1 |
| Lip pruritus | 4 | 5 |
| Lip swelling | 8 | 27 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 5 | | 1 |
| 16 | 32 | | |
| | | | 1 |
| | 1 | 1 | 1 |
| | | | 1 |
| | 1 | | |
| 1 | 2 | | |
| | 2 | | |
| | 1 | | |
| | | 1 | 2 |
| | 1 | | |
| 1 | 1 | | |
| 2 | 4 | | |
| | 1 | | |
| 4 | 13 | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 6 | 7 | 1 | 2 |
| | 1 | | |
| 2 | 13 | | 1 |
| 4 | 16 | | 1 |
| | 1 | | |
| | 1 | 2 | 2 |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| 2 | 3 | 2 | 2 |
| 4 | 18 | 4 | 9 |

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Age Range

51 - 64 years

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|---|------------------------------------|--------------------------------------|
| Liquid product physical issue | 1 | 1 |
| Livedo reticularis | 1 | 2 |
| Liver function test abnormal | | 1 |
| Liver function test increased | 1 | 1 |
| Liver injury | | 1 |
| Localised oedema | | 2 |
| Loss of consciousness | 7 | 15 |
| Loss of personal independence in daily activities | 1 | 6 |
| Lower respiratory tract congestion | | 1 |
| Lung carcinoma cell type unspecified stage I | 1 | 1 |
| Lymphadenitis | | 1 |
| Lymphadenopathy | 30 | 93 |
| Lymph node pain | 8 | 25 |
| Lymphocyte count abnormal | 1 | 1 |
| Lymphoedema | | 3 |
| Lymphoma | 1 | 1 |
| Madarosis | 1 | 1 |
| Malaise | 39 | 172 |
| Mass | | 1 |
| Mean cell volume increased | | 1 |
| Memory impairment | 2 | 6 |
| Meningitis viral | | 1 |
| Menorrhagia | 1 | 1 |
| Menstrual disorder | 1 | 1 |
| Mental disorder | | 1 |
| Mental fatigue | | 1 |
| Mental impairment | 2 | 4 |
| Metastases to meninges | | 1 |
| Middle insomnia | 2 | 6 |
| Migraine | 6 | 33 |
| Migraine with aura | 2 | 2 |
| Mobility decreased | 2 | 3 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | | 1 |
| | 2 | | |
| | | 7 | 15 |
| 1 | 6 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 26 | 81 | 4 | 12 |
| 7 | 23 | 1 | 2 |
| 1 | 1 | | |
| | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 38 | 166 | 1 | 6 |
| | 1 | | |
| | 1 | | |
| | 3 | 2 | 3 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 2 | 4 |
| | | | 1 |
| 1 | 5 | 1 | 1 |
| 4 | 29 | 2 | 4 |
| 2 | 2 | | |
| 2 | 3 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Monoplegia | 1 | 1 |
| Motion sickness | | 2 |
| Motor dysfunction | | 2 |
| Mouth haemorrhage | 1 | 1 |
| Mouth swelling | | 3 |
| Movement disorder | 5 | 12 |
| Mucosal disorder | 1 | 1 |
| Mucosa vesicle | 1 | 1 |
| Mucous stools | 1 | 1 |
| Multiple organ dysfunction syndrome | | 1 |
| Muscle discomfort | | 2 |
| Muscle rupture | 1 | 1 |
| Muscle spasms | 9 | 34 |
| Muscle spasticity | 1 | 1 |
| Muscle swelling | 1 | 1 |
| Muscle tightness | 5 | 11 |
| Muscle twitching | | 5 |
| Muscular weakness | 6 | 22 |
| Musculoskeletal chest pain | | 6 |
| Musculoskeletal discomfort | | 9 |
| Musculoskeletal stiffness | 5 | 23 |
| Myalgia | 58 | 230 |
| Mydriasis | | 1 |
| Myocardial infarction | 2 | 4 |
| Myocardial necrosis marker increased | 1 | 1 |
| Myocarditis | 1 | 1 |
| Nasal congestion | 12 | 31 |
| Nasal discomfort | 1 | 3 |
| Nasal oedema | 2 | 3 |
| Nasopharyngitis | | 19 |
| Nausea | 87 | 325 |
| Neck mass | 2 | 3 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 2 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| | 1 | | 2 |
| 3 | 10 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | 2 | | |
| | | 1 | 1 |
| 8 | 32 | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 9 | 1 | 2 |
| | 5 | | |
| 5 | 19 | 1 | 3 |
| | 6 | | |
| | 8 | | 1 |
| 5 | 22 | | 1 |
| 54 | 218 | 4 | 12 |
| | 1 | | |
| | | 2 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 11 | 28 | 1 | 3 |
| 1 | 2 | | 1 |
| | 1 | 2 | 2 |
| | 19 | | |
| 81 | 298 | 6 | 27 |
| 2 | 3 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Neck pain | 16 | 52 |
| Nephrolithiasis | | 1 |
| Nerve compression | | 1 |
| Nerve injury | 1 | 2 |
| Nervousness | 3 | 12 |
| Nervous system disorder | | 1 |
| Neuralgia | 5 | 8 |
| Neuropathy peripheral | | 2 |
| Neutrophil count decreased | 1 | 1 |
| Nightmare | 2 | 3 |
| Night sweats | 3 | 11 |
| Nipple pain | | 1 |
| Nodule | 1 | 1 |
| Noninfective encephalitis | 1 | 1 |
| Nuchal rigidity | | 1 |
| Occipital neuralgia | 1 | 1 |
| Occupational exposure to SARS-CoV-2 | | 2 |
| Ocular discomfort | | 2 |
| Ocular hyperaemia | 4 | 11 |
| Odynophagia | 1 | 2 |
| Oedema | | 2 |
| Oedema peripheral | 1 | 2 |
| Off label use | 13 | 28 |
| Oral candidiasis | | 2 |
| Oral discomfort | 1 | 2 |
| Oral disorder | | 2 |
| Oral herpes | 2 | 7 |
| Oral mucosal blistering | | 1 |
| Oral mucosal eruption | | 2 |
| Oral mucosal erythema | | 3 |
| Oral mucosal exfoliation | 1 | 1 |
| Oral pain | 1 | 4 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 16 | 51 | | 1 |
| | | | 1 |
| | 1 | | |
| | 1 | 1 | 1 |
| 3 | 12 | | |
| | | | 1 |
| 4 | 7 | 1 | 1 |
| | | | 2 |
| 1 | 1 | | |
| 2 | 3 | | |
| 3 | 10 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| | 2 | | |
| 3 | 10 | 1 | 1 |
| 1 | 2 | | |
| | 2 | | |
| 1 | 2 | | |
| 13 | 28 | | |
| | 2 | | |
| 1 | 2 | | |
| | 1 | | 1 |
| 2 | 6 | | 1 |
| | 1 | | |
| | 2 | | |
| | 2 | | 1 |
| 1 | 1 | | |
| 1 | 3 | | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Oral pruritus | 2 | 3 |
| Oral viral infection | | 1 |
| Organising pneumonia | | 1 |
| Oropharyngeal blistering | | 1 |
| Oropharyngeal pain | 12 | 49 |
| Oropharyngeal spasm | 1 | 1 |
| Orthostatic heart rate response increased | | 1 |
| Overdose | 5 | 9 |
| Overweight | | 1 |
| Oxygen saturation decreased | 3 | 9 |
| Pain | 110 | 416 |
| Painful respiration | 2 | 2 |
| Pain in extremity | 82 | 300 |
| Pain in jaw | 5 | 13 |
| Pain of skin | 3 | 5 |
| Palatal disorder | | 1 |
| Palatal swelling | | 2 |
| Pallor | 3 | 8 |
| Palmar erythema | | 1 |
| Palpitations | 17 | 47 |
| Pancreatitis | 1 | 1 |
| Pancreatitis acute | 1 | 1 |
| Panic attack | 1 | 2 |
| Panic reaction | | 1 |
| Papule | | 1 |
| Paraesthesia | 23 | 93 |
| Paraesthesia oral | 10 | 32 |
| Paralysis | | 1 |
| Paranasal sinus discomfort | | 3 |
| Paranasal sinus hypersecretion | 1 | 1 |
| Parosmia | 1 | 6 |
| Pemphigoid | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 2 | 2 |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| 12 | 46 | | 3 |
| | | 1 | 1 |
| | 1 | | |
| 4 | 8 | 1 | 1 |
| | 1 | | |
| 2 | 4 | 1 | 5 |
| 103 | 396 | 7 | 20 |
| 1 | 1 | 1 | 1 |
| 78 | 290 | 4 | 10 |
| 4 | 11 | 1 | 2 |
| 3 | 4 | | 1 |
| | 1 | | |
| | 1 | | 1 |
| 3 | 8 | | |
| | 1 | | |
| 15 | 39 | 2 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| 22 | 79 | 1 | 14 |
| 7 | 26 | 3 | 6 |
| | | | 1 |
| | 3 | | |
| 1 | 1 | | |
| 1 | 6 | | |
| | | 1 | 1 |

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Age Range

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Periorbital cellulitis | 1 | 1 |
| Periorbital discomfort | | 1 |
| Periorbital oedema | | 1 |
| Periorbital pain | 1 | 1 |
| Periorbital swelling | 2 | 6 |
| Peripheral coldness | 3 | 7 |
| Peripheral swelling | 11 | 47 |
| Peroneal nerve palsy | | 1 |
| Pertussis | | 1 |
| Petechiae | 3 | 5 |
| Pharyngeal hypoaesthesia | | 1 |
| Pharyngeal inflammation | | 1 |
| Pharyngeal oedema | | 1 |
| Pharyngeal paraesthesia | 1 | 4 |
| Pharyngeal swelling | 4 | 15 |
| Pharyngitis streptococcal | 2 | 2 |
| Photophobia | 2 | 8 |
| Photopsia | | 1 |
| Photosensitivity reaction | | 2 |
| Physical deconditioning | | 1 |
| Platelet count abnormal | 1 | 1 |
| Platelet count decreased | 2 | 3 |
| Pneumonia | | 3 |
| Pneumonitis | | 1 |
| PO2 decreased | | 1 |
| Pollakiuria | 2 | 5 |
| Polymyalgia rheumatica | | 1 |
| Polyuria | | 2 |
| Poor quality product administered | 4 | 6 |
| Poor quality sleep | 1 | 6 |
| Postural orthostatic tachycardia syndrome | | 1 |
| Posture abnormal | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 4 | 1 | 2 |
| 3 | 7 | | |
| 11 | 44 | | 3 |
| | 1 | | |
| | | | 1 |
| 1 | 3 | 2 | 2 |
| | | | 1 |
| | 1 | | |
| | | | 1 |
| 1 | 2 | | 2 |
| 1 | 10 | 3 | 5 |
| 2 | 2 | | |
| 2 | 8 | | |
| | 1 | | |
| | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 3 |
| | | | 3 |
| | 1 | | |
| | | | 1 |
| 2 | 5 | | |
| | | | 1 |
| | 2 | | |
| 4 | 6 | | |
| 1 | 6 | | |
| | 1 | | |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Posturing | | 1 | | | | 1 |
| Pre-existing condition improved | | 1 | | 1 | | |
| Presyncope | 4 | 14 | 4 | 10 | | 4 |
| Procedural pain | | 2 | | 2 | | |
| Proctalgia | 1 | 1 | 1 | 1 | | |
| Product administered at inappropriate site | 1 | 6 | 1 | 6 | | |
| Product administration error | 1 | 1 | 1 | 1 | | |
| Product dose omission issue | 1 | 1 | 1 | 1 | | |
| Productive cough | 2 | 6 | 2 | 5 | | 1 |
| Product preparation error | 1 | 4 | 1 | 4 | | |
| Product preparation issue | 2 | 2 | 1 | 1 | 1 | 1 |
| Product quality issue | 2 | 3 | 2 | 3 | | |
| Product temperature excursion issue | 1 | 1 | 1 | 1 | | |
| Product use issue | 14 | 33 | 14 | 33 | | |
| Pruritus | 26 | 111 | 21 | 96 | 5 | 15 |
| Pruritus genital | | 1 | | | | 1 |
| Psychiatric symptom | | 1 | | 1 | | |
| Psychomotor hyperactivity | | 1 | | | | 1 |
| Pulmonary congestion | 1 | 2 | | | 1 | 2 |
| Pulmonary oedema | 1 | 2 | | | 1 | 2 |
| Pulmonary pain | 1 | 1 | 1 | 1 | | |
| Pulse abnormal | | 3 | | 3 | | |
| Pupillary disorder | | 1 | | 1 | | |
| Pustule | 1 | 2 | 1 | 1 | | 1 |
| Pyrexia | 114 | 469 | 103 | 435 | 11 | 34 |
| Rash | 28 | 93 | 20 | 76 | 8 | 17 |
| Rash erythematous | 6 | 19 | 5 | 16 | 1 | 3 |
| Rash macular | 5 | 13 | 5 | 12 | | 1 |
| Rash maculo-papular | | 4 | | 4 | | |
| Rash papular | 1 | 6 | 1 | 6 | | |
| Rash pruritic | 3 | 10 | 2 | 9 | 1 | 1 |
| Rash vesicular | 2 | 3 | 2 | 3 | | |

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Age Range

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Reaction to excipient | 1 | 1 |
| Rectal haemorrhage | 1 | 1 |
| Rectal tenesmus | 1 | 1 |
| Red blood cell sedimentation rate increased | | 1 |
| Renal failure | | 1 |
| Renal pain | 3 | 5 |
| Respiratory disorder | 1 | 1 |
| Respiratory distress | 1 | 4 |
| Respiratory failure | | 1 |
| Respiratory rate decreased | | 1 |
| Respiratory rate increased | 2 | 3 |
| Respiratory symptom | | 1 |
| Respiratory tract congestion | | 2 |
| Restless legs syndrome | | 1 |
| Restlessness | | 2 |
| Retching | 1 | 4 |
| Retinal tear | 1 | 1 |
| Retinitis | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 |
| Rhinalgia | 1 | 2 |
| Rhinorrhoea | 7 | 28 |
| Rosacea | | 1 |
| Salivary gland pain | | 1 |
| Salivary hypersecretion | 1 | 1 |
| SARS-CoV-2 ant body test negative | 3 | 4 |
| SARS-CoV-2 ant body test positive | 1 | 3 |
| SARS-CoV-2 test false positive | | 1 |
| SARS-CoV-2 test positive | 6 | 29 |
| Scab | 1 | 1 |
| Scratch | 1 | 2 |
| Screaming | | 1 |
| Seizure | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| 3 | 5 | | |
| | | 1 | 1 |
| | | 1 | 4 |
| | | | 1 |
| | | | 1 |
| 2 | 2 | | 1 |
| | | | 1 |
| | 2 | | |
| | 1 | | |
| 1 | 3 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| 7 | 28 | | |
| | 1 | | |
| 1 | 1 | | |
| 3 | 4 | | |
| 1 | 2 | | 1 |
| | 1 | | |
| | 6 | 6 | 23 |
| 1 | 1 | | |
| 1 | 1 | | 1 |
| | 1 | | |
| | | | 2 |

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Age Range

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Sensation of foreign body | 1 | 4 |
| Sensitisation | | 1 |
| Sensitive skin | | 1 |
| Sensory disturbance | | 1 |
| Sensory loss | | 4 |
| Sepsis | 1 | 1 |
| Serotonin syndrome | | 1 |
| Sinus congestion | 2 | 10 |
| Sinus disorder | 3 | 7 |
| Sinus headache | 1 | 3 |
| Sinusitis | 2 | 5 |
| Sinus pain | 1 | 4 |
| Sinus tarsi syndrome | | 1 |
| Skeletal injury | 1 | 1 |
| Skin burning sensation | 2 | 6 |
| Skin discolouration | 2 | 4 |
| Skin disorder | 2 | 5 |
| Skin exfoliation | 2 | 2 |
| Skin haemorrhage | 1 | 1 |
| Skin irritation | | 2 |
| Skin lesion | 1 | 1 |
| Skin mass | 1 | 1 |
| Skin reaction | | 1 |
| Skin swelling | | 1 |
| Sleep disorder | 1 | 7 |
| Sleep disorder due to a general medical condition | 1 | 2 |
| Sleep talking | | 1 |
| Sleep terror | 1 | 1 |
| Sluggishness | 1 | 5 |
| Small intestinal obstruction | | 1 |
| Sneezing | 1 | 11 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 3 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 3 | | 1 |
| | | 1 | 1 |
| | | | 1 |
| 2 | 9 | | 1 |
| 3 | 7 | | |
| 1 | 3 | | |
| 2 | 5 | | |
| 1 | 4 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 6 | | |
| 2 | 4 | | |
| 1 | 4 | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 7 | | |
| 1 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 5 | | |
| | | | 1 |
| 1 | 11 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Snoring | | 1 |
| Soft tissue injury | 1 | 1 |
| Somnolence | 6 | 31 |
| Speech disorder | 3 | 9 |
| Spinal disorder | | 1 |
| Spinal pain | 1 | 2 |
| Sputum discoloured | | 1 |
| Staphylococcal skin infection | | 1 |
| Status asthmaticus | | 1 |
| Stiff tongue | | 1 |
| Stomatitis | | 4 |
| Streptococcal infection | 1 | 1 |
| Stress | 3 | 6 |
| Stridor | | 3 |
| Subcutaneous abscess | 1 | 1 |
| Subdural haemorrhage | 1 | 1 |
| Sunburn | | 1 |
| Supraventricular tachycardia | | 2 |
| Suspected COVID-19 | 2 | 9 |
| Swelling | 13 | 43 |
| Swelling face | 9 | 33 |
| Swelling of eyelid | | 3 |
| Swollen tongue | 5 | 17 |
| Syncope | 7 | 9 |
| Tachycardia | 6 | 23 |
| Tachyphrenia | 1 | 2 |
| Taste disorder | | 8 |
| Tearfulness | | 1 |
| Tenderness | 2 | 3 |
| Tendonitis | | 1 |
| Tendon pain | | 1 |
| Tenosynovitis | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 1 | | |
| 6 | 30 | | 1 |
| 1 | 6 | 2 | 3 |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| | | | 1 |
| | 4 | | |
| 1 | 1 | | |
| 3 | 6 | | |
| | | | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | | 2 |
| 1 | 2 | 1 | 7 |
| 8 | 31 | 5 | 12 |
| 5 | 25 | 4 | 8 |
| | 3 | | |
| 2 | 9 | 3 | 8 |
| | | 7 | 9 |
| 5 | 14 | 1 | 9 |
| 1 | 2 | | |
| | 8 | | |
| | 1 | | |
| 2 | 3 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Tension headache | 1 | 2 |
| Testicular pain | 2 | 2 |
| Therapeutic response unexpected | 4 | 7 |
| Thinking abnormal | 4 | 6 |
| Thirst | 2 | 9 |
| Thirst decreased | 1 | 1 |
| Throat irritation | 7 | 18 |
| Throat tightness | 5 | 26 |
| Thrombocytopenia | 1 | 1 |
| Thrombosis | 3 | 3 |
| Thyroid disorder | | 1 |
| Thyroid pain | | 1 |
| Tinnitus | 10 | 34 |
| Tongue blistering | | 1 |
| Tongue coated | | 1 |
| Tongue discolouration | | 2 |
| Tongue discomfort | 1 | 4 |
| Tongue disorder | 1 | 2 |
| Tongue dry | | 1 |
| Tongue erythema | | 1 |
| Tongue injury | | 1 |
| Tongue oedema | | 1 |
| Tongue pruritus | 2 | 4 |
| Tongue ulceration | | 1 |
| Tooth abscess | 1 | 1 |
| Toothache | 5 | 7 |
| Tracheitis | 1 | 1 |
| Tracheomalacia | | 1 |
| Transient ischaemic attack | | 2 |
| Tremor | 9 | 47 |
| Trigeminal nerve disorder | 1 | 1 |
| Trigeminal neuralgia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | |
| 2 | 2 | | |
| 4 | 7 | | |
| 4 | 6 | | |
| 2 | 8 | | 1 |
| 1 | 1 | | |
| 3 | 12 | 4 | 6 |
| 1 | 12 | 4 | 14 |
| | | 1 | 1 |
| | | 3 | 3 |
| | 1 | | |
| | 1 | | |
| 5 | 23 | 5 | 11 |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| 1 | 4 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| 1 | 3 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 4 | 6 | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | | 2 |
| 7 | 37 | 2 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Trismus | | 1 |
| Troponin increased | 1 | 1 |
| Tunnel vision | 1 | 1 |
| Type 2 diabetes mellitus | 1 | 1 |
| Type III immune complex mediated reaction | | 1 |
| Underdose | 3 | 10 |
| Unresponsive to stimuli | | 2 |
| Upper-airway cough syndrome | 1 | 6 |
| Upper airway obstruction | | 1 |
| Upper limb fracture | | 1 |
| Upper respiratory tract congestion | 2 | 14 |
| Upper respiratory tract infection | 1 | 1 |
| Urge incontinence | | 1 |
| Urinary tract infection | 1 | 4 |
| Urinary tract infection bacterial | 1 | 1 |
| Urticaria | 12 | 54 |
| Uterine inflammation | 1 | 1 |
| Uveitis | | 1 |
| Vaccination error | | 1 |
| Vaccination site bruising | 2 | 7 |
| Vaccination site cellulitis | | 3 |
| Vaccination site discolouration | 1 | 1 |
| Vaccination site discomfort | 1 | 4 |
| Vaccination site erythema | 13 | 56 |
| Vaccination site haemorrhage | 1 | 4 |
| Vaccination site hypoaesthesia | | 2 |
| Vaccination site induration | 2 | 6 |
| Vaccination site infection | | 2 |
| Vaccination site inflammation | | 3 |
| Vaccination site irritation | 1 | 2 |
| Vaccination site joint movement impairment | 1 | 3 |
| Vaccination site joint pain | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 3 | 10 | | |
| | 1 | | 1 |
| 1 | 6 | | |
| | | | 1 |
| | | | 1 |
| 2 | 14 | | |
| 1 | 1 | | |
| | 1 | | |
| | 2 | 1 | 2 |
| | | 1 | 1 |
| 9 | 36 | 3 | 18 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 2 | 7 | | |
| | 2 | | 1 |
| 1 | 1 | | |
| 1 | 4 | | |
| 11 | 54 | 2 | 2 |
| 1 | 4 | | |
| | 2 | | |
| 2 | 6 | | |
| | 2 | | |
| | 3 | | |
| 1 | 2 | | |
| 1 | 3 | | |
| | 1 | | |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Vaccination site lymphadenopathy | 1 | 1 |
| Vaccination site macule | 1 | 2 |
| Vaccination site mass | 5 | 12 |
| Vaccination site movement impairment | 3 | 15 |
| Vaccination site nodule | | 2 |
| Vaccination site oedema | 1 | 1 |
| Vaccination site pain | 81 | 342 |
| Vaccination site pallor | | 1 |
| Vaccination site paraesthesia | | 3 |
| Vaccination site pruritus | 7 | 27 |
| Vaccination site rash | 1 | 5 |
| Vaccination site reaction | 1 | 3 |
| Vaccination site swelling | 19 | 55 |
| Vaccination site urticaria | | 3 |
| Vaccination site vesicles | | 1 |
| Vaccination site warmth | 7 | 25 |
| Vaginal haemorrhage | | 2 |
| Varicella zoster virus infection | | 1 |
| Vasculitic rash | 1 | 1 |
| Ventricular extrasystoles | 3 | 6 |
| Vertigo | 8 | 31 |
| Vision blurred | 5 | 29 |
| Visual field defect | | 1 |
| Visual impairment | 6 | 8 |
| Vlth nerve paralysis | 1 | 1 |
| Vocal cord disorder | 2 | 2 |
| Vomiting | 22 | 80 |
| Vulvovaginal pruritus | | 1 |
| Vulvovaginal rash | | 1 |
| Vulvovaginal swelling | | 1 |
| Weight decreased | 2 | 13 |
| Wheezing | 5 | 17 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 2 | | |
| 5 | 12 | | |
| 3 | 14 | | 1 |
| | 2 | | |
| | | 1 | 1 |
| 79 | 337 | 2 | 5 |
| | 1 | | |
| | 3 | | |
| 7 | 26 | | 1 |
| 1 | 5 | | |
| 1 | 3 | | |
| 19 | 55 | | |
| | 3 | | |
| | 1 | | |
| 6 | 24 | 1 | 1 |
| | 1 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | 2 | 4 |
| 7 | 30 | 1 | 1 |
| 3 | 20 | 2 | 9 |
| | 1 | | |
| 6 | 8 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 18 | 67 | 4 | 13 |
| | | | 1 |
| | | | 1 |
| | | | 1 |
| 2 | 9 | | 4 |
| 3 | 9 | 2 | 8 |

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Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| White blood cell count decreased | 1 | 1 | 1 | 1 | | |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| Wound | | 2 | | 2 | | |
| Wound haemorrhage | 1 | 2 | 1 | 1 | | 1 |
| Wrong product administered | | 1 | | 1 | | |
| Wrong technique in product usage process | 3 | 6 | 3 | 6 | | |
| | 2,763 | 9,749 | 2283 | 8318 | 480 | 1431 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 14 | 20 | | | 14 | 20 | | |
| Abdominal distension | 2 | 5 | | | 2 | 5 | | |
| Abdominal pain | 6 | 13 | | | 5 | 12 | 1 | 1 |
| Abdominal pain upper | 17 | 25 | | | 15 | 22 | 2 | 3 |
| Abdominal symptom | 1 | 1 | | | 1 | 1 | | |
| Abdominal wall haematoma | 1 | 1 | | | | | 1 | 1 |
| Abdominal wall haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Abnormal behaviour | 2 | 2 | | | 2 | 2 | | |
| Abnormal dreams | 3 | 4 | | | 3 | 4 | | |
| Acarodermatitis | 1 | 1 | | | | | 1 | 1 |
| Accidental exposure to product | 1 | 2 | | | 1 | 1 | | 1 |
| Accidental overdose | | 1 | | | | 1 | | |
| Acne | | 2 | | | | 2 | | |
| Acoustic neuritis | | 1 | | | | | | 1 |
| Activated partial thromboplastin time prolonged | 1 | 1 | | | 1 | 1 | | |
| Acute myocardial infarction | | 1 | | | | | | 1 |
| Acute respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Adnexa uteri pain | | 1 | | | | 1 | | |
| Adrenocortical insufficiency acute | 1 | 1 | | | | | 1 | 1 |
| Ageusia | 6 | 10 | | | 5 | 9 | 1 | 1 |
| Agitation | | 1 | | | | 1 | | |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 | | |
| Allergy to arthropod sting | 1 | 1 | | | 1 | 1 | | |
| Allergy to vaccine | 6 | 6 | | | 6 | 6 | | |
| Allodynia | | 1 | | | | 1 | | |
| Altered state of consciousness | | 1 | | | | | | 1 |
| Amnesia | 1 | 2 | | | 1 | 2 | | |
| Anaemia | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 6 | 7 | | | | | 6 | 7 |
| Aneurysm | 1 | 1 | | | | | 1 | 1 |
| Angina pectoris | 4 | 4 | | | | | 4 | 4 |
| Angioedema | 1 | 1 | | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Anosmia | 3 | 8 |
| Antibody test abnormal | 1 | 1 |
| Anxiety | 13 | 15 |
| Aphasia | 3 | 4 |
| Appendicitis | | 2 |
| Appetite disorder | | 1 |
| Aptyalism | 1 | 1 |
| Areflexia | 1 | 1 |
| Arrhythmia | 1 | 1 |
| Arthralgia | 80 | 140 |
| Arthritis | 2 | 7 |
| Arthropathy | 2 | 2 |
| Arthropod bite | | 2 |
| Asthenia | 53 | 92 |
| Asthenopia | | 2 |
| Asthma | 2 | 4 |
| Ataxia | | 1 |
| Atrial fibrillation | 13 | 16 |
| Autoimmune haemolytic anaemia | 1 | 1 |
| Autoimmune thyroiditis | 1 | 2 |
| Axillary pain | 4 | 6 |
| Back injury | | 1 |
| Back pain | 29 | 41 |
| Bacterial infection | | 1 |
| Balance disorder | 9 | 14 |
| Bedridden | | 2 |
| Bladder disorder | 1 | 1 |
| Bladder pain | 1 | 1 |
| Blindness | 4 | 5 |
| Blindness transient | 2 | 2 |
| Blister | 2 | 6 |
| Blood bilirubin increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 7 | 1 | 1 |
| | | 1 | 1 | | |
| | | 10 | 12 | 3 | 3 |
| | | 1 | 2 | 2 | 2 |
| | | | | | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 76 | 135 | 4 | 5 |
| | | 2 | 7 | | |
| | | 2 | 2 | | |
| | | | 2 | | |
| | | 44 | 79 | 9 | 13 |
| | | | 2 | | |
| | | 2 | 4 | | |
| | | | | | 1 |
| | | | | 13 | 16 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 4 | 6 | | |
| | | | 1 | | |
| | | 26 | 38 | 3 | 3 |
| | | | | | 1 |
| | | 8 | 13 | 1 | 1 |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 4 | 5 |
| | | | | 2 | 2 |
| | | | 4 | 2 | 2 |
| | | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Blood chloride decreased | 1 | 1 |
| Blood cholesterol increased | 1 | 1 |
| Blood count abnormal | 1 | 1 |
| Blood creatinine increased | 1 | 1 |
| Blood disorder | | 1 |
| Blood glucose abnormal | 2 | 2 |
| Blood glucose decreased | 2 | 3 |
| Blood glucose increased | 6 | 10 |
| Blood immunoglobulin G decreased | | 1 |
| Blood pressure abnormal | 1 | 2 |
| Blood pressure decreased | 4 | 5 |
| Blood pressure fluctuation | 2 | 3 |
| Blood pressure increased | 24 | 29 |
| Blood sodium decreased | 1 | 1 |
| Blood urine present | 3 | 6 |
| Body height decreased | 4 | 7 |
| Body temperature abnormal | 2 | 3 |
| Body temperature increased | 8 | 16 |
| Bone pain | 4 | 8 |
| Bone swelling | | 2 |
| Bowel movement irregularity | 1 | 2 |
| Bradycardia | | 1 |
| Breast discomfort | | 1 |
| Breast pain | 4 | 6 |
| Breast swelling | 1 | 1 |
| Bronchitis | | 2 |
| Burning sensation | 12 | 14 |
| Burn oral cavity | | 1 |
| Butterfly rash | 1 | 1 |
| Cardiac arrest | 2 | 5 |
| Cardiac discomfort | | 1 |
| Cardiac disorder | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 4 | 7 | 2 | 3 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | 2 | 3 | 2 | 2 |
| | | 2 | 3 | | |
| | | 14 | 18 | 10 | 11 |
| | | | | 1 | 1 |
| | | 2 | 5 | 1 | 1 |
| | | 3 | 6 | 1 | 1 |
| | | 2 | 3 | | |
| | | 8 | 16 | | |
| | | 4 | 7 | | 1 |
| | | | 2 | | |
| | | 1 | 2 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | 4 | 6 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 11 | 13 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 5 |
| | | | 1 | | |
| | | 1 | 2 | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Cardiac failure chronic | 1 | 1 |
| Cardiac failure congestive | 3 | 3 |
| Cardiac flutter | 2 | 2 |
| Cardio-respiratory arrest | | 1 |
| Cellulitis | 2 | 3 |
| Cerebral disorder | | 1 |
| Cerebrovascular accident | 13 | 18 |
| Chalazion | | 1 |
| Chapped lips | | 1 |
| Chest discomfort | 20 | 26 |
| Chest pain | 16 | 21 |
| Chills | 139 | 272 |
| Choking | | 2 |
| Chondritis | 1 | 1 |
| Chromaturia | | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Circumstance or information capable of leading to medication error | 2 | 18 |
| Cluster headache | | 1 |
| Cognitive disorder | 1 | 1 |
| Cold sweat | 5 | 5 |
| Communication disorder | | 1 |
| Condition aggravated | 12 | 20 |
| Confusional state | 6 | 10 |
| Conjunctival haemorrhage | 1 | 1 |
| Conjunctivitis | 1 | 1 |
| Conjunctivitis allergic | | 1 |
| Constipation | 2 | 2 |
| Contraindication to vaccination | | 1 |
| Contrast media allergy | | 1 |
| Contusion | 7 | 12 |
| Cough | 35 | 65 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 2 | 3 |
| | | | | 13 | 18 |
| | | | 1 | | |
| | | | 1 | | |
| | | 15 | 20 | 5 | 6 |
| | | 12 | 15 | 4 | 6 |
| | | 126 | 252 | 13 | 20 |
| | | | | | 2 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 18 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 4 | 1 | 1 |
| | | | 1 | | |
| | | 10 | 16 | 2 | 4 |
| | | 3 | 6 | 3 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 7 | 12 | | |
| | | 35 | 65 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| COVID-19 | 47 | 72 |
| COVID-19 immunisation | | 1 |
| COVID-19 pneumonia | 2 | 3 |
| C-reactive protein increased | 2 | 2 |
| Crying | 1 | 2 |
| CSF protein increased | 1 | 1 |
| Cyanosis | 1 | 1 |
| Cystitis | 2 | 3 |
| Daydreaming | 1 | 1 |
| Deafness | 4 | 5 |
| Deafness neurosensory | | 2 |
| Deafness unilateral | 3 | 4 |
| Death | 5 | 10 |
| Decreased appetite | 15 | 31 |
| Deep vein thrombosis | 3 | 3 |
| Dehydration | 7 | 10 |
| Delirium | 1 | 2 |
| Dementia | 2 | 2 |
| Dental paraesthesia | | 1 |
| Dental restoration failure | | 1 |
| Depressed level of consciousness | 1 | 1 |
| Depressed mood | 3 | 3 |
| Depression | 1 | 1 |
| Dermatitis contact | | 1 |
| Diabetes mellitus | 1 | 2 |
| Diabetic wound | 1 | 1 |
| Diarrhoea | 60 | 106 |
| Diarrhoea haemorrhagic | 2 | 2 |
| Diplopia | 1 | 2 |
| Discomfort | 8 | 13 |
| Disease recurrence | 11 | 14 |
| Disorientation | 3 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 3 | 7 | 44 | 65 |
| | | | 1 | | |
| | | | | 2 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | | 1 |
| | | 1 | 1 | | |
| | | | | 4 | 5 |
| | | | | | 2 |
| | | | | 3 | 4 |
| | | | | 5 | 10 |
| | | 14 | 27 | 1 | 4 |
| | | | | 3 | 3 |
| | | 5 | 8 | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 55 | 99 | 5 | 7 |
| | | | | 2 | 2 |
| | | 1 | 2 | | |
| | | 8 | 13 | | |
| | | 4 | 6 | 7 | 8 |
| | | 1 | 3 | 2 | 3 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Disturbance in attention | 2 | 4 |
| Diverticulitis | 3 | 3 |
| Diverticulum intestinal | 1 | 1 |
| Dizziness | 101 | 177 |
| Dizziness postural | 6 | 7 |
| Drug eruption | | 1 |
| Drug hypersensitivity | 2 | 4 |
| Drug ineffective | 50 | 89 |
| Drug interaction | | 1 |
| Dry mouth | 8 | 11 |
| Dry skin | 3 | 4 |
| Dry throat | 1 | 2 |
| Dysarthria | 1 | 1 |
| Dysentery | 1 | 1 |
| Dysgeusia | 10 | 19 |
| Dyskinesia | | 1 |
| Dyspepsia | 3 | 3 |
| Dysphagia | 7 | 10 |
| Dysphonia | 5 | 9 |
| Dyspnoea | 42 | 64 |
| Dyspnoea exertional | 2 | 2 |
| Dysstasia | 4 | 5 |
| Dysuria | 1 | 1 |
| Ear discomfort | 6 | 9 |
| Ear infection | 1 | 1 |
| Ear pain | 4 | 8 |
| Ear pruritus | 1 | 2 |
| Ear swelling | 1 | 2 |
| Eating disorder | 2 | 3 |
| Ecchymosis | | 1 |
| Ejection fraction decreased | 1 | 1 |
| Emotional disorder | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 4 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 92 | 162 | 9 | 15 |
| | | 5 | 6 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 3 | 1 | 1 |
| 1 | 1 | 1 | 5 | 49 | 84 |
| | | | | | 1 |
| | | 8 | 11 | | |
| | | 3 | 4 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 9 | 18 | 1 | 1 |
| | | | 1 | | |
| | | 3 | 3 | | |
| | | 6 | 9 | 1 | 1 |
| | | 3 | 7 | 2 | 2 |
| | | 23 | 39 | 19 | 25 |
| | | 2 | 2 | | |
| | | 2 | 2 | 2 | 3 |
| | | 1 | 1 | | |
| | | 6 | 8 | | 1 |
| | | 1 | 1 | | |
| | | 3 | 7 | 1 | 1 |
| | | 1 | 2 | | |
| | | 1 | 2 | | |
| | | 2 | 3 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Encephalitis | 1 | 1 |
| Energy increased | | 1 |
| Eosinophil count increased | | 1 |
| Epistaxis | 5 | 9 |
| Erythema | 24 | 41 |
| Erythema of eyelid | | 1 |
| Eustachian tube disorder | 1 | 1 |
| Excessive cerumen production | 2 | 2 |
| Exposure to SARS-CoV-2 | 4 | 5 |
| Exposure via skin contact | 1 | 2 |
| Extraocular muscle paresis | 1 | 1 |
| Eye contusion | | 1 |
| Eye discharge | 1 | 1 |
| Eye disorder | 2 | 3 |
| Eye haemorrhage | 2 | 2 |
| Eye infection | 1 | 1 |
| Eye irritation | 2 | 3 |
| Eyelid disorder | | 1 |
| Eyelid function disorder | | 1 |
| Eyelid oedema | | 2 |
| Eyelid pain | 2 | 2 |
| Eyelid ptosis | 1 | 1 |
| Eye oedema | 1 | 2 |
| Eye pain | 3 | 5 |
| Eye pruritus | 7 | 8 |
| Eye swelling | 9 | 11 |
| Facial pain | 1 | 4 |
| Facial paralysis | 24 | 31 |
| Facial paresis | 1 | 1 |
| Faeces discoloured | 1 | 2 |
| Faeces soft | | 1 |
| Fall | 15 | 21 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | 4 | 8 | 1 | 1 |
| | | 21 | 38 | 3 | 3 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | 4 | 5 | | |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 2 | | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 2 | 3 | 3 |
| | | 7 | 8 | | |
| | | 6 | 8 | 3 | 3 |
| | | 1 | 4 | | |
| | | 1 | 1 | 23 | 30 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 12 | 16 | 3 | 5 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Fatigue | 157 | 290 |
| Fear | 3 | 6 |
| Feeding disorder | | 3 |
| Feeling abnormal | 48 | 85 |
| Feeling cold | 19 | 36 |
| Feeling drunk | | 2 |
| Feeling hot | 29 | 42 |
| Feeling jittery | 1 | 2 |
| Feeling of body temperature change | 3 | 8 |
| Fibromyalgia | 1 | 1 |
| Flatulence | 2 | 3 |
| Flushing | 10 | 15 |
| Food poisoning | | 1 |
| Foot deformity | 1 | 1 |
| Foreign body in throat | 1 | 1 |
| Frustration tolerance decreased | 1 | 1 |
| Fungal infection | 1 | 2 |
| Gait disturbance | 21 | 33 |
| Gait inability | 3 | 6 |
| Gastric disorder | 4 | 4 |
| Gastritis bacterial | 1 | 1 |
| Gastroenteritis viral | | 1 |
| Gastrointestinal hypomotility | 1 | 1 |
| Gastrointestinal pain | 1 | 3 |
| Gastrointestinal sounds abnormal | | 1 |
| Gastrointestinal stoma complication | 1 | 1 |
| Gastrooesophageal reflux disease | 3 | 4 |
| Giant cell arteritis | | 1 |
| Gingival erythema | 1 | 1 |
| Gingival pain | | 1 |
| Gingival swelling | 1 | 1 |
| Gingivitis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 146 | 275 | 11 | 15 |
| | | 3 | 6 | | |
| | | | 2 | | 1 |
| | | 43 | 79 | 5 | 6 |
| | | 16 | 33 | 3 | 3 |
| | | | 2 | | |
| | | 26 | 39 | 3 | 3 |
| | | 1 | 2 | | |
| | | 3 | 8 | | |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | 7 | 12 | 3 | 3 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 17 | 27 | 4 | 6 |
| | | 1 | 3 | 2 | 3 |
| | | 4 | 4 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 3 | 4 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Glassy eyes | 1 | 1 |
| Glaucoma | 1 | 1 |
| Glossitis | | 1 |
| Glossodynia | 2 | 3 |
| Glycosylated haemoglobin increased | 1 | 1 |
| Gout | | 1 |
| Guillain-Barre syndrome | 2 | 2 |
| Haematochezia | 7 | 8 |
| Haemoptysis | 2 | 3 |
| Haemorrhage | 2 | 4 |
| Haemorrhoids | 1 | 1 |
| Hallucination | 5 | 5 |
| Hallucination, visual | | 1 |
| Headache | 166 | 359 |
| Head discomfort | 6 | 10 |
| Head injury | 1 | 3 |
| Heart rate abnormal | 2 | 3 |
| Heart rate decreased | 4 | 5 |
| Heart rate increased | 23 | 36 |
| Heart rate irregular | 6 | 8 |
| Hemiplegia | 1 | 1 |
| Hepatic pain | 1 | 1 |
| Hepatitis | 2 | 2 |
| Hereditary haemorrhagic telangiectasia | 1 | 1 |
| Herpes simplex | 1 | 3 |
| Herpes simplex reactivation | 1 | 1 |
| Herpes zoster | 9 | 13 |
| Hiccups | 1 | 2 |
| Hordeolum | 1 | 1 |
| Hot flush | 4 | 5 |
| Hyperacusis | | 1 |
| Hyperaesthesia | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 7 | 8 |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | 1 | 1 | | |
| | | | | 5 | 5 |
| | | | | | 1 |
| | | 148 | 333 | 18 | 26 |
| | | 5 | 9 | 1 | 1 |
| | | | | 1 | 3 |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 2 | 3 | 3 |
| | | 18 | 29 | 5 | 7 |
| | | 6 | 8 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | 7 | 11 | 2 | 2 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 4 | 5 | | |
| | | | | | 1 |
| | | 1 | 2 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyperaesthesia teeth | 1 | 1 |
| Hyperglycaemia | | 1 |
| Hyperhidrosis | 20 | 36 |
| Hyperlipidaemia | 1 | 1 |
| Hyperreflexia | 1 | 1 |
| Hypersensitivity | 9 | 14 |
| Hypersomnia | 3 | 6 |
| Hypertension | 24 | 33 |
| Hypertensive crisis | 1 | 1 |
| Hypertensive emergency | | 1 |
| Hyperthermia | 1 | 1 |
| Hyperventilation | | 1 |
| Hypoacusis | 3 | 5 |
| Hypoaesthesia | 32 | 39 |
| Hypoaesthesia eye | 1 | 1 |
| Hypoaesthesia oral | 6 | 13 |
| Hypoaesthesia teeth | 1 | 1 |
| Hypogeusia | 1 | 1 |
| Hypoglycaemia | 1 | 2 |
| Hypokalaemia | 1 | 1 |
| Hypopnoea | 1 | 2 |
| Hypotension | 8 | 11 |
| Hypothermia | 1 | 1 |
| Hypothyroidism | 1 | 1 |
| Hypotonia | 1 | 1 |
| Hypoxia | | 1 |
| Ill-defined disorder | | 1 |
| Illness | 15 | 34 |
| Immune system disorder | | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Impaired work ability | 1 | 1 |
| Inappropriate schedule of product administration | 16 | 37 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 18 | 33 | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 4 | 8 | 5 | 6 |
| | | 2 | 5 | 1 | 1 |
| | | 13 | 21 | 11 | 12 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 2 | 4 | 1 | 1 |
| | | 25 | 31 | 7 | 8 |
| | | 1 | 1 | | |
| | | 5 | 11 | 1 | 2 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 3 | 4 | 5 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 15 | 34 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 16 | 37 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Incision site haemorrhage | | 1 |
| Incoherent | 1 | 1 |
| Incomplete course of vaccination | | 2 |
| Incontinence | | 2 |
| Incorrect dosage administered | 2 | 2 |
| Incorrect dose administered | | 1 |
| Incorrect route of product administration | 4 | 8 |
| Increased bronchial secretion | | 1 |
| Increased upper airway secretion | 1 | 1 |
| Increased viscosity of upper respiratory secretion | 1 | 1 |
| Inflammation | 3 | 3 |
| Influenza | 5 | 10 |
| Influenza like illness | 15 | 38 |
| Initial insomnia | | 1 |
| Injected limb mobility decreased | | 1 |
| Injection site erythema | 1 | 4 |
| Injection site haemorrhage | | 1 |
| Injection site hypoaesthesia | | 1 |
| Injection site joint pain | | 1 |
| Injection site mass | | 1 |
| Injection site pain | 2 | 18 |
| Injection site rash | | 1 |
| Injection site swelling | | 5 |
| Injection site warmth | 1 | 1 |
| Insomnia | 19 | 34 |
| International normalised ratio decreased | | 1 |
| Intranasal paraesthesia | 1 | 2 |
| Intraocular pressure increased | 1 | 1 |
| Irritability | 1 | 1 |
| Irritability postvaccinal | | 1 |
| Irritable bowel syndrome | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | | 1 | | 1 |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | 4 | 8 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | | |
| | | 5 | 8 | | 2 |
| | | 14 | 37 | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 17 | 1 | 1 |
| | | | 1 | | |
| | | | 5 | | |
| | | 1 | 1 | | |
| | | 18 | 33 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Ischaemic stroke | 3 | 3 |
| Joint injury | | 1 |
| Joint range of motion decreased | 4 | 6 |
| Joint stiffness | 1 | 1 |
| Joint swelling | 5 | 10 |
| Kidney infection | 4 | 4 |
| Lacrimation increased | 2 | 3 |
| Lacunar infarction | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Laryngeal pain | | 1 |
| Lethargy | 6 | 19 |
| Leukaemia | 1 | 1 |
| Leukocytosis | | 2 |
| Limb discomfort | 4 | 11 |
| Lip discolouration | 1 | 1 |
| Lip disorder | 2 | 2 |
| Lip swelling | 12 | 15 |
| Liquid product physical issue | 1 | 1 |
| Liver disorder | 1 | 1 |
| Localised infection | 1 | 2 |
| Loss of consciousness | 17 | 24 |
| Loss of personal independence in daily activities | 4 | 5 |
| Lumbar puncture abnormal | 1 | 1 |
| Lung disorder | 1 | 1 |
| Lymphadenopathy | 12 | 27 |
| Lymph node pain | 4 | 9 |
| Lymphocytosis | 1 | 1 |
| Lymphoedema | 1 | 1 |
| Malaise | 71 | 134 |
| Mass | 3 | 3 |
| Maternal exposure during pregnancy | | 1 |
| May-Thurner syndrome | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | 4 | 6 | | |
| | | | | 1 | 1 |
| | | 5 | 10 | | |
| | | | | 4 | 4 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 6 | 18 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | 4 | 11 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 11 | 13 | 1 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | | 17 | 24 |
| | | 3 | 4 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 11 | 26 | 1 | 1 |
| | | 4 | 9 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 66 | 123 | 5 | 11 |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | | | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Mechanical urticaria | | 1 |
| Memory impairment | 1 | 4 |
| Meningitis aseptic | 1 | 1 |
| Meningitis viral | 2 | 2 |
| Mental disorder | | 1 |
| Mental impairment | 2 | 3 |
| Mental status changes | | 1 |
| Middle insomnia | 1 | 4 |
| Migraine | 7 | 8 |
| Migraine with aura | 1 | 1 |
| Miliaria | 1 | 1 |
| Mixed connective tissue disease | | 1 |
| Mobility decreased | 4 | 4 |
| Monocyte count increased | | 1 |
| Mouth haemorrhage | 2 | 2 |
| Mouth injury | 1 | 1 |
| Mouth swelling | 4 | 4 |
| Movement disorder | 5 | 7 |
| Mucosal disorder | | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Muscle contractions involuntary | 1 | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle disorder | 1 | 1 |
| Muscle fatigue | 1 | 1 |
| Muscle spasms | 12 | 16 |
| Muscle strain | 2 | 2 |
| Muscle tightness | 5 | 9 |
| Muscle twitching | 4 | 5 |
| Muscular weakness | 12 | 15 |
| Musculoskeletal chest pain | | 1 |
| Musculoskeletal discomfort | 1 | 2 |
| Musculoskeletal disorder | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | 1 | 4 | | |
| | | 6 | 7 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 4 | 4 | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | 2 | 2 |
| | | 3 | 5 | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 10 | 13 | 2 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | 5 | 9 | | |
| | | 4 | 5 | | |
| | | 6 | 9 | 6 | 6 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | 1 | 1 | 1 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Musculoskeletal pain | 1 | 2 |
| Musculoskeletal stiffness | 15 | 27 |
| Myalgia | 72 | 136 |
| Myelitis transverse | 1 | 1 |
| Myocardial infarction | 8 | 8 |
| Myositis | 1 | 1 |
| Nasal congestion | 12 | 23 |
| Nasal crusting | 1 | 1 |
| Nasal discomfort | 2 | 2 |
| Nasal dryness | 1 | 1 |
| Nasal oedema | 1 | 1 |
| Nasal pruritus | 1 | 1 |
| Nasopharyngitis | 15 | 24 |
| Nausea | 103 | 200 |
| Near death experience | 2 | 2 |
| Neck mass | 1 | 1 |
| Neck pain | 14 | 30 |
| Nephrolithiasis | 2 | 2 |
| Nerve compression | 2 | 2 |
| Nervousness | 9 | 16 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 4 | 5 |
| Neurological symptom | 1 | 1 |
| Neuropathy peripheral | 3 | 3 |
| Neutropenia | 1 | 1 |
| Nightmare | 3 | 4 |
| Night sweats | 6 | 6 |
| Nipple pain | | 1 |
| Nipple swelling | | 1 |
| Nodal rhythm | | 1 |
| Normocytic anaemia | 1 | 1 |
| Nystagmus | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | 13 | 24 | 2 | 3 |
| | | 69 | 127 | 3 | 9 |
| | | | | 1 | 1 |
| | | | | 8 | 8 |
| | | 1 | 1 | | |
| | | 12 | 23 | | |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 15 | 24 | | |
| | | 92 | 185 | 11 | 15 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 10 | 26 | 4 | 4 |
| | | | | 2 | 2 |
| | | 2 | 2 | | |
| | | 9 | 16 | | |
| | | 1 | 1 | | |
| | | 4 | 5 | | |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 3 | 4 | | |
| | | 6 | 6 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Obstructive airways disorder | | 1 |
| Occipital neuralgia | | 1 |
| Ocular discomfort | 4 | 4 |
| Ocular hyperaemia | 2 | 3 |
| Odynophagia | 2 | 3 |
| Oedema | 1 | 1 |
| Oedema peripheral | | 1 |
| Oesophageal pain | 1 | 1 |
| Off label use | 30 | 42 |
| Oligodipsia | | 1 |
| Oral discomfort | 3 | 3 |
| Oral disorder | 2 | 2 |
| Oral herpes | 3 | 3 |
| Oral pain | | 1 |
| Oral pruritus | 1 | 3 |
| Oropharyngeal discomfort | 2 | 2 |
| Oropharyngeal pain | 18 | 27 |
| Orthostatic hypotension | | 1 |
| Osteoarthritis | 1 | 1 |
| Overdose | 9 | 9 |
| Oxygen saturation abnormal | 1 | 1 |
| Oxygen saturation decreased | 6 | 7 |
| Pain | 89 | 183 |
| Pain in extremity | 122 | 245 |
| Pain in jaw | 3 | 6 |
| Pain of skin | | 1 |
| Palatal disorder | 1 | 1 |
| Pallor | 2 | 2 |
| Palpitations | 23 | 30 |
| Paraesthesia | 27 | 35 |
| Paraesthesia oral | 9 | 15 |
| Paralysis | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | | |
| | | 4 | 4 | | |
| | | 1 | 2 | 1 | 1 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 30 | 42 | | |
| | | | | | 1 |
| | | 3 | 3 | | |
| | | 2 | 2 | | |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | 1 | 1 | 1 | 1 |
| | | 16 | 25 | 2 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 9 | 9 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | 5 | 5 |
| | | 79 | 168 | 10 | 15 |
| | | 117 | 237 | 5 | 8 |
| | | 2 | 5 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 17 | 24 | 6 | 6 |
| | | 19 | 27 | 8 | 8 |
| | | 5 | 11 | 4 | 4 |
| | | | | 4 | 5 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Paranasal sinus discomfort | 2 | 3 |
| Paranasal sinus hypersecretion | 1 | 1 |
| Paranoia | | 1 |
| Parosmia | 5 | 7 |
| Penile haemorrhage | | 1 |
| Pericardial effusion | | 1 |
| Pericarditis | 2 | 2 |
| Periorbital swelling | 3 | 5 |
| Peripheral coldness | 4 | 6 |
| Peripheral swelling | 22 | 38 |
| Peroneal nerve palsy | 1 | 1 |
| Pharyngeal swelling | 8 | 15 |
| Pharyngitis | 1 | 1 |
| Phlebitis | | 1 |
| Photophobia | 3 | 5 |
| Photopsia | 1 | 1 |
| Platelet count decreased | 2 | 2 |
| Platelet count increased | | 1 |
| Pleural effusion | | 1 |
| Plicated tongue | | 1 |
| Pneumonia | 6 | 7 |
| Pollakiuria | 4 | 4 |
| Polychondritis | 1 | 1 |
| Polycythaemia | 1 | 1 |
| Polydipsia | | 1 |
| Polymyalgia rheumatica | 2 | 2 |
| Poor quality product administered | 4 | 5 |
| Poor quality sleep | 3 | 5 |
| Post procedural haemorrhage | | 1 |
| Post-traumatic neuralgia | 1 | 1 |
| Post-traumatic stress disorder | | 1 |
| Presyncope | 7 | 9 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 5 | 7 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | 3 | 5 | | |
| | | 4 | 6 | | |
| | | 19 | 35 | 3 | 3 |
| | | | | 1 | 1 |
| | | 5 | 9 | 3 | 6 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 3 | 5 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 6 | 7 |
| | | 4 | 4 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 4 | 5 | | |
| | | 3 | 5 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 5 | 7 | 2 | 2 |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Product administered at inappropriate site | 2 | 5 |
| Product administration error | 2 | 3 |
| Product communication issue | 1 | 1 |
| Product dose omission issue | 1 | 1 |
| Productive cough | 2 | 4 |
| Product preparation error | 2 | 4 |
| Product preparation issue | 3 | 3 |
| Product temperature excursion issue | 1 | 1 |
| Product use issue | 29 | 45 |
| Pruritus | 50 | 85 |
| Psoriasis | | 1 |
| Pulmonary congestion | | 1 |
| Pulmonary oedema | 1 | 1 |
| Pulmonary pain | | 1 |
| Pulmonary thrombosis | 2 | 2 |
| Pulse abnormal | 2 | 3 |
| Pyrexia | 123 | 231 |
| Rash | 36 | 62 |
| Rash erythematous | 7 | 11 |
| Rash macular | 4 | 5 |
| Rash maculo-papular | 1 | 1 |
| Rash papular | 4 | 6 |
| Rash pruritic | 7 | 14 |
| Rash vesicular | 1 | 3 |
| Rectal discharge | 1 | 1 |
| Rectal haemorrhage | 1 | 1 |
| Red blood cell sedimentation rate abnormal | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 2 |
| Reduced facial expression | 1 | 1 |
| Renal disorder | 2 | 2 |
| Renal failure | 2 | 2 |
| Renal pain | 3 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 5 | | |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 4 | | |
| | | 2 | 4 | | |
| | | 3 | 3 | | |
| | | 1 | 1 | | |
| | | 29 | 44 | | 1 |
| | | 42 | 75 | 8 | 10 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 2 | 3 |
| | | 113 | 215 | 10 | 16 |
| | | 30 | 54 | 6 | 8 |
| | | 7 | 11 | | |
| | | 2 | 3 | 2 | 2 |
| | | 1 | 1 | | |
| | | 4 | 6 | | |
| | | 7 | 14 | | |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | 3 | 4 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Respiration abnormal | 1 | 1 |
| Respiratory arrest | 1 | 1 |
| Respiratory disorder | 3 | 3 |
| Respiratory distress | | 2 |
| Respiratory rate increased | 1 | 2 |
| Respiratory tract congestion | 2 | 3 |
| Respiratory tract infection | 1 | 1 |
| Restlessness | 3 | 4 |
| Retching | 4 | 4 |
| Rheumatoid arthritis | 2 | 3 |
| Rhinalgia | 1 | 1 |
| Rhinitis | | 2 |
| Rhinorrhoea | 16 | 22 |
| Rotator cuff syndrome | 1 | 1 |
| Salivary hypersecretion | | 1 |
| SARS-CoV-1 test positive | | 1 |
| SARS-CoV-2 ant body test negative | 3 | 4 |
| SARS-CoV-2 ant body test positive | | 1 |
| SARS-CoV-2 test positive | 7 | 19 |
| Scar | 2 | 2 |
| Sciatica | 3 | 5 |
| Scratch | 1 | 1 |
| Scrotal disorder | 1 | 1 |
| Scrotal erythema | 1 | 1 |
| Scrotal inflammation | 1 | 1 |
| Scrotal pain | 1 | 1 |
| Seasonal allergy | | 1 |
| Secretion discharge | | 1 |
| Seizure | 6 | 8 |
| Sensation of blood flow | 1 | 1 |
| Sensation of foreign body | 4 | 6 |
| Sensitivity to weather change | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 2 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | 2 | 3 | 1 | 1 |
| | | 3 | 3 | 1 | 1 |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 15 | 21 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 3 | 4 | | |
| | | | 1 | | |
| | | 4 | 7 | 3 | 12 |
| | | | | 2 | 2 |
| | | 1 | 3 | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 6 | 8 |
| | | | | 1 | 1 |
| | | 4 | 6 | | |
| | | 1 | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Sensory disturbance | 3 | 4 |
| Sensory loss | 1 | 2 |
| Sepsis | 1 | 2 |
| Shock | 1 | 1 |
| Shock symptom | 1 | 1 |
| Sinus disorder | 2 | 2 |
| Sinus headache | 2 | 3 |
| Sinusitis | 3 | 4 |
| Sinus pain | | 2 |
| Sinus tachycardia | 1 | 1 |
| Skin burning sensation | 3 | 5 |
| Skin discolouration | 4 | 5 |
| Skin disorder | 4 | 5 |
| Skin exfoliation | 1 | 1 |
| Skin fissures | 1 | 1 |
| Skin laceration | 2 | 3 |
| Skin laxity | 1 | 1 |
| Skin lesion | 3 | 4 |
| Skin mass | | 1 |
| Skin reaction | 1 | 1 |
| Skin swelling | 2 | 3 |
| Sleep disorder | 4 | 12 |
| Sleep disorder due to a general medical condition | | 1 |
| Sleep disorder due to general medical condition, insomnia type | | 1 |
| Sluggishness | 2 | 2 |
| Small intestinal obstruction | 1 | 1 |
| Sneezing | 5 | 10 |
| Somatic symptom disorder | | 1 |
| Somnolence | 15 | 34 |
| Speech disorder | 3 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 4 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 3 | | |
| | | 3 | 4 | | |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 3 | 5 | | |
| | | 3 | 4 | 1 | 1 |
| | | 4 | 5 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 1 | | |
| | | 3 | 4 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | 4 | 10 | | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 5 | 10 | | |
| | | | 1 | | |
| | | 15 | 33 | | 1 |
| | | 3 | 6 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Spinal fusion surgery | | 1 |
| Spinal pain | 2 | 3 |
| Staphylococcal infection | 1 | 1 |
| Staring | 1 | 1 |
| Stomatitis | 1 | 1 |
| Streptococcus test positive | | 1 |
| Stress | 1 | 2 |
| Subarachnoid haemorrhage | 1 | 1 |
| Sudden death | | 1 |
| Sudden hearing loss | 1 | 2 |
| Suffocation feeling | | 1 |
| Superficial vein prominence | | 1 |
| Supraventricular extrasystoles | | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Suspected COVID-19 | 2 | 8 |
| Swelling | 12 | 21 |
| Swelling face | 19 | 31 |
| Swelling of eyelid | 1 | 5 |
| Swollen tongue | 8 | 14 |
| Syncope | 8 | 11 |
| Synovitis | 1 | 1 |
| Tachycardia | 2 | 2 |
| Taste disorder | 5 | 10 |
| Temperature intolerance | 1 | 2 |
| Temperature regulation disorder | | 1 |
| Tenderness | 2 | 4 |
| Tenosynovitis | 1 | 1 |
| Tension | | 1 |
| Tension headache | 1 | 2 |
| Terminal insomnia | 1 | 1 |
| Therapeutic response unexpected | 5 | 7 |
| Thermal burn | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 7 |
| | | 9 | 17 | 3 | 4 |
| | | 14 | 24 | 5 | 7 |
| | | | 4 | 1 | 1 |
| | | 6 | 12 | 2 | 2 |
| | | | | 8 | 11 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 5 | 10 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 2 | 4 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | 5 | 7 | | |
| | | | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Thinking abnormal | 3 | 4 |
| Thirst | 2 | 3 |
| Throat irritation | 5 | 9 |
| Throat tightness | 4 | 7 |
| Thrombocytopenia | 2 | 2 |
| Thrombosis | 2 | 2 |
| Thyroid disorder | 1 | 1 |
| Tic | | 1 |
| Tinnitus | 10 | 18 |
| Tongue discolouration | 1 | 1 |
| Tongue discomfort | 2 | 3 |
| Tongue disorder | 2 | 4 |
| Tongue erythema | | 2 |
| Tongue haematoma | | 1 |
| Tongue pruritus | 1 | 3 |
| Tonsillar hypertrophy | 1 | 1 |
| Toothache | 1 | 4 |
| Tooth disorder | 1 | 1 |
| Transient global amnesia | | 1 |
| Transient ischaemic attack | 1 | 1 |
| Tremor | 20 | 31 |
| Trigeminal nerve disorder | | 1 |
| Troponin increased | | 1 |
| Tunnel vision | 1 | 1 |
| Type 1 diabetes mellitus | 1 | 1 |
| Ulcer | 1 | 1 |
| Underdose | 9 | 14 |
| Unresponsive to stimuli | 3 | 3 |
| Upper-airway cough syndrome | 1 | 3 |
| Upper respiratory tract congestion | 3 | 4 |
| Upper respiratory tract infection | 3 | 3 |
| Urinary incontinence | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 4 | | |
| | | 2 | 3 | | |
| | | 5 | 9 | | |
| | | 3 | 5 | 1 | 2 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 10 | 17 | | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | 2 | 4 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | | 3 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 15 | 25 | 5 | 6 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 9 | 14 | | |
| | | | | 3 | 3 |
| | | 1 | 3 | | |
| | | 3 | 4 | | |
| | | 3 | 3 | | |
| | | 1 | 2 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Urinary retention | 1 | 1 |
| Urinary tract infection | 5 | 6 |
| Urinary tract infection bacterial | 1 | 1 |
| Urine output increased | 1 | 1 |
| Urticaria | 13 | 31 |
| Vaccination site bruising | 4 | 7 |
| Vaccination site cellulitis | 2 | 2 |
| Vaccination site coldness | 2 | 2 |
| Vaccination site discolouration | 2 | 2 |
| Vaccination site discomfort | 5 | 7 |
| Vaccination site erythema | 22 | 49 |
| Vaccination site haemorrhage | 5 | 5 |
| Vaccination site hypoaesthesia | | 1 |
| Vaccination site induration | 2 | 3 |
| Vaccination site infection | 1 | 2 |
| Vaccination site inflammation | 2 | 2 |
| Vaccination site joint movement impairment | 1 | 1 |
| Vaccination site joint pain | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 |
| Vaccination site macule | | 1 |
| Vaccination site mass | 7 | 11 |
| Vaccination site movement impairment | | 5 |
| Vaccination site nodule | 1 | 2 |
| Vaccination site oedema | | 1 |
| Vaccination site pain | 114 | 209 |
| Vaccination site paraesthesia | 4 | 4 |
| Vaccination site pruritus | 18 | 30 |
| Vaccination site rash | 4 | 7 |
| Vaccination site reaction | 1 | 2 |
| Vaccination site swelling | 27 | 47 |
| Vaccination site urticaria | 1 | 4 |
| Vaccination site vesicles | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 3 | 4 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 10 | 27 | 3 | 4 |
| | | 3 | 6 | 1 | 1 |
| | | | | 2 | 2 |
| | | 2 | 2 | | |
| | | 2 | 2 | | |
| | | 5 | 7 | | |
| | | 20 | 44 | 2 | 5 |
| | | 5 | 5 | | |
| | | | 1 | | |
| | | 2 | 3 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 7 | 10 | | 1 |
| | | | 5 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | 113 | 207 | 1 | 2 |
| | | 4 | 4 | | |
| | | 16 | 27 | 2 | 3 |
| | | 4 | 7 | | |
| | | 1 | 2 | | |
| | | 23 | 43 | 4 | 4 |
| | | 1 | 4 | | |
| | | | 1 | | |

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Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Vaccination site warmth | 12 | 21 |
| Vaginal discharge | 1 | 1 |
| Vaginal haemorrhage | | 1 |
| Varicose vein | | 1 |
| Vascular pain | | 1 |
| Vein discolouration | | 1 |
| Vein disorder | 1 | 1 |
| Ventricular fibrillation | 1 | 2 |
| Vertigo | 15 | 23 |
| Viral upper respiratory tract infection | 1 | 1 |
| Vision blurred | 7 | 18 |
| Visual field defect | 1 | 1 |
| Visual impairment | 10 | 12 |
| Vlth nerve paralysis | 1 | 1 |
| Vitreous floaters | 1 | 1 |
| Vomiting | 39 | 69 |
| Vomiting projectile | 1 | 1 |
| Weight decreased | 4 | 7 |
| Weight fluctuation | 1 | 1 |
| Weight increased | | 2 |
| Wheezing | 2 | 2 |
| White blood cell count decreased | 2 | 2 |
| White blood cell count increased | 2 | 3 |
| White matter lesion | 1 | 1 |
| Wrong product administered | | 1 |
| Wrong technique in device usage process | 1 | 1 |
| Wrong technique in product usage process | 2 | 3 |
| | 3,939 | 6,832 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 9 | 17 | 3 | 4 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | 14 | 22 | 1 | 1 |
| | | 1 | 1 | | |
| | | 7 | 17 | | 1 |
| | | 1 | 1 | | |
| | | 9 | 11 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 38 | 68 | 1 | 1 |
| | | 1 | 1 | | |
| | | 4 | 7 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | 2 | 2 | | |
| | | 3114 | 5697 | 825 | 1135 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 2 | 3 | | | 2 | 3 | | |
| Abdominal pain | 1 | 4 | | | 1 | 3 | | 1 |
| Abdominal pain upper | 9 | 13 | | | 8 | 12 | 1 | 1 |
| Abnormal behaviour | | 1 | | | | | | 1 |
| Abnormal dreams | 1 | 1 | | | | | 1 | 1 |
| Abnormal faeces | 2 | 2 | | | 2 | 2 | | |
| Acarodermatitis | | 1 | | | | 1 | | |
| Accidental exposure to product | 1 | 1 | | | 1 | 1 | | |
| Acne | 1 | 1 | | | 1 | 1 | | |
| Acute hepatic failure | | 1 | | | | | | 1 |
| Acute kidney injury | | 1 | | | | | | 1 |
| Acute myeloid leukaemia | 2 | 2 | | | | | 2 | 2 |
| Ageusia | 4 | 4 | | | 4 | 4 | | |
| Aggression | | 1 | | | | 1 | | |
| Allergy to vaccine | 2 | 2 | | | 2 | 2 | | |
| Altered state of consciousness | 1 | 1 | | | | | 1 | 1 |
| Amnesia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Amyloidosis | 1 | 1 | | | | | 1 | 1 |
| Anaemia | 1 | 1 | | | | | 1 | 1 |
| Anal haemorrhage | 1 | 1 | | | 1 | 1 | | |
| Anal incontinence | 1 | 1 | | | 1 | 1 | | |
| Anaphylactic reaction | | 1 | | | | | | 1 |
| Anger | 1 | 2 | | | | 1 | 1 | 1 |
| Angina pectoris | 1 | 1 | | | | | 1 | 1 |
| Anorectal discomfort | 1 | 1 | | | 1 | 1 | | |
| Anosmia | 1 | 1 | | | 1 | 1 | | |
| Antibody test abnormal | 1 | 1 | | | 1 | 1 | | |
| Anxiety | 4 | 7 | | | 2 | 3 | 2 | 4 |
| Apathy | 1 | 1 | | | 1 | 1 | | |
| Aphonia | 1 | 1 | | | 1 | 1 | | |
| Arrhythmia | | 1 | | | | | | 1 |
| Arthralgia | 27 | 42 | | | 27 | 42 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Arthritis | 3 | 4 |
| Asthenia | 34 | 47 |
| Asthenopia | 1 | 1 |
| Asymptomatic COVID-19 | 1 | 1 |
| Atrial fibrillation | 1 | 2 |
| Autoimmune thyroiditis | 1 | 1 |
| Axillary pain | 1 | 1 |
| Back disorder | 2 | 2 |
| Back injury | 1 | 1 |
| Back pain | 5 | 8 |
| Balance disorder | 7 | 7 |
| Basal ganglia stroke | 1 | 1 |
| Bedridden | | 1 |
| Belligerence | 1 | 1 |
| Blindness | 2 | 2 |
| Blister | 3 | 3 |
| Blood albumin decreased | | 1 |
| Blood blister | 1 | 1 |
| Blood calcium decreased | | 1 |
| Blood chloride decreased | | 1 |
| Blood count abnormal | 1 | 1 |
| Blood creatinine increased | | 1 |
| Blood glucose decreased | 1 | 1 |
| Blood glucose increased | 1 | 1 |
| Blood iron decreased | 1 | 1 |
| Blood potassium decreased | | 1 |
| Blood pressure decreased | | 1 |
| Blood pressure fluctuation | 1 | 1 |
| Blood pressure increased | 9 | 13 |
| Blood pressure systolic increased | | 1 |
| Blood test abnormal | 1 | 1 |
| Body height decreased | 4 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 4 | | |
| | | 31 | 43 | 3 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 4 | 7 | 1 | 1 |
| | | 7 | 7 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 6 | 7 | 3 | 6 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 4 | 8 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Body temperature increased | 5 | 6 |
| Bone pain | 1 | 2 |
| Bowel movement irregularity | | 1 |
| Bronchitis | | 1 |
| Bundle branch block left | 1 | 1 |
| Burning sensation | 4 | 7 |
| Cardiac arrest | | 1 |
| Cardiac disorder | 1 | 1 |
| Cardiac failure | 1 | 1 |
| Cardiac failure congestive | | 1 |
| Cataract | 1 | 1 |
| Cellulitis | | 1 |
| Central nervous system lesion | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 |
| Cerebral infarction | 1 | 1 |
| Cerebral thrombosis | 1 | 1 |
| Cerebrovascular accident | 10 | 10 |
| Chest discomfort | 3 | 4 |
| Chest injury | 1 | 1 |
| Chest pain | 4 | 6 |
| Chills | 32 | 44 |
| Cholecystitis | | 1 |
| Chromaturia | 1 | 2 |
| Chronic myeloid leukaemia recurrent | 1 | 1 |
| Circumstance or information capable of leading to medication error | 7 | 12 |
| Cognitive disorder | 3 | 3 |
| Cold sweat | | 1 |
| Colon cancer | 1 | 1 |
| Coma | 1 | 1 |
| Condition aggravated | 5 | 6 |
| Confusional state | 8 | 10 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 6 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 3 | 6 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 10 | 10 |
| | | 2 | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 2 | 2 |
| | | 31 | 43 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 7 | 12 | | |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 5 | 1 | 1 |
| | | 4 | 6 | 4 | 4 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Constipation | 2 | 2 |
| Contusion | 4 | 5 |
| Cough | 11 | 16 |
| COVID-19 | 19 | 39 |
| COVID-19 pneumonia | 2 | 2 |
| C-reactive protein increased | | 1 |
| Crying | 2 | 3 |
| Culture urine positive | | 1 |
| Cystitis | 1 | 1 |
| Deafness | 6 | 6 |
| Death | 3 | 17 |
| Decreased appetite | 10 | 13 |
| Deep vein thrombosis | | 1 |
| Defaecation urgency | 1 | 1 |
| Dehydration | 1 | 1 |
| Delirium | 3 | 5 |
| Delusional perception | | 3 |
| Dementia | 2 | 2 |
| Depressed mood | | 1 |
| Dermatitis | 1 | 2 |
| Dermatitis contact | | 1 |
| Dermatitis diaper | 1 | 1 |
| Diabetes mellitus inadequate control | 2 | 2 |
| Diarrhoea | 22 | 34 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diet refusal | | 1 |
| Diplopia | | 1 |
| Discomfort | 5 | 6 |
| Disease recurrence | 3 | 4 |
| Disorientation | 4 | 4 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 42 | 66 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 2 | | |
| | | 4 | 5 | | |
| | | 10 | 15 | 1 | 1 |
| 1 | 1 | 1 | 7 | 18 | 32 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 5 | 5 |
| | | | | 3 | 17 |
| | | 9 | 12 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 3 | 5 |
| | | | 2 | | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 22 | 34 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 4 | 5 | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 39 | 60 | 3 | 6 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Drooling | 1 | 1 |
| Drug ineffective | 20 | 35 |
| Drug interaction | 1 | 1 |
| Dry eye | 1 | 1 |
| Dry mouth | | 1 |
| Dry throat | 1 | 1 |
| Dysarthria | 3 | 3 |
| Dysentery | 1 | 1 |
| Dysgeusia | 1 | 1 |
| Dyskinesia | 2 | 2 |
| Dyspepsia | | 1 |
| Dysphagia | 2 | 4 |
| Dyspnoea | 14 | 25 |
| Dyspnoea exertional | 1 | 1 |
| Dysstasia | 4 | 5 |
| Dysuria | 2 | 2 |
| Ear discomfort | 1 | 1 |
| Ear disorder | 2 | 2 |
| Ear haemorrhage | 1 | 1 |
| Ear pain | 2 | 4 |
| Eating disorder | | 4 |
| Eosinophil count decreased | 1 | 1 |
| Eosinophil count increased | 1 | 1 |
| Epistaxis | 5 | 6 |
| Eructation | 2 | 2 |
| Erythema | 9 | 11 |
| Erythema of eyelid | | 1 |
| Exposure via skin contact | 1 | 1 |
| Extrasystoles | 1 | 2 |
| Eye infection | 1 | 1 |
| Eye inflammation | | 1 |
| Eye movement disorder | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| 1 | 1 | | | 20 | 35 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | 1 | 2 |
| | | 10 | 18 | 4 | 7 |
| | | 1 | 1 | | |
| | | 3 | 4 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 2 | 4 | | |
| | | | 3 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 3 | 2 | 3 |
| | | 2 | 2 | | |
| | | 8 | 10 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Eye pain | 4 | 6 |
| Eye pruritus | 1 | 1 |
| Eye swelling | 3 | 4 |
| Face injury | | 1 |
| Facial pain | 1 | 1 |
| Facial paralysis | 5 | 5 |
| Faeces discoloured | 1 | 1 |
| Faeces soft | 1 | 1 |
| Fall | 13 | 16 |
| Fatigue | 53 | 75 |
| Fear | 1 | 1 |
| Feeding disorder | 3 | 5 |
| Feeling abnormal | 21 | 30 |
| Feeling cold | 4 | 6 |
| Feeling hot | 7 | 13 |
| Feeling of body temperature change | | 1 |
| Flank pain | 1 | 1 |
| Flatulence | 2 | 2 |
| Fluid retention | 1 | 1 |
| Flushing | 3 | 5 |
| Frequent bowel movements | 2 | 2 |
| Gait disturbance | 11 | 16 |
| Gait inability | 5 | 6 |
| Gastric disorder | 1 | 1 |
| Gastric ulcer | 1 | 1 |
| Gastrointestinal disorder | 2 | 2 |
| Gastrointestinal motility disorder | 1 | 1 |
| Gastroesophageal reflux disease | 2 | 2 |
| General physical health deterioration | | 2 |
| Gingival bleeding | 1 | 1 |
| Glomerular filtration rate decreased | | 1 |
| Glossodynia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 6 | | |
| | | 1 | 1 | | |
| | | 2 | 3 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 5 | 5 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 6 | 8 | 7 | 8 |
| | | 49 | 70 | 4 | 5 |
| | | 1 | 1 | | |
| | | 3 | 5 | | |
| | | 19 | 28 | 2 | 2 |
| | | 4 | 6 | | |
| | | 7 | 13 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 1 | 1 |
| | | 2 | 2 | | |
| | | 7 | 12 | 4 | 4 |
| | | 2 | 2 | 3 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | | | | 2 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Gout | 2 | 2 |
| Groin pain | 2 | 2 |
| Haematochezia | 1 | 2 |
| Haematocrit decreased | 1 | 2 |
| Haemoglobin decreased | 3 | 4 |
| Haemoptysis | 1 | 4 |
| Haemorrhage | 1 | 2 |
| Haemorrhagic varicella syndrome | 1 | 1 |
| Hallucination | 3 | 3 |
| Hallucination, visual | 2 | 2 |
| Headache | 40 | 62 |
| Head discomfort | 3 | 3 |
| Head injury | 1 | 2 |
| Heart rate abnormal | 1 | 1 |
| Heart rate increased | 7 | 11 |
| Heart rate irregular | 1 | 2 |
| Herpes zoster | 2 | 4 |
| Hip fracture | 2 | 2 |
| Hunger | | 1 |
| Hyperhidrosis | 3 | 6 |
| Hypersensitivity | 5 | 7 |
| Hypersomnia | 3 | 6 |
| Hypertension | 7 | 9 |
| Hypoacusis | 2 | 6 |
| Hypoaesthesia | 2 | 3 |
| Hypoaesthesia oral | 2 | 3 |
| Hypophagia | | 1 |
| Illrd nerve paralysis | 1 | 1 |
| Illness | 6 | 10 |
| Immune thrombocytopenia | 2 | 2 |
| Immunodeficiency | 1 | 1 |
| Impaired driving ability | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | 1 | 3 | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | 38 | 59 | 2 | 3 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | | 1 |
| | | 1 | 1 | | |
| | | 7 | 11 | | |
| | | 1 | 2 | | |
| | | 2 | 4 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 3 | 6 | | |
| | | 4 | 6 | 1 | 1 |
| | | 3 | 5 | | 1 |
| | | 4 | 4 | 3 | 5 |
| | | 2 | 6 | | |
| | | 2 | 3 | | |
| | | 2 | 3 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 6 | 10 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Inappropriate schedule of product administration | 5 | 15 |
| Incoherent | 1 | 1 |
| Incorrect dosage administered | 1 | 1 |
| Inflammation | 1 | 1 |
| Influenza | 1 | 1 |
| Influenza like illness | 3 | 3 |
| Injection site erythema | | 1 |
| Injection site pain | 1 | 3 |
| Injection site pruritus | | 1 |
| Insomnia | 9 | 18 |
| International normalised ratio decreased | 1 | 1 |
| International normalised ratio increased | | 1 |
| Intestinal ischaemia | 1 | 1 |
| Intestinal perforation | 1 | 1 |
| Ischaemic stroke | 1 | 1 |
| Jaw disorder | 1 | 1 |
| Joint range of motion decreased | 1 | 1 |
| Joint stiffness | 1 | 2 |
| Joint swelling | 4 | 6 |
| Lacrimation increased | | 1 |
| Laziness | | 1 |
| Lethargy | 6 | 7 |
| Leukocytosis | | 1 |
| Ligament sprain | | 1 |
| Limb discomfort | 5 | 7 |
| Limb injury | 3 | 3 |
| Lip dry | | 1 |
| Lip swelling | | 4 |
| Loss of consciousness | 9 | 10 |
| Loss of personal independence in daily activities | 2 | 2 |
| Lung infiltration | 1 | 2 |
| Lymphadenopathy | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 15 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 9 | 17 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 4 | 6 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 5 | 6 | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 4 | 5 | 1 | 2 |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | | 3 | | 1 |
| | | 1 | 1 | 8 | 9 |
| | | 2 | 2 | | |
| | | | 1 | 1 | 1 |
| | | 4 | 5 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Lymph node pain | 2 | 2 |
| Lymphocyte count decreased | | 1 |
| Malaise | 25 | 38 |
| Mass | 1 | 1 |
| Memory impairment | | 1 |
| Mental disorder | 2 | 3 |
| Mental impairment | 1 | 1 |
| Mental status changes | 1 | 1 |
| Migraine | 1 | 1 |
| Migraine with aura | 1 | 1 |
| Mobility decreased | 3 | 3 |
| Mouth haemorrhage | 1 | 1 |
| Mouth ulceration | 1 | 1 |
| Movement disorder | 1 | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle spasms | 3 | 4 |
| Muscle tightness | 2 | 3 |
| Muscular weakness | 4 | 4 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal disorder | 1 | 3 |
| Musculoskeletal stiffness | 8 | 9 |
| Mutism | | 1 |
| Myalgia | 11 | 17 |
| Myocardial infarction | 3 | 6 |
| Nasal congestion | 4 | 7 |
| Nasopharyngitis | 2 | 2 |
| Nausea | 24 | 45 |
| Near death experience | 1 | 1 |
| Neck pain | 7 | 12 |
| Nerve injury | 1 | 1 |
| Nervousness | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | 22 | 33 | 3 | 5 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 2 | 2 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 4 | | |
| | | 2 | 3 | | |
| | | 3 | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 2 |
| | | 8 | 9 | | |
| | | | | | 1 |
| | | 11 | 17 | | |
| | | | | 3 | 6 |
| | | 4 | 6 | | 1 |
| | | 2 | 2 | | |
| | | 23 | 43 | 1 | 2 |
| | | | | 1 | 1 |
| | | 6 | 11 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Nervous system disorder | 1 | 1 |
| Neuropathy peripheral | | 1 |
| Neutrophil count decreased | | 1 |
| Nightmare | | 1 |
| Night sweats | 1 | 1 |
| No adverse event | 1 | 1 |
| Nocturia | | 1 |
| Ocular hyperaemia | 1 | 2 |
| Oedema peripheral | 1 | 1 |
| Off label use | 6 | 9 |
| Oral discomfort | | 1 |
| Oral herpes | | 1 |
| Oral pain | 2 | 2 |
| Oropharyngeal discomfort | 2 | 3 |
| Oropharyngeal pain | 2 | 2 |
| Osteoarthritis | 1 | 1 |
| Overdose | 3 | 4 |
| Oxygen saturation abnormal | 1 | 1 |
| Oxygen saturation decreased | 4 | 6 |
| Pain | 29 | 43 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 53 | 76 |
| Pain of skin | 1 | 2 |
| Pallor | 1 | 1 |
| Palpable purpura | 1 | 1 |
| Palpitations | 2 | 4 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 6 | 6 |
| Paraesthesia oral | 3 | 3 |
| Paraganglion neoplasm | 1 | 1 |
| Paranasal sinus hypersecretion | 1 | 1 |
| Parkinson's disease | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | 6 | 9 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | 2 | 3 | | |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | 3 | 4 | | |
| | | 1 | 1 | | |
| | | 1 | 3 | 3 | 3 |
| | | 27 | 41 | 2 | 2 |
| | | | | 1 | 1 |
| | | 46 | 68 | 7 | 8 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 2 | 2 | 2 |
| | | 1 | 1 | | |
| | | 5 | 5 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Parosmia | | 1 |
| Periorbital swelling | | 1 |
| Peripheral swelling | 9 | 13 |
| Personality change | 1 | 1 |
| Pharyngeal disorder | 1 | 1 |
| Pharyngeal erythema | | 1 |
| Pharyngeal hypoesthesia | 1 | 1 |
| Pharyngeal swelling | 1 | 2 |
| Photopsia | 1 | 1 |
| Platelet count decreased | 1 | 1 |
| Pleurisy | 2 | 2 |
| Pneumonia | 6 | 10 |
| Pneumonia aspiration | 1 | 1 |
| Pollakiuria | | 1 |
| Polydipsia | | 1 |
| Poor quality product administered | 2 | 4 |
| Poor quality sleep | 3 | 4 |
| Post herpetic neuralgia | 1 | 1 |
| Presyncope | 4 | 5 |
| Productive cough | | 1 |
| Product preparation error | | 3 |
| Product preparation issue | 2 | 2 |
| Product storage error | 1 | 1 |
| Product use issue | 4 | 7 |
| Pruritus | 16 | 27 |
| Psoriasis | 2 | 2 |
| Pulmonary congestion | | 1 |
| Pulse abnormal | 2 | 2 |
| Purpura | 1 | 1 |
| Pyrexia | 30 | 47 |
| Rash | 13 | 17 |
| Rash erythematous | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 1 | | |
| | | 9 | 13 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 6 | 10 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 4 | | |
| | | 3 | 4 | | |
| | | 1 | 1 | | |
| | | 3 | 3 | 1 | 2 |
| | | | 1 | | |
| | | | 3 | | |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | 4 | 7 | | |
| | | 15 | 25 | 1 | 2 |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 26 | 42 | 4 | 5 |
| | | 13 | 17 | | |
| | | 2 | 3 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Rash macular | 2 | 3 |
| Rash maculo-papular | 1 | 1 |
| Rash morbilliform | 1 | 1 |
| Rash papular | 2 | 2 |
| Rash pruritic | 3 | 4 |
| Rash vesicular | | 1 |
| Red blood cell count decreased | | 1 |
| Renal atrophy | 1 | 1 |
| Renal disorder | 1 | 2 |
| Renal haemorrhage | 1 | 1 |
| Renal impairment | 1 | 2 |
| Respiratory arrest | | 2 |
| Respiratory distress | 1 | 2 |
| Respiratory failure | 1 | 2 |
| Restlessness | 1 | 2 |
| Retching | 2 | 2 |
| Rheumatoid arthritis | 1 | 1 |
| Rhinorrhoea | 3 | 4 |
| SARS-CoV-2 test positive | 3 | 7 |
| Sciatica | 1 | 1 |
| Seizure | 3 | 3 |
| Sensation of foreign body | | 1 |
| Sensory loss | 1 | 1 |
| Sepsis | 1 | 1 |
| Shock | 1 | 1 |
| Sinus disorder | 3 | 3 |
| Sinus headache | 2 | 2 |
| Skin burning sensation | | 1 |
| Skin discolouration | 1 | 2 |
| Skin disorder | 1 | 1 |
| Skin exfoliation | | 1 |
| Skin irritation | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 2 | 3 | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | 1 | 2 | | |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 3 | 4 | | |
| | | 2 | 2 | 1 | 5 |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | | |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Skin lesion | 1 | 1 |
| Skin reaction | | 1 |
| Skin swelling | 1 | 1 |
| Sleep disorder | 2 | 4 |
| Small intestinal haemorrhage | 1 | 1 |
| Sneezing | 5 | 6 |
| Somnolence | 8 | 12 |
| Speech disorder | 2 | 3 |
| Stoma site haemorrhage | 1 | 1 |
| Stomatitis | | 1 |
| Stress | 1 | 1 |
| Sunburn | | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Suspected COVID-19 | | 1 |
| Swelling | 3 | 6 |
| Swelling face | 3 | 4 |
| Swelling of eyelid | | 2 |
| Swollen tongue | 1 | 3 |
| Syncope | 5 | 5 |
| Systolic hypertension | 1 | 1 |
| Tachycardia | | 1 |
| Taste disorder | 1 | 1 |
| Tenderness | | 1 |
| Tendonitis | 1 | 1 |
| Terminal insomnia | | 1 |
| Therapeutic response unexpected | 1 | 1 |
| Thinking abnormal | | 2 |
| Throat irritation | 3 | 3 |
| Throat tightness | 2 | 4 |
| Thrombosis | 2 | 3 |
| Thyroid cancer | 1 | 1 |
| Tongue discomfort | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 4 | | |
| | | | | 1 | 1 |
| | | 5 | 6 | | |
| | | 7 | 10 | 1 | 2 |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 6 | | |
| | | 3 | 4 | | |
| | | | 2 | | |
| | | 1 | 2 | | 1 |
| | | | | 5 | 5 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 3 | 3 | | |
| | | 1 | 3 | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Tonsillar hypertrophy | 1 | 1 |
| Transient ischaemic attack | 3 | 4 |
| Tremor | 4 | 5 |
| Ulcer | | 1 |
| Underdose | 2 | 2 |
| Unresponsive to stimuli | 3 | 4 |
| Upper respiratory tract congestion | | 1 |
| Urinary incontinence | | 1 |
| Urinary retention | 1 | 2 |
| Urinary tract infection | 6 | 6 |
| Urticaria | 6 | 10 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | 3 | 4 |
| Vaccination site discolouration | 4 | 5 |
| Vaccination site discomfort | 3 | 4 |
| Vaccination site erythema | 7 | 14 |
| Vaccination site haemorrhage | 3 | 3 |
| Vaccination site hypoaesthesia | 1 | 1 |
| Vaccination site induration | 1 | 1 |
| Vaccination site mass | 1 | 2 |
| Vaccination site pain | 35 | 54 |
| Vaccination site pruritus | 4 | 6 |
| Vaccination site rash | 2 | 2 |
| Vaccination site swelling | 6 | 8 |
| Vaccination site warmth | 5 | 6 |
| Varicella | | 1 |
| Vascular dementia | 1 | 1 |
| Vertigo | 5 | 6 |
| Vision blurred | 6 | 10 |
| Visual field defect | 1 | 1 |
| Visual impairment | 3 | 5 |
| Volvulus | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 3 | 4 |
| | | 2 | 3 | 2 | 2 |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | | | 3 | 4 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | 2 | 2 | 4 | 4 |
| | | 6 | 10 | | |
| | | | | 1 | 1 |
| | | 3 | 4 | | |
| | | 3 | 4 | 1 | 1 |
| | | 2 | 3 | 1 | 1 |
| | | 6 | 13 | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | 1 |
| | | 34 | 52 | 1 | 2 |
| | | 4 | 5 | | 1 |
| | | 2 | 2 | | |
| | | 5 | 7 | 1 | 1 |
| | | 4 | 5 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 5 | 6 | | |
| | | 5 | 9 | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 4 | 1 | 1 |
| | | | | 1 | 1 |

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Age Range

Greater than or equal to 80 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|------|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vomiting | 18 | 25 | | | 17 | 24 | 1 | 1 |
| Weight decreased | 4 | 4 | | | 4 | 4 | | |
| Weight fluctuation | 1 | 1 | | | 1 | 1 | | |
| Weight increased | | 1 | | | | 1 | | |
| Wheezing | 1 | 2 | | | 1 | 2 | | |
| White blood cell count decreased | | 1 | | | | 1 | | |
| Wound | 1 | 1 | | | 1 | 1 | | |
| Wrong technique in device usage process | 1 | 1 | | | 1 | 1 | | |
| Wrong technique in product usage process | 1 | 1 | | | 1 | 1 | | |
| | 1,386 | 2,075 | 2 | 2 | 1046 | 1600 | 340 | 475 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 3 | 10 | 3 | 10 | | |
| Abdominal distension | 1 | 3 | 1 | 3 | | |
| Abdominal pain | 2 | 8 | 1 | 7 | 1 | 1 |
| Abdominal pain upper | 2 | 15 | 2 | 15 | | |
| Abnormal behaviour | 1 | 1 | 1 | 1 | | |
| Abnormal dreams | | 1 | | 1 | | |
| Abnormal faeces | 1 | 1 | 1 | 1 | | |
| Abnormal sensation in eye | | 2 | | 2 | | |
| Abortion spontaneous | 1 | 2 | | | 1 | 2 |
| Accidental exposure to product | 10 | 21 | 10 | 21 | | |
| Accidental overdose | 3 | 17 | 3 | 17 | | |
| Accidental underdose | 1 | 2 | 1 | 2 | | |
| Acute kidney injury | | 1 | | | | 1 |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Ageusia | 4 | 10 | 3 | 7 | 1 | 3 |
| Aggression | | 1 | | 1 | | |
| Allergy to vaccine | 3 | 9 | 3 | 8 | | 1 |
| Anaesthesia | | 1 | | 1 | | |
| Anaphylactic reaction | 6 | 26 | | | 6 | 26 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Anger | | 1 | | 1 | | |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | | 1 | | | | 1 |
| Animal bite | | 1 | | 1 | | |
| Anosmia | 5 | 15 | 4 | 12 | 1 | 3 |
| Antibody test abnormal | 1 | 1 | 1 | 1 | | |
| Antibody test negative | 1 | 2 | 1 | 2 | | |
| Anxiety | 7 | 19 | 6 | 18 | 1 | 1 |
| Aphasia | | 1 | | 1 | | |
| Aphonia | | 1 | | 1 | | |
| Aphthous ulcer | | 2 | | 2 | | |
| Appendicitis | 1 | 1 | | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Appetite disorder | 1 | 1 |
| Arrhythmia | 1 | 1 |
| Arthralgia | 37 | 100 |
| Arthritis | 5 | 6 |
| Arthropathy | 3 | 6 |
| Arthropod bite | | 2 |
| Aspiration | 1 | 1 |
| Asthenia | 12 | 42 |
| Asthenopia | | 1 |
| Asthma | 4 | 5 |
| Asymptomatic COVID-19 | 1 | 2 |
| Atrial f brillation | 4 | 4 |
| Autoimmune disorder | 1 | 2 |
| Axillary mass | | 2 |
| Axillary pain | 1 | 5 |
| Back disorder | 3 | 3 |
| Back pain | 13 | 42 |
| Balance disorder | | 2 |
| Bedridden | 1 | 1 |
| Bladder discomfort | | 1 |
| Blindness | 3 | 4 |
| Blister | 1 | 5 |
| Blood bilirubin increased | 1 | 1 |
| Blood creatinine increased | 1 | 1 |
| Blood glucose abnormal | | 1 |
| Blood glucose decreased | | 3 |
| Blood glucose increased | | 3 |
| Blood immunoglobulin G decreased | 1 | 1 |
| Blood immunoglobulin G increased | | 2 |
| Blood pressure abnormal | 2 | 2 |
| Blood pressure decreased | | 3 |
| Blood pressure increased | 6 | 12 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| 35 | 96 | 2 | 4 |
| 5 | 6 | | |
| 2 | 5 | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |
| 10 | 40 | 2 | 2 |
| | 1 | | |
| 3 | 4 | 1 | 1 |
| | | 1 | 2 |
| | | 4 | 4 |
| | | 1 | 2 |
| | 2 | | |
| 1 | 5 | | |
| 3 | 3 | | |
| 13 | 40 | | 2 |
| | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 3 | 4 |
| 1 | 5 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | 1 |
| | 3 | | |
| 1 | 1 | | |
| | 2 | | |
| 2 | 2 | | |
| | 3 | | |
| 2 | 6 | 4 | 6 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Blood pressure systolic increased | | 1 |
| Blood testosterone decreased | | 1 |
| Blood urine present | 2 | 2 |
| Body temperature abnormal | 1 | 4 |
| Body temperature decreased | 1 | 5 |
| Body temperature increased | 1 | 8 |
| Bone pain | 1 | 8 |
| Bone swelling | | 2 |
| Booster dose missed | | 1 |
| Brain oedema | | 1 |
| Breast cancer | 1 | 1 |
| Breast discharge | 1 | 1 |
| Breast mass | | 1 |
| Breast milk discolouration | | 1 |
| Breast pain | | 1 |
| Breast swelling | | 1 |
| Breath odour | 1 | 1 |
| Bronchiectasis | 1 | 1 |
| Bronchitis | 2 | 4 |
| Bronchospasm | 1 | 1 |
| Burning sensation | 4 | 8 |
| Cardiac arrest | | 1 |
| Cardiac disorder | 2 | 3 |
| Cardiac failure | 1 | 1 |
| Cardiac flutter | 1 | 1 |
| Carpal tunnel syndrome | 1 | 1 |
| Cataract | 1 | 1 |
| Cellulitis | 3 | 3 |
| Cerebral haemorrhage | 1 | 1 |
| Cerebrovascular accident | 5 | 5 |
| Chapped lips | 1 | 2 |
| Chest discomfort | 8 | 20 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 4 | | |
| 1 | 4 | | 1 |
| 1 | 8 | | |
| 1 | 8 | | |
| | 2 | | |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 2 |
| | | 1 | 1 |
| 4 | 8 | | |
| | | | 1 |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 5 | 5 |
| 1 | 2 | | |
| 8 | 16 | | 4 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Chest pain | 8 | 13 |
| Chillblains | | 1 |
| Chills | 94 | 259 |
| Chronic obstructive pulmonary disease | 2 | 3 |
| Circulatory collapse | | 1 |
| Circumstance or information capable of leading to medication error | 18 | 63 |
| Clumsiness | 1 | 1 |
| Cluster headache | 1 | 1 |
| Coagulopathy | | 1 |
| Cognitive disorder | 1 | 2 |
| Cold sweat | 1 | 6 |
| Colitis ulcerative | | 1 |
| Computerised tomogram normal | 1 | 1 |
| Condition aggravated | 7 | 13 |
| Confusional state | 3 | 4 |
| Conjunctivitis | | 1 |
| Conjunctivitis allergic | | 1 |
| Constipation | 1 | 1 |
| Contraindicated product administered | | 2 |
| Contraindication to vaccination | 1 | 1 |
| Contusion | 3 | 5 |
| Coronavirus test positive | | 1 |
| Cough | 17 | 46 |
| COVID-19 | 150 | 373 |
| C-reactive protein increased | | 1 |
| Crohn's disease | 2 | 2 |
| Crying | 1 | 2 |
| Cyanosis | | 2 |
| Cystitis | 1 | 1 |
| Deafness | 3 | 5 |
| Death | 12 | 18 |

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 7 | 4 | 6 |
| | 1 | | |
| 93 | 256 | 1 | 3 |
| | 1 | 2 | 2 |
| | | | 1 |
| 18 | 63 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 2 | | |
| 1 | 6 | | |
| | | | 1 |
| 1 | 1 | | |
| 4 | 9 | 3 | 4 |
| 3 | 4 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| 1 | 1 | | |
| 2 | 4 | 1 | 1 |
| | | | 1 |
| 16 | 44 | 1 | 2 |
| 7 | 9 | 143 | 364 |
| | 1 | | |
| | | 2 | 2 |
| 1 | 2 | | |
| | 2 | | |
| 1 | 1 | | |
| | | 3 | 5 |
| | | 12 | 18 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Decreased appetite | 5 | 11 |
| Deep vein thrombosis | | 1 |
| Dehydration | | 4 |
| Dementia | 3 | 3 |
| Dental restoration failure | | 1 |
| Depressed mood | 1 | 4 |
| Dermatitis | | 1 |
| Dermatitis contact | | 1 |
| Diabetes mellitus | 1 | 3 |
| Diabetic foot infection | 1 | 1 |
| Diarrhoea | 32 | 71 |
| Diarrhoea haemorrhagic | 2 | 2 |
| Diastolic hypotension | | 1 |
| Diplopia | | 1 |
| Discomfort | 2 | 8 |
| Disease recurrence | 3 | 3 |
| Disorientation | | 2 |
| Dissociation | 1 | 1 |
| Disturbance in attention | 1 | 4 |
| Diverticulitis | 3 | 3 |
| Dizziness | 35 | 114 |
| Dizziness postural | 1 | 1 |
| Drug hypersensitivity | 2 | 7 |
| Drug ineffective | 164 | 507 |
| Drug interaction | | 2 |
| Dry eye | | 1 |
| Dry mouth | 1 | 3 |
| Dry throat | 1 | 4 |
| Dysaesthesia | 1 | 1 |
| Dysarthria | 1 | 2 |
| Dysgeusia | 8 | 25 |
| Dyskinesia | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 5 | 11 | | |
| | | | 1 |
| | 3 | | 1 |
| | | 3 | 3 |
| | 1 | | |
| 1 | 4 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 3 |
| 1 | 1 | | |
| 30 | 69 | 2 | 2 |
| | | 2 | 2 |
| | | | 1 |
| | 1 | | |
| 2 | 8 | | |
| 2 | 2 | 1 | 1 |
| | 2 | | |
| 1 | 1 | | |
| 1 | 4 | | |
| | | 3 | 3 |
| 31 | 105 | 4 | 9 |
| 1 | 1 | | |
| 2 | 6 | | 1 |
| 3 | 9 | 161 | 498 |
| | 2 | | |
| | 1 | | |
| | 2 | 1 | 1 |
| 1 | 4 | | |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 8 | 25 | | |
| | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Dyspepsia | 3 | 8 |
| Dysphagia | | 6 |
| Dysphemia | 1 | 1 |
| Dysphonia | | 5 |
| Dyspnoea | 14 | 35 |
| Dysstasia | 3 | 6 |
| Dysuria | | 2 |
| Ear congestion | 1 | 1 |
| Ear discomfort | 1 | 4 |
| Ear disorder | | 1 |
| Ear infection | 2 | 4 |
| Ear neoplasm | | 1 |
| Ear pain | 3 | 6 |
| Ear pruritus | | 1 |
| Eating disorder | 1 | 1 |
| Eczema | 1 | 1 |
| Ejection fraction decreased | 1 | 1 |
| Encephalitis | 2 | 2 |
| Epistaxis | 2 | 5 |
| Erectile dysfunction | 1 | 1 |
| Erythema | 12 | 32 |
| Escherichia infection | | 1 |
| Euphoric mood | | 1 |
| Expired product administered | 1 | 2 |
| Exposure during pregnancy | 3 | 9 |
| Exposure to SARS-CoV-2 | 2 | 27 |
| Exposure via breast milk | 4 | 44 |
| Exposure via eye contact | | 2 |
| Exposure via skin contact | 9 | 19 |
| Eye allergy | | 1 |
| Eye contusion | | 1 |
| Eye discharge | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 8 | | |
| | 4 | | 2 |
| 1 | 1 | | |
| | 2 | | 3 |
| 13 | 29 | 1 | 6 |
| 2 | 3 | 1 | 3 |
| | 2 | | |
| 1 | 1 | | |
| 1 | 4 | | |
| | 1 | | |
| 1 | 3 | 1 | 1 |
| | 1 | | |
| 3 | 5 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 4 | 1 | 1 |
| | | 1 | 1 |
| 12 | 31 | | 1 |
| | | | 1 |
| | 1 | | |
| 1 | 2 | | |
| 3 | 9 | | |
| 2 | 21 | | 6 |
| 4 | 44 | | |
| | 2 | | |
| 9 | 19 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eye disorder | 1 | 2 |
| Eye haemorrhage | 2 | 3 |
| Eye irritation | | 5 |
| Eye oedema | | 1 |
| Eye pain | | 2 |
| Eye pruritus | 1 | 6 |
| Eye swelling | 3 | 9 |
| Facial asymmetry | | 1 |
| Facial pain | 1 | 3 |
| Facial paralysis | 6 | 23 |
| Fall | 4 | 8 |
| Fasciitis | 1 | 1 |
| Fatigue | 82 | 263 |
| Fear | | 2 |
| Febrile neutropenia | | 1 |
| Feeding disorder | 2 | 4 |
| Feeling abnormal | 25 | 65 |
| Feeling cold | 10 | 26 |
| Feeling drunk | 1 | 2 |
| Feeling hot | 11 | 28 |
| Feeling jittery | | 3 |
| Feeling of body temperature change | 1 | 3 |
| Fibrin D dimer increased | | 1 |
| Fibromyalgia | | 1 |
| Flank pain | 1 | 1 |
| Flatulence | | 1 |
| Flushing | 6 | 27 |
| Food allergy | | 1 |
| Frustration tolerance decreased | 1 | 2 |
| Fungal infection | | 1 |
| Furuncle | | 1 |
| Gait disturbance | 4 | 8 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | 1 |
| | | 2 | 3 |
| | 5 | | |
| | 1 | | |
| | 2 | | |
| 1 | 6 | | |
| 3 | 9 | | |
| | 1 | | |
| 1 | 3 | | |
| | | 6 | 23 |
| 1 | 4 | 3 | 4 |
| | | 1 | 1 |
| 81 | 261 | 1 | 2 |
| | 2 | | |
| | | | 1 |
| 2 | 4 | | |
| 21 | 60 | 4 | 5 |
| 10 | 26 | | |
| | 1 | 1 | 1 |
| 11 | 26 | | 2 |
| | 3 | | |
| 1 | 3 | | |
| | | | 1 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 6 | 23 | | 4 |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| 4 | 7 | | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Gait inability | 1 | 3 |
| Gal bladder disorder | 1 | 1 |
| Gastrointestinal disorder | 1 | 7 |
| Gastrointestinal haemorrhage | 1 | 1 |
| Gastrointestinal pain | 1 | 2 |
| Gastrooesophageal reflux disease | 1 | 2 |
| Gingival swelling | 1 | 4 |
| Glare | | 1 |
| Glassy eyes | | 1 |
| Glaucoma | | 2 |
| Glossodynia | 1 | 2 |
| Gout | 2 | 3 |
| Guillain-Barre syndrome | 3 | 3 |
| Haematochezia | | 3 |
| Haematuria | 1 | 2 |
| Haemoptysis | | 2 |
| Haemorrhage | 4 | 4 |
| Haemorrhage urinary tract | 1 | 1 |
| Haemorrhagic stroke | 1 | 1 |
| Hallucination | 1 | 1 |
| Hangover | | 2 |
| Headache | 113 | 366 |
| Head discomfort | 2 | 4 |
| Head titubation | 1 | 1 |
| Heart rate abnormal | | 1 |
| Heart rate decreased | | 2 |
| Heart rate increased | 14 | 45 |
| Hemiparesis | 1 | 1 |
| Hepatic cirrhosis | 1 | 1 |
| Hepatic enzyme increased | 2 | 2 |
| Herpes virus infection | 2 | 3 |
| Herpes zoster | 8 | 16 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 3 | | |
| 1 | 1 | | |
| 1 | 7 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 2 | | |
| 1 | 4 | | |
| | 1 | | |
| | 1 | | |
| | | | 2 |
| 1 | 2 | | |
| 2 | 3 | | |
| | | 3 | 3 |
| 1 | 1 | | 1 |
| | 2 | | |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| 110 | 358 | 3 | 8 |
| 2 | 4 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | 1 |
| 10 | 36 | 4 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 2 | 3 | | |
| 8 | 16 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hiccups | 1 | 3 |
| Hordeolum | | 1 |
| Hot flush | | 5 |
| Hyperaesthesia | 1 | 1 |
| Hyperhidrosis | 6 | 13 |
| Hypersensitivity | 9 | 31 |
| Hypersomnia | 1 | 5 |
| Hypertension | 5 | 12 |
| Hyperventilation | | 1 |
| Hypoacusis | 3 | 6 |
| Hypoaesthesia | 5 | 23 |
| Hypoaesthesia eye | | 1 |
| Hypoaesthesia oral | 2 | 9 |
| Hypogeusia | | 3 |
| Hypokinesia | | 3 |
| Hyposmia | | 1 |
| Hypotension | 1 | 3 |
| Hypothermia | 1 | 1 |
| Hypotonia | | 1 |
| Illness | 21 | 46 |
| Immune system disorder | 1 | 1 |
| Impaired driving ability | 1 | 2 |
| Inappropriate schedule of product administration | 39 | 129 |
| Incomplete course of vaccination | | 5 |
| Incorrect dose administered | 4 | 10 |
| Incorrect route of product administration | 6 | 40 |
| Induration | 1 | 2 |
| Infection | 2 | 4 |
| Infection parasitic | | 1 |
| Infertility | 1 | 1 |
| Inflammation | | 3 |
| Influenza | 3 | 14 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 3 | | |
| | 1 | | |
| | 5 | | |
| 1 | 1 | | |
| 6 | 13 | | |
| 7 | 27 | 2 | 4 |
| 1 | 5 | | |
| 3 | 9 | 2 | 3 |
| | | | 1 |
| 3 | 6 | | |
| 4 | 21 | 1 | 2 |
| | 1 | | |
| 2 | 9 | | |
| | 3 | | |
| | 3 | | |
| | 1 | | |
| 1 | 2 | | 1 |
| | | 1 | 1 |
| | 1 | | |
| 21 | 46 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 39 | 129 | | |
| | 5 | | |
| 4 | 10 | | |
| 6 | 39 | | 1 |
| 1 | 1 | | 1 |
| 2 | 3 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 3 | | |
| 3 | 14 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Influenza like illness | 13 | 45 |
| Infrequent bowel movements | | 1 |
| Injection site bruising | | 1 |
| Injection site erythema | | 1 |
| Injection site extravasation | 1 | 2 |
| Injection site irritation | 1 | 1 |
| Injection site mass | | 1 |
| Injection site pain | | 3 |
| Injection site reaction | | 1 |
| Injection site swelling | | 1 |
| Insomnia | 5 | 20 |
| Intentional overdose | 1 | 1 |
| Intentional product misuse | | 1 |
| Intercepted medication error | 1 | 1 |
| Internal haemorrhage | 1 | 1 |
| International normalised ratio increased | | 1 |
| Intraocular pressure increased | | 1 |
| Irritability | 1 | 2 |
| Jaundice | 1 | 1 |
| Joint effusion | 1 | 1 |
| Joint range of motion decreased | 2 | 2 |
| Joint swelling | 5 | 6 |
| Kidney infection | 1 | 1 |
| Laboratory test normal | 1 | 1 |
| Lacrimation increased | 2 | 3 |
| Lethargy | 4 | 13 |
| Limb discomfort | 4 | 14 |
| Limb injury | 2 | 3 |
| Limb mass | 1 | 2 |
| Lip blister | 1 | 2 |
| Lip oedema | | 1 |
| Lip pain | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 13 | 45 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | 3 | | |
| | 1 | | |
| | 1 | | |
| 5 | 20 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| 4 | 5 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 3 | | |
| 3 | 12 | 1 | 1 |
| 4 | 14 | | |
| 2 | 3 | | |
| 1 | 1 | | 1 |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Lip pruritus | 1 | 2 |
| Lip swelling | 4 | 8 |
| Liquid product physical issue | 1 | 6 |
| Localised infection | | 1 |
| Loss of consciousness | 6 | 10 |
| Loss of personal independence in daily activities | 4 | 7 |
| Lower respiratory tract infection | 1 | 1 |
| Lung disorder | 1 | 1 |
| Lung neoplasm malignant | | 1 |
| Lymphadenitis | | 3 |
| Lymphadenopathy | 21 | 68 |
| Lymph node pain | 2 | 9 |
| Lymphoedema | | 2 |
| Macule | 1 | 1 |
| Malaise | 43 | 126 |
| Mass | 1 | 1 |
| Mastication disorder | 1 | 1 |
| Maternal exposure during breast feeding | | 1 |
| Maternal exposure during pregnancy | 5 | 40 |
| Maternal exposure timing unspecified | 1 | 2 |
| Memory impairment | 1 | 1 |
| Meningitis viral | | 1 |
| Menorrhagia | 1 | 1 |
| Menstrual disorder | | 4 |
| Menstruation irregular | | 3 |
| Mental disorder | | 1 |
| Mental impairment | 2 | 3 |
| Metrorrhagia | | 1 |
| Microembolism | | 1 |
| Micturition urgency | 1 | 2 |
| Middle insomnia | 1 | 3 |
| Migraine | 4 | 15 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | |
| 3 | 7 | 1 | 1 |
| 1 | 6 | | |
| | 1 | | |
| | | 6 | 10 |
| 2 | 5 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 3 | | |
| 21 | 67 | | 1 |
| 2 | 9 | | |
| | 2 | | |
| 1 | 1 | | |
| 39 | 120 | 4 | 6 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 5 | 40 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | 4 | | |
| | 3 | | |
| | 1 | | |
| | | 2 | 3 |
| | 1 | | |
| | | | 1 |
| | 1 | 1 | 1 |
| 1 | 3 | | |
| 4 | 15 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Mobility decreased | 4 | 7 |
| Motor dysfunction | | 1 |
| Mouth swelling | | 1 |
| Movement disorder | 3 | 8 |
| Mucous stools | | 1 |
| Muscle fatigue | 1 | 1 |
| Muscle spasms | 2 | 10 |
| Muscle tightness | | 3 |
| Muscle twitching | 4 | 6 |
| Muscular weakness | 3 | 9 |
| Musculoskeletal chest pain | 1 | 5 |
| Musculoskeletal discomfort | | 4 |
| Musculoskeletal pain | | 2 |
| Musculoskeletal stiffness | 8 | 14 |
| Myalgia | 41 | 120 |
| Myocardial infarction | 1 | 3 |
| Nasal congestion | 2 | 29 |
| Nasal discomfort | 2 | 3 |
| Nasal oedema | | 1 |
| Nasopharyngitis | 8 | 24 |
| Nausea | 48 | 135 |
| Near death experience | 1 | 1 |
| Neck mass | | 3 |
| Neck pain | 5 | 22 |
| Needle issue | 1 | 4 |
| Neoplasm malignant | 1 | 1 |
| Nerve compression | | 3 |
| Nerve injury | | 1 |
| Nervousness | 5 | 9 |
| Nervous system disorder | 1 | 2 |
| Neuralgia | 1 | 3 |
| Neuritis | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 4 | 2 | 3 |
| | | | 1 |
| | 1 | | |
| 3 | 8 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 10 | | |
| | 3 | | |
| 4 | 6 | | |
| 3 | 8 | | 1 |
| 1 | 5 | | |
| | 4 | | |
| | 2 | | |
| 8 | 14 | | |
| 39 | 118 | 2 | 2 |
| | | 1 | 3 |
| 2 | 29 | | |
| 2 | 3 | | |
| | 1 | | |
| 8 | 24 | | |
| 46 | 132 | 2 | 3 |
| | | 1 | 1 |
| | 3 | | |
| 4 | 21 | 1 | 1 |
| 1 | 4 | | |
| | | 1 | 1 |
| | 3 | | |
| | 1 | | |
| 4 | 8 | 1 | 1 |
| 1 | 1 | | 1 |
| 1 | 3 | | |
| | 1 | | |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Neurological examination normal | 1 | 1 |
| Neuropathy peripheral | | 2 |
| Neutropenia | 1 | 1 |
| Nightmare | 1 | 2 |
| Night sweats | 3 | 7 |
| No adverse event | 11 | 11 |
| Noninfective gingivitis | 2 | 3 |
| Occupational exposure to product | 2 | 3 |
| Occupational exposure to SARS-CoV-2 | | 2 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | 1 | 5 |
| Oesophageal pain | | 1 |
| Off label use | 35 | 136 |
| Oral disorder | 3 | 3 |
| Oral dysaesthesia | | 1 |
| Oral herpes | 1 | 6 |
| Oral mucosal blistering | | 1 |
| Oral pain | 1 | 2 |
| Oropharyngeal discomfort | 1 | 5 |
| Oropharyngeal pain | 12 | 42 |
| Oropharyngeal spasm | 1 | 1 |
| Orthostatic hypotension | 1 | 1 |
| Osteoarthritis | | 1 |
| Overdose | 3 | 27 |
| Oxygen consumption | | 1 |
| Oxygen saturation decreased | 2 | 6 |
| Pain | 89 | 254 |
| Pain in extremity | 100 | 289 |
| Pain in jaw | 1 | 5 |
| Pain of skin | | 1 |
| Pallor | 1 | 3 |
| Palpitations | 8 | 17 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | | 2 |
| | | 1 | 1 |
| 1 | 2 | | |
| 3 | 7 | | |
| 11 | 11 | | |
| 2 | 3 | | |
| 2 | 3 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| 1 | 5 | | |
| | 1 | | |
| 35 | 136 | | |
| 3 | 3 | | |
| | | | 1 |
| 1 | 6 | | |
| | 1 | | |
| 1 | 2 | | |
| 1 | 4 | | 1 |
| 12 | 41 | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 3 | 27 | | |
| | 1 | | |
| | 2 | 2 | 4 |
| 89 | 254 | | |
| 99 | 287 | 1 | 2 |
| 1 | 5 | | |
| | 1 | | |
| 1 | 3 | | |
| 8 | 15 | | 2 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Pancytopenia | | 1 |
| Panic attack | | 1 |
| Papule | | 1 |
| Paraesthesia | 11 | 50 |
| Paraesthesia oral | 3 | 19 |
| Paralysis | 1 | 1 |
| Paranasal sinus hypersecretion | | 2 |
| Parosmia | | 3 |
| Pelvic pain | | 1 |
| Pericardial effusion | 2 | 2 |
| Pericarditis | | 2 |
| Periorbital swelling | 2 | 2 |
| Peripheral coldness | 1 | 3 |
| Peripheral swelling | 12 | 52 |
| Peripheral vascular disorder | | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal disorder | | 1 |
| Pharyngeal hypoaesthesia | | 1 |
| Pharyngeal inflammation | 1 | 3 |
| Pharyngeal paraesthesia | 1 | 4 |
| Pharyngeal swelling | 3 | 8 |
| Photophobia | | 3 |
| Photopsia | | 1 |
| Plantar erythema | | 1 |
| Platelet count decreased | 4 | 5 |
| Platelet count increased | | 2 |
| Platelet disorder | 1 | 1 |
| Pleurisy | | 1 |
| Pneumonia | 5 | 6 |
| Pneumonia aspiration | 1 | 1 |
| Pollakiuria | 1 | 2 |
| Polyneuropathy | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| 11 | 48 | | 2 |
| 3 | 19 | | |
| | | 1 | 1 |
| | 2 | | |
| | 3 | | |
| | 1 | | |
| | | 2 | 2 |
| | | | 2 |
| 2 | 2 | | |
| 1 | 3 | | |
| 12 | 51 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 3 | | |
| 1 | 3 | | 1 |
| 2 | 6 | 1 | 2 |
| | 3 | | |
| | 1 | | 1 |
| 2 | 3 | 2 | 2 |
| | 2 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 5 | 6 |
| | | 1 | 1 |
| 1 | 2 | | |
| | | | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Poor quality product administered | 27 | 212 |
| Poor quality sleep | | 4 |
| Presyncope | | 3 |
| Product administered at inappropriate site | 1 | 17 |
| Product administration error | 1 | 8 |
| Product colour issue | 2 | 2 |
| Product complaint | | 1 |
| Product container issue | 2 | 2 |
| Product dose omission issue | 1 | 3 |
| Productive cough | | 1 |
| Product leakage | 2 | 10 |
| Product lot number issue | 1 | 1 |
| Product packaging quantity issue | | 4 |
| Product preparation error | 12 | 75 |
| Product preparation issue | 4 | 58 |
| Product prescribing error | 1 | 6 |
| Product quality issue | | 2 |
| Product storage error | 1 | 1 |
| Product supply issue | 1 | 2 |
| Product temperature excursion issue | 22 | 126 |
| Product use issue | 31 | 129 |
| Pruritus | 15 | 49 |
| Psoriatic arthropathy | | 1 |
| Pulmonary congestion | | 1 |
| Pulmonary embolism | | 2 |
| Pulse abnormal | 1 | 2 |
| Pustule | 1 | 3 |
| Pyrexia | 105 | 330 |
| Rash | 22 | 63 |
| Rash erythematous | 4 | 9 |
| Rash macular | 1 | 7 |
| Rash morbilliform | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 27 | 212 | | |
| | 4 | | |
| | 3 | | |
| 1 | 17 | | |
| 1 | 8 | | |
| 2 | 2 | | |
| | 1 | | |
| 2 | 2 | | |
| 1 | 3 | | |
| | | | 1 |
| 2 | 10 | | |
| 1 | 1 | | |
| | 4 | | |
| 12 | 75 | | |
| 4 | 58 | | |
| 1 | 6 | | |
| | 2 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 22 | 126 | | |
| 31 | 129 | | |
| 15 | 49 | | |
| | | | 1 |
| | | | 1 |
| | | | 2 |
| | 1 | 1 | 1 |
| 1 | 3 | | |
| 103 | 326 | 2 | 4 |
| 20 | 60 | 2 | 3 |
| 4 | 9 | | |
| 1 | 6 | | 1 |
| 1 | 1 | | |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Rash papular | | 2 |
| Rash pruritic | 3 | 10 |
| Rash vesicular | | 2 |
| Raynaud's phenomenon | 1 | 1 |
| Reaction to excipient | | 1 |
| Renal disorder | 2 | 2 |
| Renal pain | 1 | 2 |
| Respiration abnormal | | 1 |
| Respiratory arrest | 1 | 1 |
| Respiratory disorder | | 1 |
| Respiratory tract congestion | | 2 |
| Respiratory tract infection | 1 | 2 |
| Restlessness | | 1 |
| Retching | 2 | 4 |
| Rhinalgia | | 2 |
| Rhinorrhoea | 12 | 39 |
| Rhinovirus infection | | 1 |
| Rosacea | 1 | 1 |
| Rubber sensitivity | | 1 |
| Saliva discolouration | 1 | 1 |
| SARS-CoV-2 ant body test negative | 10 | 17 |
| SARS-CoV-2 ant body test positive | 2 | 6 |
| SARS-CoV-2 test positive | 16 | 129 |
| Scratch | | 1 |
| Seasonal allergy | 1 | 2 |
| Secretion discharge | 1 | 1 |
| Sedation | 1 | 2 |
| Seizure | 3 | 4 |
| Sensation of foreign body | 1 | 5 |
| Sensitive skin | 2 | 3 |
| Sensory disturbance | 2 | 3 |
| Sepsis | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| 3 | 10 | | |
| | 2 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 2 | | |
| | | 1 | 2 |
| | 1 | | |
| 2 | 4 | | |
| | 2 | | |
| 12 | 39 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 10 | 17 | | |
| 2 | 6 | | |
| 1 | 7 | 15 | 122 |
| | | | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | | 3 | 4 |
| 1 | 5 | | |
| 2 | 3 | | |
| 2 | 3 | | |
| | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Shock symptom | | 1 |
| Sinus disorder | 2 | 5 |
| Sinus headache | 2 | 3 |
| Sinusitis | | 5 |
| Sitophobia | | 1 |
| Skin burning sensation | 2 | 2 |
| Skin discolouration | | 5 |
| Skin disorder | | 3 |
| Skin irritation | | 3 |
| Skin laceration | | 1 |
| Skin reaction | 2 | 2 |
| Sleep disorder | 1 | 4 |
| Sneezing | 2 | 7 |
| Somnolence | 4 | 14 |
| Speech disorder | 5 | 7 |
| Spinal cord disorder | 1 | 1 |
| Spinal pain | 3 | 4 |
| Spinal stenosis | 1 | 1 |
| Splenomegaly | 1 | 1 |
| Sputum discoloured | | 1 |
| Staphylococcal infection | | 1 |
| Streptococcus test positive | 1 | 1 |
| Stress | | 1 |
| Suicide attempt | 1 | 1 |
| Suppressed lactation | | 1 |
| Supraventricular tachycardia | | 2 |
| Suspected COVID-19 | 1 | 12 |
| Swelling | 8 | 28 |
| Swelling face | 7 | 11 |
| Swelling of eyelid | | 1 |
| Swollen tongue | 3 | 5 |
| Syncope | 4 | 8 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 2 | 5 | | |
| 2 | 3 | | |
| | 4 | | 1 |
| | 1 | | |
| 2 | 2 | | |
| | 2 | | 3 |
| | 3 | | |
| | 3 | | |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 4 | | |
| 2 | 7 | | |
| 3 | 13 | 1 | 1 |
| 5 | 7 | | |
| | | 1 | 1 |
| 3 | 4 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 2 | | |
| | 3 | 1 | 9 |
| 8 | 26 | | 2 |
| 7 | 11 | | |
| | 1 | | |
| 1 | 2 | 2 | 3 |
| | | 4 | 8 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Syringe issue | 1 | 1 |
| Tachycardia | 4 | 19 |
| Tachypnoea | | 1 |
| Taste disorder | 3 | 3 |
| Tenderness | 2 | 4 |
| Tension | | 1 |
| Therapeutic response unexpected | 2 | 4 |
| Thirst | | 1 |
| Throat irritation | 5 | 19 |
| Throat tightness | 5 | 12 |
| Thrombocytopenia | 2 | 3 |
| Thrombosis | 6 | 8 |
| Tinnitus | 2 | 7 |
| Tongue pruritus | | 1 |
| Tongue ulceration | | 1 |
| Tonic clonic movements | 1 | 1 |
| Tonsillar erythema | | 1 |
| Tonsillar hypertrophy | | 1 |
| Toothache | 4 | 6 |
| Tooth infection | | 1 |
| Tremor | 11 | 28 |
| Tuberculosis | | 2 |
| Tunnel vision | | 1 |
| Underdose | 30 | 111 |
| Unresponsive to stimuli | 1 | 1 |
| Upper-airway cough syndrome | 1 | 1 |
| Upper airway obstruction | | 1 |
| Upper respiratory tract congestion | 2 | 4 |
| Upper respiratory tract infection | | 1 |
| Urethral haemorrhage | 1 | 1 |
| Urinary assistance device user | 1 | 1 |
| Urinary retention | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 3 | 15 | 1 | 4 |
| | 1 | | |
| 3 | 3 | | |
| 2 | 4 | | |
| | 1 | | |
| 2 | 4 | | |
| | 1 | | |
| 5 | 16 | | 3 |
| 3 | 9 | 2 | 3 |
| | | 2 | 3 |
| | | 6 | 8 |
| 2 | 6 | | 1 |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 3 | 5 | 1 | 1 |
| | 1 | | |
| 11 | 25 | | 3 |
| | | | 2 |
| | | | 1 |
| 30 | 111 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| 2 | 4 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |

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Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Urinary tract infection | 9 | 13 |
| Urine analysis abnormal | | 1 |
| Urine odour abnormal | 1 | 1 |
| Urticaria | 9 | 44 |
| Vaccination complication | | 2 |
| Vaccination error | | 1 |
| Vaccination site bruising | 4 | 6 |
| Vaccination site discharge | 1 | 4 |
| Vaccination site discolouration | | 2 |
| Vaccination site discomfort | 1 | 7 |
| Vaccination site erythema | 11 | 36 |
| Vaccination site extravasation | 2 | 5 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site haemorrhage | 3 | 9 |
| Vaccination site hypoaesthesia | 1 | 2 |
| Vaccination site induration | 2 | 8 |
| Vaccination site inflammation | | 2 |
| Vaccination site injury | 1 | 1 |
| Vaccination site mass | 8 | 15 |
| Vaccination site movement impairment | | 3 |
| Vaccination site nodule | | 1 |
| Vaccination site pain | 62 | 205 |
| Vaccination site paraesthesia | | 3 |
| Vaccination site pruritus | 7 | 12 |
| Vaccination site rash | 3 | 10 |
| Vaccination site reaction | 1 | 9 |
| Vaccination site scab | 1 | 1 |
| Vaccination site swelling | 16 | 30 |
| Vaccination site urticaria | | 3 |
| Vaccination site vesicles | | 1 |
| Vaccination site warmth | 9 | 15 |
| Vaginal haemorrhage | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 7 | 11 | 2 | 2 |
| | 1 | | |
| | | 1 | 1 |
| 9 | 41 | | 3 |
| | 2 | | |
| | 1 | | |
| 3 | 4 | 1 | 2 |
| 1 | 4 | | |
| | 2 | | |
| 1 | 7 | | |
| 11 | 36 | | |
| 2 | 5 | | |
| | | 1 | 1 |
| 3 | 9 | | |
| 1 | 2 | | |
| 2 | 7 | | 1 |
| | 2 | | |
| 1 | 1 | | |
| 8 | 13 | | 2 |
| | 3 | | |
| | 1 | | |
| 62 | 205 | | |
| | 1 | | 2 |
| 7 | 12 | | |
| 3 | 10 | | |
| 1 | 9 | | |
| 1 | 1 | | |
| 16 | 30 | | |
| | 3 | | |
| | 1 | | |
| 9 | 15 | | |
| | | | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|------|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Varicella | | 1 | | 1 | | | |
| Vasodilatation | | 1 | | 1 | | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 | |
| Vertigo | 6 | 11 | 6 | 11 | | | |
| Vessel puncture site haemorrhage | | 1 | | 1 | | | |
| Vessel puncture site injury | | 1 | | 1 | | | |
| Viral infection | 2 | 3 | | 1 | 2 | 2 | |
| Vision blurred | 3 | 6 | 3 | 6 | | | |
| Visual impairment | 3 | 4 | 2 | 3 | 1 | 1 | |
| Vitreous floaters | 2 | 2 | 2 | 2 | | | |
| Vomiting | 18 | 44 | 18 | 44 | | | |
| Vomiting projectile | | 1 | | 1 | | | |
| Von Willebrand's disease | | 1 | | | | 1 | |
| Weight decreased | | 1 | | 1 | | | |
| Wheezing | 1 | 5 | 1 | 4 | | 1 | |
| White blood cell count decreased | 1 | 1 | 1 | 1 | | | |
| White blood cell count increased | 1 | 1 | | | 1 | 1 | |
| Wrong product administered | 6 | 13 | 6 | 13 | | | |
| Wrong schedule | | 1 | | 1 | | | |
| Wrong technique in product usage process | 6 | 44 | 6 | 44 | | | |
| Yellow skin | 1 | 1 | | | 1 | 1 | |
| | 2,597 | 8,073 | 2019 | 6568 | 578 | 1505 | |

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* I=Interval, C=Cumulative
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 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred
UNITED STATES MINOR OUTLYING ISLA

Age Range

51 - 64 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vaccination site pain | | 1 | | 1 |
| | | 1 | | 1 |

Age Range

65 - 79 years

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Cough | 1 | 1 | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 |
| Sinus congestion | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

Age Range

Unknown

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | | 1 | | 1 |
| | | 1 | | 1 |

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* I=Interval, C=Cumulative
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APPENDIX 2.5.3: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Gender by Preferred Term per Country

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval) / 42,086 (Cumulative)

Total Number of Adverse Events (PT): 91,739 (Interval) / 158,648 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

AFGHANISTAN

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chills | | 1 | | 1 | | |
| Erythema | | 1 | | 1 | | |
| Facial paralysis | | 1 | | | | 1 |
| Feeling of body temperature change | | 1 | | 1 | | |
| Muscle tightness | | 1 | | 1 | | |
| Paraesthesia | | 1 | | 1 | | |
| Pruritus | | 1 | | 1 | | |
| Rash | | 1 | | 1 | | |
| Swelling face | | 1 | | 1 | | |
| | | 9 | | 8 | | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANDORRA

Gender

MALE

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous

Nonserious

I

C

Product administered to patient of inappropriate age

1

1

1

1

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANGOLA

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 1 | 1 | 4 | 4 |

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* I=Interval, C=Cumulative
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Country Where Event Occurred

AUSTRIA

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* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Ageusia | 2 | 2 | 2 | 2 | | |
| Alopecia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 3 | 4 | | | 3 | 4 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Antiphospholipid syndrome | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arthralgia | 17 | 17 | 6 | 6 | 11 | 11 |
| Asthenia | 8 | 10 | 7 | 7 | 1 | 3 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blepharospasm | 1 | 1 | | | 1 | 1 |
| Blood creatine phosphokinase MB increased | 1 | 1 | | | 1 | 1 |
| Blood lactate dehydrogenase increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure immeasurable | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 3 | 3 | 1 | 1 | 2 | 2 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 5 | 5 | 4 | 4 | 1 | 1 |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Bradycardia | 2 | 2 | | | 2 | 2 |
| Breast pain | 1 | 1 | 1 | 1 | | |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Breath sounds | 1 | 1 |
| Bundle branch block right | 1 | 1 |
| Burning sensation | 1 | 2 |
| Bursitis | 2 | 2 |
| Cardiac failure | 1 | 2 |
| Cardiovascular disorder | 7 | 8 |
| Chapped lips | 1 | 1 |
| Chest discomfort | 3 | 3 |
| Chest pain | 3 | 3 |
| Chills | 28 | 28 |
| Choking | 1 | 1 |
| Cholestasis | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Circulatory collapse | 8 | 8 |
| Concomitant disease aggravated | 1 | 1 |
| Conjunctivitis | 1 | 1 |
| Cough | 3 | 3 |
| COVID-19 | 6 | 6 |
| C-reactive protein increased | 2 | 2 |
| Death | 5 | 7 |
| Dermatitis allergic | 1 | 1 |
| Diarrhoea | 8 | 10 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplopia | 2 | 2 |
| Discomfort | 1 | 1 |
| Disease progression | 1 | 1 |
| Disorganised speech | 1 | 1 |
| Disorientation | 1 | 1 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 28 | 28 |
| Drug ineffective | 2 | 2 |
| Dry mouth | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 2 |
| 6 | 7 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 15 | 15 | 13 | 13 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 8 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| 4 | 4 | 2 | 2 |
| | | 2 | 2 |
| | | 5 | 7 |
| | | 1 | 1 |
| 6 | 8 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| 18 | 18 | 10 | 10 |
| | | 2 | 2 |
| 2 | 2 | 1 | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Dry throat | 1 | 1 |
| Dysaesthesia | 1 | 1 |
| Dysgeusia | 3 | 3 |
| Dysgraphia | 1 | 1 |
| Dysphagia | 3 | 3 |
| Dyspnoea | 11 | 11 |
| Dyspnoea exertional | 1 | 1 |
| Ear discomfort | 2 | 2 |
| Ear infection | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Epilepsy | 1 | 1 |
| Erythema | 4 | 4 |
| Eye irritation | 1 | 1 |
| Eye movement disorder | 1 | 1 |
| Eye pain | 1 | 1 |
| Eye pruritus | 2 | 2 |
| Eye swelling | 1 | 1 |
| Face oedema | 1 | 1 |
| Facial paralysis | 2 | 2 |
| Facial paresis | 2 | 2 |
| Fatigue | 38 | 42 |
| Feeling abnormal | 2 | 2 |
| Feeling cold | 2 | 2 |
| Feeling drunk | 1 | 2 |
| Feeling hot | 3 | 3 |
| Feeling of body temperature change | 1 | 1 |
| Fibrin D dimer increased | 1 | 1 |
| Flushing | 7 | 7 |
| Formication | 1 | 1 |
| Gait disturbance | 2 | 2 |
| Gastrointestinal disorder | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| 3 | 3 | 8 | 8 |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| 32 | 35 | 6 | 7 |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 6 | 6 |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| General physical health deterioration | 3 | 3 | | | 3 | 3 |
| Groin pain | 1 | 1 | 1 | 1 | | |
| Hangover | | 1 | | 1 | | |
| Headache | 51 | 52 | 38 | 39 | 13 | 13 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Hemiparaesthesia | 1 | 1 | | | 1 | 1 |
| Hepatic pain | 1 | 1 | 1 | 1 | | |
| Herpes zoster | 1 | 1 | | | 1 | 1 |
| Histamine intolerance | 1 | 1 | | | 1 | 1 |
| Hot flush | 3 | 3 | 1 | 1 | 2 | 2 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 7 | 7 | 1 | 1 | 6 | 6 |
| Hypersomnia | 1 | 1 | 1 | 1 | | |
| Hypertension | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hypertensive emergency | 1 | 1 | | | 1 | 1 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 9 | 9 | 3 | 3 | 6 | 6 |
| Hypoaesthesia oral | 3 | 3 | | | 3 | 3 |
| Hypogeusia | 1 | 1 | | | 1 | 1 |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Hyposmia | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypotonia | 2 | 2 | 1 | 1 | 1 | 1 |
| Impaired work ability | 2 | 2 | | | 2 | 2 |
| Incorrect route of product administration | 2 | 3 | 2 | 3 | | |
| Inflammation | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 3 | 3 | 2 | 2 | 1 | 1 |
| Injection site urticaria | 1 | 1 | 1 | 1 | | |
| Insomnia | 3 | 3 | 3 | 3 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Interleukin level increased | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Laryngeal pain | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Lip dry | 1 | 1 |
| Lip erythema | 1 | 1 |
| Lip pruritus | 1 | 1 |
| Lip swelling | 4 | 4 |
| Lividity | 1 | 1 |
| Loss of consciousness | 5 | 5 |
| Lung infiltration | 1 | 1 |
| Lymphadenopathy | 10 | 10 |
| Lymph node pain | 1 | 1 |
| Malaise | 4 | 5 |
| Marasmus | 1 | 1 |
| Memory impairment | 1 | 1 |
| Migraine | 1 | 2 |
| Monoplegia | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Movement disorder | 2 | 2 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Muscle spasms | 4 | 4 |
| Muscular weakness | 3 | 3 |
| Myalgia | 11 | 12 |
| Myocardial infarction | | 1 |
| Myocarditis | 2 | 2 |
| Narcolepsy | 1 | 1 |
| Nausea | 22 | 26 |
| Neck pain | 1 | 1 |
| Neuralgia | 2 | 2 |
| Neuralgic amyotrophy | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 5 | 5 |
| | | 1 | 1 |
| 4 | 4 | 6 | 6 |
| 1 | 1 | | |
| 3 | 4 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 2 | 2 |
| 3 | 4 | 8 | 8 |
| | | | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 12 | 16 | 10 | 10 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Neuritis | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Night sweats | 1 | 1 |
| Nuchal rigidity | 1 | 1 |
| Obstructive airways disorder | 1 | 1 |
| Ocular hyperaemia | 2 | 2 |
| Oedema mucosal | 1 | 1 |
| Off label use | 2 | 2 |
| Oral discomfort | 2 | 2 |
| Oral mucosal erythema | 1 | 1 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal pain | 3 | 3 |
| Oxygen saturation | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Oxygen saturation immeasurable | 1 | 1 |
| Pain | 4 | 4 |
| Pain in extremity | 20 | 20 |
| Palatal swelling | 1 | 1 |
| Pallor | 4 | 4 |
| Palmar erythema | 1 | 1 |
| Palpitations | 5 | 5 |
| Panic attack | 1 | 1 |
| Panic reaction | 1 | 1 |
| Paraesthesia | 21 | 21 |
| Paraesthesia oral | 4 | 4 |
| Paresis | 1 | 1 |
| Pericarditis | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal swelling | 2 | 2 |
| Photophobia | 1 | 1 |
| Pleural effusion | 1 | 1 |
| Pneumonia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 1 | 1 |
| 15 | 15 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| 9 | 9 | 12 | 12 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Poor peripheral circulation | 1 | 1 | 1 | 1 | | |
| Presyncope | 11 | 11 | 3 | 3 | 8 | 8 |
| Product administered at inappropriate site | 1 | 1 | 1 | 1 | | |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Pruritus | 18 | 19 | 3 | 4 | 15 | 15 |
| Pulmonary embolism | 1 | 2 | | | 1 | 2 |
| Pulmonary oedema | | 1 | | | | 1 |
| Pupils unequal | 1 | 1 | | | 1 | 1 |
| Pyrexia | 37 | 37 | 22 | 22 | 15 | 15 |
| Rales | 1 | 2 | 1 | 1 | | 1 |
| Rash | 10 | 10 | 3 | 3 | 7 | 7 |
| Rash macular | 2 | 2 | | | 2 | 2 |
| Rash morbilliform | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 3 | 3 | 1 | 1 | 2 | 2 |
| Rash pustular | 3 | 3 | 1 | 1 | 2 | 2 |
| Reduced facial expression | 1 | 1 | 1 | 1 | | |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Respiratory depression | | 1 | | | | 1 |
| Respiratory disorder | 1 | 1 | 1 | 1 | | |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| Restlessness | 2 | 2 | 2 | 2 | | |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Rhinitis allergic | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Sensation of foreign body | 2 | 2 | | | 2 | 2 |
| Septic shock | 1 | 1 | | | 1 | 1 |
| Serum ferritin increased | 1 | 1 | 1 | 1 | | |
| Shock | 1 | 1 | | | 1 | 1 |
| Sinus congestion | 1 | 1 | 1 | 1 | | |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Skin discolouration | 1 | 1 |
| Skin tightness | 1 | 1 |
| Sleep attacks | 1 | 1 |
| Sleep disorder due to general medical condition, hypersomnia type | 1 | 1 |
| Somatic symptom disorder | 1 | 1 |
| Somnolence | 6 | 7 |
| Speech disorder | 3 | 3 |
| Swelling | 2 | 2 |
| Swelling face | 5 | 5 |
| Swelling of eyelid | 1 | 1 |
| Swollen tongue | 4 | 4 |
| Syncope | 4 | 4 |
| Syringe issue | 1 | 1 |
| Tachycardia | 5 | 5 |
| Tachypnoea | 1 | 1 |
| Taste disorder | 1 | 1 |
| Tendon disorder | 1 | 1 |
| Tension headache | 2 | 2 |
| Throat irritation | 3 | 3 |
| Throat tightness | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue discomfort | 2 | 2 |
| Transaminases increased | 1 | 1 |
| Tremor | 1 | 1 |
| Trigeminal neuralgia | 1 | 1 |
| Tunnel vision | 2 | 2 |
| Underdose | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 |
| Urinary retention | | 1 |
| Urticaria | 4 | 4 |
| Urticaria pressure | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 5 | 5 | 1 | 2 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | 4 | 4 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 5 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | | 1 |
| | | 4 | 4 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site discolouration | 2 | 2 | | | 2 | 2 |
| Vaccination site erythema | 6 | 6 | 4 | 4 | 2 | 2 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site lymphadenopathy | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site movement impairment | 4 | 4 | 3 | 3 | 1 | 1 |
| Vaccination site pain | 30 | 34 | 25 | 29 | 5 | 5 |
| Vaccination site pruritus | 2 | 3 | | 1 | 2 | 2 |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 7 | 7 | 5 | 5 | 2 | 2 |
| Vaccination site warmth | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaginal discharge | | 1 | | 1 | | |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 10 | 10 | 5 | 5 | 5 | 5 |
| Viral rash | 1 | 1 | | | 1 | 1 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 2 | 5 | 1 | 4 | 1 | 1 |
| Wrong technique in product usage process | 1 | 2 | 1 | 2 | | |
| | 841 | 884 | 405 | 434 | 436 | 450 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute coronary syndrome | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Asthenia | 4 | 4 | 4 | 4 | | |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Autoimmune haemolytic anaemia | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 3 | 3 | 1 | 1 | 2 | 2 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Cachexia | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | 1 | 1 | 3 | 3 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Complication associated with device | 1 | 1 | 1 | 1 | | |
| COVID-19 | 3 | 4 | | | 3 | 4 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Death | 3 | 3 | | | 3 | 3 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Dizziness postural | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 4 | 6 | | | 4 | 6 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Dyspnoea exertional | 1 | 1 | | | 1 | 1 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Escherichia sepsis | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Facial paresis | 1 | 1 | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Fatigue | 8 | 8 |
| Feeling jittery | 1 | 1 |
| Flushing | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Headache | 11 | 12 |
| Hypersensitivity | 1 | 1 |
| Hypertension | 2 | 2 |
| Hypertensive crisis | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 |
| Hypotension | 1 | 1 |
| Incorrect route of product administration | 2 | 2 |
| Influenza | | 1 |
| Influenza like illness | 1 | 1 |
| Intraocular pressure increased | 1 | 1 |
| Left ventricular failure | 1 | 1 |
| Lymphadenopathy | 3 | 3 |
| Lymph node pain | 3 | 3 |
| Lymph node palpable | 1 | 1 |
| Malaise | 3 | 3 |
| Meningitis bacterial | 1 | 1 |
| Migraine | 1 | 2 |
| Muscular weakness | 2 | 2 |
| Nausea | 6 | 6 |
| Occipital neuralgia | 1 | 1 |
| Off label use | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 2 | 2 |
| Pain of skin | 1 | 1 |
| Paraesthesia | 2 | 2 |
| Parosmia | 1 | 1 |
| Pemphigus | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 6 | 6 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 8 | 9 | 3 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| 4 | 4 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Peripheral coldness | 1 | 1 |
| Petechiae | 1 | 1 |
| Pneumonia | 2 | 2 |
| Pneumonia aspiration | 1 | 1 |
| Poor quality product administered | | 1 |
| Presyncope | 2 | 2 |
| Product preparation error | | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 1 | 2 |
| Pyrexia | 8 | 8 |
| Rash | 1 | 1 |
| Respiratory failure | 1 | 1 |
| Restlessness | 1 | 1 |
| Retching | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 2 |
| Seizure | 3 | 3 |
| Sinus tachycardia | 1 | 1 |
| Somnolence | 2 | 2 |
| Swelling | 1 | 1 |
| Swollen tongue | 1 | 1 |
| Syncope | 3 | 3 |
| Systemic inflammatory response syndrome | 1 | 1 |
| Tachycardia | 1 | 1 |
| Taste disorder | 1 | 1 |
| Thrombocytopenia | 1 | 1 |
| Urticaria | | 1 |
| Vaccination site lymphadenopathy | 2 | 2 |
| Vaccination site pain | 11 | 12 |
| Vaccination site pustule | 1 | 1 |
| Vaccination site rash | 1 | 1 |
| Vaccination site swelling | 2 | 2 |
| Vision blurred | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 3 | 3 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 10 | 11 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 5 | 5 | 3 | 3 | 2 | 2 |
| | 178 | 190 | 82 | 90 | 96 | 100 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| COVID-19 | 10 | 10 | | | 10 | 10 |
| Drug ineffective | 11 | 11 | | | 11 | 11 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 23 | 23 | 1 | 1 | 22 | 22 |

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Country Where Event Occurred

BAHRAIN

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Chills | 2 | 2 | 2 | 2 |
| Hot flush | 1 | 1 | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 |
| Pruritus | | 1 | | 1 |
| Pyrexia | 2 | 2 | 2 | 2 |
| | 10 | 11 | 10 | 11 |

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Country Where Event Occurred

BELGIUM

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 2 | | | 1 | 2 |
| Abdominal pain upper | 3 | 3 | 1 | 1 | 2 | 2 |
| Acute kidney injury | 1 | 2 | | | 1 | 2 |
| Acute respiratory failure | 2 | 2 | | | 2 | 2 |
| Agitation | 2 | 2 | | | 2 | 2 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 12 | 12 | | | 12 | 12 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 3 | 3 | | | 3 | 3 |
| Anxiety | 3 | 3 | | | 3 | 3 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 14 | 14 | 1 | 1 | 13 | 13 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Asthma exercise induced | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 2 | 2 | | |
| Balance disorder | 3 | 3 | | | 3 | 3 |
| Blood lactic acid increased | 1 | 2 | | | 1 | 2 |
| Blood pressure decreased | 3 | 3 | 2 | 2 | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 3 | 3 | | | 3 | 3 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cardiac disorder | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 3 | 3 | | | 3 | 3 |
| Cardiovascular disorder | 7 | 8 | 1 | 1 | 6 | 7 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 4 | 4 | 1 | 1 | 3 | 3 |
| Cheyne-Stokes respiration | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Chillblains | 1 | 1 |
| Chills | 29 | 29 |
| Coma | 1 | 1 |
| Cough | 2 | 2 |
| COVID-19 | 7 | 8 |
| COVID-19 pneumonia | 1 | 1 |
| C-reactive protein increased | 1 | 1 |
| Cyanosis | 1 | 1 |
| Deafness unilateral | 1 | 1 |
| Death | 1 | 2 |
| Depressed level of consciousness | 6 | 6 |
| Diarrhoea | 1 | 1 |
| Dizziness | 6 | 7 |
| Dizziness postural | 1 | 1 |
| Drug ineffective | 4 | 5 |
| Dry mouth | 1 | 1 |
| Dry throat | 1 | 1 |
| Dysgeusia | 1 | 1 |
| Dysphagia | 2 | 3 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 7 | 7 |
| Dystonia | 1 | 1 |
| Ear pain | 1 | 1 |
| Endolymphatic hydrops | 1 | 1 |
| Epilepsy | 5 | 5 |
| Erythema | 5 | 5 |
| Eye swelling | 1 | 1 |
| Face oedema | 1 | 1 |
| Facial paresis | 1 | 1 |
| Fall | 1 | 2 |
| Fatigue | 39 | 40 |
| Feeling cold | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 2 | 2 | 27 | 27 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 7 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 6 | 6 |
| | | 1 | 1 |
| 1 | 1 | 5 | 6 |
| | | 1 | 1 |
| | | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | | |
| | | 1 | 1 |
| | | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| 2 | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 6 | 7 | 33 | 33 |
| | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Feeling of body temperature change | 1 | 1 |
| Flushing | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Generalised tonic-clonic seizure | 2 | 2 |
| General physical health deterioration | 4 | 4 |
| Haemorrhage intracranial | | 1 |
| Headache | 45 | 45 |
| Heart rate increased | 2 | 2 |
| Heart rate irregular | 1 | 1 |
| Hemiparesis | 1 | 1 |
| Hemiplegia | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Hot flush | 2 | 2 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 1 | 1 |
| Hypertension | 7 | 7 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoglycaemia | 1 | 2 |
| Hypokalaemia | 1 | 1 |
| Hyponatraemia | 1 | 1 |
| Hypotension | 2 | 2 |
| Hypoxia | 1 | 1 |
| Illness | | 1 |
| Incorrect route of product administration | 1 | 1 |
| Infection | 1 | 1 |
| Influenza | 1 | 1 |
| Influenza like illness | 3 | 3 |
| Insomnia | 1 | 1 |
| Intestinal dilatation | | 1 |
| Intestinal ischaemia | | 1 |
| Joint stiffness | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 4 | 4 |
| | | | 1 |
| 6 | 6 | 39 | 39 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 5 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Laryngitis | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Leukocytosis | | 1 |
| Lip swelling | 2 | 2 |
| Livedo reticularis | 1 | 1 |
| Liver function test abnormal | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lung infiltration | | 1 |
| Lymphadenopathy | 2 | 3 |
| Lymph node pain | 1 | 1 |
| Lymphoedema | 1 | 1 |
| Malaise | 28 | 30 |
| Maternal exposure during pregnancy | 1 | 1 |
| Memory impairment | | 1 |
| Mobility decreased | 1 | 1 |
| Muscle tightness | 1 | 1 |
| Musculoskeletal stiffness | 3 | 4 |
| Myalgia | 35 | 35 |
| Nasal congestion | 1 | 1 |
| Nausea | 28 | 28 |
| Neck pain | 5 | 5 |
| Nervous system disorder | 4 | 5 |
| Neuralgia | 1 | 1 |
| Neurogenic shock | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Off label use | 2 | 2 |
| Oropharyngeal pain | 2 | 2 |
| Oxygen saturation decreased | 3 | 3 |
| Pain | 2 | 2 |
| Pain in extremity | 7 | 8 |
| Pallor | 1 | 1 |
| Palpitations | 3 | 4 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | 24 | 25 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 3 | 3 |
| 4 | 4 | 31 | 31 |
| 1 | 1 | | |
| 3 | 3 | 25 | 25 |
| 1 | 1 | 4 | 4 |
| | | 4 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 2 | 2 |
| | | 3 | 3 |
| | | 2 | 2 |
| 1 | 2 | 6 | 6 |
| | | 1 | 1 |
| 2 | 3 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Paraesthesia | 2 | 2 |
| Paraesthesia oral | 2 | 2 |
| Paresis | 1 | 1 |
| Peripheral swelling | 5 | 5 |
| Pharyngeal swelling | 1 | 1 |
| Pleural effusion | 1 | 1 |
| Pneumonia | 1 | 1 |
| Pneumonitis | 1 | 2 |
| Presyncope | 2 | 2 |
| Productive cough | 1 | 1 |
| Product use issue | 2 | 2 |
| Pruritus | 3 | 3 |
| Pulmonary embolism | | 1 |
| Pulmonary oedema | 2 | 2 |
| Pyrexia | 28 | 28 |
| Rales | 1 | 1 |
| Rash | 2 | 2 |
| Rash erythematous | 1 | 1 |
| Renal failure | 1 | 1 |
| Respiration abnormal | 1 | 1 |
| Respiratory disorder | 4 | 5 |
| Respiratory distress | 1 | 1 |
| Respiratory failure | 1 | 1 |
| Respiratory rate increased | 1 | 1 |
| Respiratory tract infection | 1 | 1 |
| Restlessness | 1 | 1 |
| Rhinorrhoea | 3 | 3 |
| Salivary hypersecretion | 2 | 2 |
| SARS-CoV-2 test positive | 1 | 1 |
| Sedation | 1 | 1 |
| Seizure | 1 | 1 |
| Sensation of foreign body | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | 2 | 2 |
| | | | 1 |
| | | 2 | 2 |
| 2 | 2 | 26 | 26 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Sense of oppression | 1 | 1 |
| Sensory disturbance | 1 | 2 |
| Sepsis | | 1 |
| Sinus tachycardia | 1 | 1 |
| Skin disorder | 4 | 4 |
| Sleep disorder due to a general medical condition | 1 | 1 |
| Somnolence | 2 | 2 |
| Sudden death | 4 | 5 |
| Swelling | 1 | 1 |
| Swollen tongue | 2 | 3 |
| Syncope | 7 | 7 |
| Tachycardia | 5 | 5 |
| Tachypnoea | 1 | 1 |
| Thoracic outlet syndrome | 1 | 1 |
| Thrombocytopenia | 1 | 1 |
| Tongue discomfort | 1 | 1 |
| Tremor | 2 | 2 |
| Troponin increased | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 |
| Upper airway obstruction | 1 | 1 |
| Urticaria | 2 | 2 |
| Vaccination site erythema | 4 | 6 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 |
| Vaccination site pain | 9 | 9 |
| Vaccination site pruritus | | 1 |
| Vaccination site reaction | 15 | 15 |
| Vaccination site swelling | 4 | 4 |
| Vaccination site warmth | 1 | 2 |
| Vertigo | 6 | 6 |
| Vision blurred | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 2 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 4 | 5 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | | 7 | 7 |
| 1 | 1 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 4 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 7 | 7 |
| | 1 | | |
| 1 | 1 | 14 | 14 |
| 3 | 3 | 1 | 1 |
| 1 | 2 | | |
| | | 6 | 6 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 4 | 5 | | | 4 | 5 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 608 | 647 | 88 | 104 | 520 | 543 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | | 1 | | | | 1 |
| Agitation | | 2 | | | | 2 |
| Amnesia | | 1 | | | | 1 |
| Angle closure glaucoma | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 4 | 4 | | | 4 | 4 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Bradycardia | | 1 | | | | 1 |
| Cardiac arrest | | 1 | | | | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 1 | 4 | | | 1 | 4 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chills | 6 | 6 | | | 6 | 6 |
| Coagulopathy | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Confusional state | | 2 | | | | 2 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | | 1 | | | | 1 |
| Diabetic complication | 1 | 1 | | | 1 | 1 |
| Disorientation | | 1 | | | | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dry skin | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Exposure via skin contact | | 1 | | 1 | | |
| Eye movement disorder | | 1 | | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Eye pain | 1 | 1 |
| Fall | 3 | 3 |
| Fatigue | 8 | 10 |
| Feeling abnormal | 1 | 1 |
| Fibrin D dimer increased | 1 | 1 |
| Gait disturbance | 1 | 1 |
| General physical health deterioration | 2 | 3 |
| Glaucoma | 1 | 1 |
| Headache | 6 | 7 |
| Herpes ophthalmic | 2 | 2 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypotension | 3 | 4 |
| Hypovolaemic shock | | 1 |
| Insomnia | 1 | 1 |
| Intestinal ischaemia | | 1 |
| Lacrimation increased | 1 | 1 |
| Liver function test abnormal | 1 | 2 |
| Malaise | 5 | 8 |
| Metabolic acidosis | | 1 |
| Musculoskeletal stiffness | 2 | 3 |
| Myalgia | 6 | 6 |
| Myocardial infarction | 1 | 1 |
| Nausea | 3 | 3 |
| Nervous system disorder | | 1 |
| Neurogenic shock | 1 | 1 |
| Neutropenia | | 1 |
| Neutrophilia | 1 | 1 |
| Occupational exposure to product | | 1 |
| Ocular hyperaemia | 1 | 1 |
| Oral herpes | 2 | 2 |
| Oropharyngeal pain | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 2 | 4 | 6 | 6 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | 1 | 6 | 6 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 4 |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 2 |
| | | 5 | 8 |
| | | | 1 |
| 1 | 2 | 1 | 1 |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------|--|--|
| Oxygen saturation decreased | 3 | 4 |
| Pain in extremity | 1 | 1 |
| Patient elopement | | 1 |
| Peripheral coldness | 1 | 1 |
| Peripheral swelling | 2 | 2 |
| Poor quality sleep | | 1 |
| Presyncope | | 2 |
| Pruritus | 1 | 1 |
| Pulmonary embolism | 1 | 1 |
| Pyrexia | 9 | 10 |
| Renal disorder | | 1 |
| Renal failure | 1 | 1 |
| Respiratory disorder | 1 | 2 |
| Respiratory tract infection | 1 | 1 |
| Sepsis | 1 | 1 |
| Septic shock | | 1 |
| Sleep deficit | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Sneezing | 1 | 1 |
| Staring | | 1 |
| Sudden death | 2 | 2 |
| Syncope | 4 | 4 |
| Tachycardia | | 1 |
| Tachypnoea | | 1 |
| Thrombophlebitis | 1 | 1 |
| Thrombosis | 1 | 1 |
| Tonsillitis | 1 | 1 |
| Troponin increased | 1 | 1 |
| Vaccination site pain | 2 | 4 |
| Vaccination site reaction | 2 | 2 |
| Vaccination site swelling | | 1 |
| Vertigo | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 4 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | | |
| | | | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 8 | 9 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 2 | 2 |
| | | 4 | 4 |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 4 | | |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| | 128 | 175 | 17 | 27 | 111 | 148 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 27 | 31 | | | 27 | 31 |
| Drug ineffective | 26 | 30 | | | 26 | 30 |
| Fatigue | | 1 | | 1 | | |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Malaise | | 1 | | 1 | | |
| Nausea | 1 | 2 | | 1 | 1 | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| | 57 | 68 | 1 | 4 | 56 | 64 |

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Country Where Event Occurred

BERMUDA

Gender

FEMALE

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous

Nonserious

I

C

Diarrhoea

1

1

1

1

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Country Where Event Occurred

BULGARIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Anti-thyroid antibody positive | 1 | 1 | | | 1 | 1 |
| Arthralgia | 5 | 7 | 5 | 7 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Asthenia | 4 | 6 | 3 | 5 | 1 | 1 |
| Back pain | 1 | 2 | 1 | 2 | | |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure inadequately controlled | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Body temperature increased | 3 | 4 | 1 | 2 | 2 | 2 |
| Chills | 7 | 9 | 5 | 6 | 2 | 3 |
| Conjunctivitis allergic | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 1 | | | | 1 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Dental discomfort | 1 | 1 | 1 | 1 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 6 | 4 | 5 | | 1 |
| Dizziness postural | | 1 | | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Dyspnoea | | 1 | | | | 1 |
| Erythema | 2 | 3 | 2 | 3 | | |
| Extrasystoles | 1 | 1 | 1 | 1 | | |
| Fatigue | 7 | 7 | 7 | 7 | | |
| Gastrointestinal disorder | 1 | 1 | 1 | 1 | | |
| Headache | 8 | 10 | 6 | 7 | 2 | 3 |
| Head discomfort | | 1 | | | | 1 |
| Hyperhidrosis | 1 | 2 | | | 1 | 2 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 2 | 1 | 2 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-------------------------------|--|--|
| Lymph node pain | | 1 |
| Lymphocyte count decreased | | 1 |
| Malaise | 1 | 1 |
| Mobility decreased | 1 | 1 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 8 | 12 |
| Nausea | 3 | 5 |
| Neck pain | | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 1 | 2 |
| Pain in extremity | 2 | 2 |
| Pallor | | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | 1 | 2 |
| Paraesthesia oral | | 1 |
| Peripheral coldness | | 1 |
| Peripheral sensory neuropathy | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pyrexia | 8 | 9 |
| Rash | 1 | 2 |
| Rash erythematous | | 1 |
| Rash pruritic | | 1 |
| Renal pain | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 |
| Rheumatoid factor positive | 1 | 1 |
| Seizure | 1 | 1 |
| Spinal pain | 1 | 1 |
| Swelling | | 2 |
| Swollen tongue | 1 | 1 |
| Tachycardia | 1 | 1 |
| Urticaria | 1 | 1 |
| Vaccination site erythema | 6 | 7 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 8 | 12 | | |
| 3 | 4 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 2 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 6 | 7 | 2 | 2 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 13 | 21 | 12 | 20 | 1 | 1 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 8 | 10 | 6 | 8 | 2 | 2 |
| Vasospasm | 1 | 1 | | | 1 | 1 |
| Vertigo | 2 | 3 | 1 | 1 | 1 | 2 |
| Vomiting | | 1 | | 1 | | |
| | 132 | 186 | 101 | 145 | 31 | 41 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Ageusia | | 1 | | 1 | | |
| Anosmia | | 1 | | 1 | | |
| Application site pain | 1 | 1 | 1 | 1 | | |
| Arthralgia | 3 | 4 | 3 | 4 | | |
| Asthenia | 4 | 5 | 3 | 4 | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 5 | 7 | 5 | 7 | | |
| Chills | 3 | 4 | 3 | 4 | | |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 2 | | | | 2 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Diarrhoea | | 2 | | 2 | | |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Drug ineffective | | 2 | | | | 2 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Epigastric discomfort | 1 | 1 | 1 | 1 | | |
| Erectile dysfunction | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fatigue | | 1 | | 1 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 7 | 4 | 7 | | |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 2 | 3 | 2 | 3 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Jugular vein distension | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 3 | 5 | 2 | 4 | 1 | 1 |
| Malaise | 2 | 2 | 2 | 2 | | |
| Meningism | 1 | 1 | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myalgia | 4 | 5 | 4 | 5 | | |
| Nausea | | 1 | | 1 | | |
| Pain in extremity | | 1 | | 1 | | |
| Palpitations | | 1 | | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 3 | 2 | 3 | | |
| Reduced facial expression | 1 | 1 | | | 1 | 1 |
| Sweating fever | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 2 | 2 | 2 | | |
| Vaccination site erythema | 1 | 2 | 1 | 2 | | |
| Vaccination site extravasation | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 4 | 4 | 4 | 4 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 67 | 94 | 58 | 81 | 9 | 13 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | | 1 | | | | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| | 2 | 4 | 2 | 2 | | 2 |

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Country Where Event Occurred

CANADA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 2 | 1 | 2 | | |
| Abdominal pain lower | | 1 | | 1 | | |
| Abdominal pain upper | | 1 | | 1 | | |
| Abortion spontaneous | 1 | 1 | | | 1 | 1 |
| Acne | 1 | 1 | 1 | 1 | | |
| Affect lability | | 1 | | 1 | | |
| Ageusia | 2 | 2 | 2 | 2 | | |
| Allergy to vaccine | | 1 | | 1 | | |
| Anaphylactic reaction | 1 | 6 | | | 1 | 6 |
| Angioedema | | 1 | | | | 1 |
| Anxiety | 1 | 2 | 1 | 2 | | |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Aphthous ulcer | | 1 | | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 6 | 16 | 6 | 14 | | 2 |
| Asthenia | 2 | 6 | 1 | 5 | 1 | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Back pain | | 1 | | 1 | | |
| Beta haemolytic streptococcal infection | 1 | 1 | | | 1 | 1 |
| Blood glucose decreased | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 3 | 1 | 1 | 1 | 2 |
| Chest pain | 2 | 3 | 2 | 2 | | 1 |
| Chills | 10 | 21 | 10 | 21 | | |
| Cognitive disorder | 1 | 1 | 1 | 1 | | |
| Cold sweat | 1 | 2 | 1 | 2 | | |
| Condition aggravated | | 1 | | | | 1 |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Cough | 4 | 4 | 3 | 3 | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------|--|--|
| COVID-19 | 2 | 4 |
| Decreased appetite | 1 | 3 |
| Dehydration | 1 | 1 |
| Depression | | 1 |
| Diarrhoea | 1 | 9 |
| Diplopia | 1 | 1 |
| Disease recurrence | 1 | 2 |
| Distractibility | | 1 |
| Disturbance in attention | 1 | 2 |
| Dizziness | 10 | 15 |
| Drug ineffective | 2 | 3 |
| Dysgeusia | 2 | 3 |
| Dyskinesia | 1 | 1 |
| Dysphagia | 1 | 4 |
| Dyspnoea | 8 | 11 |
| Ear discomfort | 1 | 2 |
| Eczema | | 1 |
| Erythema | 1 | 3 |
| Erythema multiforme | 1 | 1 |
| Exposure during pregnancy | 2 | 6 |
| Exposure via breast milk | | 3 |
| Eyelid function disorder | 1 | 1 |
| Eyelid sensory disorder | 1 | 1 |
| Eye pain | | 1 |
| Eye pruritus | | 1 |
| Eye swelling | 1 | 2 |
| Face oedema | | 1 |
| Facial pain | 3 | 3 |
| Facial paralysis | 3 | 4 |
| Fatigue | 15 | 37 |
| Fear | | 1 |
| Feeling abnormal | 2 | 5 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 2 | 3 |
| 1 | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 9 | | |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | | |
| 1 | 2 | | |
| 10 | 15 | | |
| | | 2 | 3 |
| 2 | 3 | | |
| 1 | 1 | | |
| 1 | 4 | | |
| 5 | 7 | 3 | 4 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 2 | | 1 |
| | | 1 | 1 |
| 2 | 6 | | |
| | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | | | 1 |
| 3 | 3 | | |
| | | 3 | 4 |
| 14 | 35 | 1 | 2 |
| | 1 | | |
| 2 | 5 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Feeling cold | | 2 |
| Feeling drunk | 1 | 1 |
| Feeling hot | 2 | 3 |
| Feeling of body temperature change | 1 | 1 |
| Fibromyalgia | | 1 |
| Fluid retention | 1 | 2 |
| Flushing | | 1 |
| Gait disturbance | 1 | 1 |
| Gastric disorder | 1 | 1 |
| Gastroenteritis | | 1 |
| Gastroesophageal reflux disease | | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Grip strength decreased | 1 | 1 |
| Headache | 13 | 42 |
| Head discomfort | | 1 |
| Heart rate increased | | 1 |
| Herpes zoster | | 1 |
| Hyperaesthesia | 1 | 2 |
| Hyperhidrosis | | 1 |
| Hypersensitivity | 1 | 3 |
| Hypersomnia | 1 | 2 |
| Hypertension | 2 | 5 |
| Hypertensive crisis | 1 | 1 |
| Hypoacusis | 2 | 2 |
| Hypoaesthesia | 5 | 8 |
| Hypoaesthesia eye | 1 | 1 |
| Hypoaesthesia oral | 1 | 2 |
| Hypotension | 1 | 3 |
| Illness | | 1 |
| Impaired driving ability | 1 | 1 |
| Impaired work ability | 1 | 2 |
| Inappropriate schedule of product administration | 8 | 11 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | 1 |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 13 | 42 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| 1 | 2 | | 1 |
| | 1 | 2 | 4 |
| | | 1 | 1 |
| 2 | 2 | | |
| 5 | 6 | | 2 |
| 1 | 1 | | |
| | | 1 | 2 |
| 1 | 1 | | 2 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 8 | 11 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Incomplete course of vaccination | 1 | 1 |
| Influenza like illness | 2 | 4 |
| Insomnia | | 1 |
| IVth nerve paralysis | 1 | 1 |
| Joint swelling | | 2 |
| Leukoplakia | | 1 |
| Limb discomfort | 1 | 1 |
| Lip swelling | | 2 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lung disorder | | 1 |
| Lymphadenopathy | 6 | 12 |
| Lymph node pain | 1 | 1 |
| Malaise | 6 | 8 |
| Maternal exposure during pregnancy | 2 | 13 |
| Maternal exposure timing unspecified | | 2 |
| Menstruation delayed | 1 | 1 |
| Menstruation irregular | | 1 |
| Migraine | 3 | 4 |
| Mouth swelling | | 1 |
| Muscle spasms | | 1 |
| Muscle twitching | | 1 |
| Muscular weakness | 1 | 2 |
| Musculoskeletal pain | | 1 |
| Musculoskeletal stiffness | 1 | 3 |
| Myalgia | 9 | 23 |
| Nasal congestion | | 1 |
| Nasopharyngitis | | 1 |
| Nausea | 9 | 21 |
| Neck pain | 2 | 4 |
| Neuralgia | 1 | 1 |
| Odynophagia | | 1 |
| Oesophageal disorder | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 2 | 4 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| | | | 1 |
| 5 | 11 | 1 | 1 |
| 1 | 1 | | |
| 6 | 8 | | |
| 2 | 13 | | |
| | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 2 | 3 | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| 1 | 3 | | |
| 9 | 21 | | 2 |
| | 1 | | |
| 9 | 21 | | |
| 1 | 3 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Off label use | 7 | 27 |
| Oral candidiasis | 1 | 1 |
| Oral herpes | | 1 |
| Oral mucosal blistering | | 1 |
| Oropharyngeal pain | 2 | 5 |
| Overdose | 1 | 3 |
| Pain | 6 | 14 |
| Pain in extremity | 5 | 19 |
| Pain in jaw | 2 | 2 |
| Pain of skin | | 1 |
| Palpitations | 1 | 2 |
| Paraesthesia | 4 | 11 |
| Paraesthesia oral | 3 | 7 |
| Periorbital swelling | 1 | 1 |
| Peripheral swelling | | 1 |
| Petechiae | | 1 |
| Pharyngeal hypoaesthesia | | 1 |
| Pharyngeal swelling | | 2 |
| Polydipsia | 1 | 1 |
| Polyuria | 1 | 1 |
| Presyncope | 1 | 3 |
| Product administered at inappropriate site | | 2 |
| Product preparation issue | 1 | 1 |
| Product supply issue | 1 | 1 |
| Product use issue | 6 | 24 |
| Pruritus | 1 | 7 |
| Psychotic disorder due to a general medical condition | 1 | 1 |
| Pulmonary embolism | 2 | 2 |
| Pulmonary infarction | 1 | 1 |
| Pulmonary pain | | 1 |
| Pyrexia | 13 | 28 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 7 | 27 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 2 | 5 | | |
| 1 | 3 | | |
| 6 | 14 | | |
| 3 | 17 | 2 | 2 |
| 2 | 2 | | |
| | 1 | | |
| 1 | 2 | | |
| 3 | 8 | 1 | 3 |
| 2 | 5 | 1 | 2 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | 1 |
| | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 6 | 24 | | |
| 1 | 6 | | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | | 1 |
| 13 | 28 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Rash | 2 | 6 |
| Rash erythematous | 2 | 2 |
| Rash macular | | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Rheumatoid arthritis | | 1 |
| Secretion discharge | 1 | 1 |
| Sinus pain | | 1 |
| Skin burning sensation | | 1 |
| Skin lesion | | 1 |
| Sneezing | | 1 |
| Somnolence | 1 | 1 |
| Stress | | 1 |
| Swelling | 2 | 4 |
| Swelling face | 4 | 4 |
| Swollen tongue | 1 | 4 |
| Syncope | | 1 |
| Systemic lupus erythematosus | 1 | 1 |
| Tachycardia | 2 | 7 |
| Tachypnoea | | 1 |
| Taste disorder | | 1 |
| Temporomandibular joint syndrome | 1 | 1 |
| Thirst | | 1 |
| Throat irritation | | 2 |
| Throat tightness | | 2 |
| Tinnitus | 1 | 1 |
| Tongue disorder | | 1 |
| Tongue pruritus | | 1 |
| Tremor | | 2 |
| Type I hypersensitivity | 2 | 2 |
| Type IV hypersensitivity reaction | | 1 |
| Underdose | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 5 | | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 2 | 3 | | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 3 | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 3 | 2 | 4 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | |
| | 1 | | 1 |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | 1 |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Upper-airway cough syndrome | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 6 | 1 | 6 | | |
| Vaccination site erythema | 3 | 3 | 3 | 3 | | |
| Vaccination site induration | 1 | 2 | 1 | 2 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 8 | 22 | 8 | 21 | | 1 |
| Vaccination site rash | | 1 | | 1 | | |
| Vaccination site reaction | | 1 | | 1 | | |
| Vaccination site swelling | 3 | 5 | 3 | 5 | | |
| Vaccination site urticaria | 3 | 3 | 3 | 3 | | |
| Vaccination site warmth | 1 | 2 | 1 | 2 | | |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 2 | 1 | 2 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 6 | 1 | 6 | | |
| Vulval disorder | | 1 | | | | 1 |
| Wheezing | 4 | 4 | 3 | 3 | 1 | 1 |
| | 321 | 742 | 266 | 634 | 55 | 108 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | | 1 | | 1 | | |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Agitation | | 1 | | 1 | | |
| Anxiety | | 1 | | 1 | | |
| Arthralgia | | 1 | | 1 | | |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Cellulitis | | 1 | | | | 1 |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| COVID-19 | | 3 | | | | 3 |
| Deafness | | 1 | | | | 1 |
| Decreased appetite | 1 | 2 | | 1 | 1 | 1 |
| Diarrhoea | | 2 | | 2 | | |
| Disseminated varicella zoster virus infection | | 1 | | | | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | | 3 | | | | 3 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Fatigue | 3 | 3 | 3 | 3 | | |
| Gout | | 1 | | 1 | | |
| Headache | 3 | 5 | 3 | 5 | | |
| Herpes zoster | | 1 | | 1 | | |
| Hot flush | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypokinesia | | 1 | | 1 | | |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Inappropriate schedule of product administration | 1 | 2 |
| Incorrect route of product administration | 1 | 1 |
| Insomnia | | 1 |
| Joint range of motion decreased | 1 | 1 |
| Lethargy | | 1 |
| Limb discomfort | | 1 |
| Lymphadenopathy | 1 | 2 |
| Lymphoedema | | 1 |
| Malaise | | 1 |
| Meningitis aseptic | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Myalgia | 1 | 3 |
| Nausea | 1 | 2 |
| Neck pain | 1 | 1 |
| Oedema | | 1 |
| Overdose | 1 | 1 |
| Pain | 1 | 4 |
| Pain in extremity | 4 | 5 |
| Pharyngeal swelling | 1 | 1 |
| Pneumonia | 1 | 1 |
| Product administered at inappropriate site | 1 | 1 |
| Product preparation issue | 1 | 1 |
| Pyrexia | | 3 |
| Rash | 1 | 1 |
| Rash macular | | 1 |
| Rash maculo-papular | 1 | 1 |
| Rash pustular | | 1 |
| Skin injury | | 1 |
| Somnolence | | 1 |
| Tendonitis | 1 | 1 |
| Urticaria | 1 | 1 |
| Vaccination site mass | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 4 | | |
| 4 | 5 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 1 | 3 | 1 | 3 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Varicella | | 1 | | 1 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Visual impairment | | 1 | | 1 | | |
| Vital functions abnormal | | 1 | | | | 1 |
| Vomiting | | 1 | | 1 | | |
| | 49 | 100 | 43 | 84 | 6 | 16 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 2 | | | 1 | 2 |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 3 | | | 1 | 3 |
| Exposure during pregnancy | 2 | 2 | | | 2 | 2 |
| Exposure via breast milk | | 3 | | 3 | | |
| Fatigue | 1 | 3 | 1 | 3 | | |
| Foetal growth restriction | 2 | 2 | | | 2 | 2 |
| Headache | 1 | 2 | 1 | 2 | | |
| Herpes zoster | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 5 | 7 | | | 5 | 7 |
| Hypertension | 3 | 3 | 3 | 3 | | |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incomplete course of vaccination | | 1 | | 1 | | |
| Incorrect dose administered | 2 | 2 | 2 | 2 | | |
| Injection site pain | | 1 | | 1 | | |
| Lethargy | | 2 | | 2 | | |
| Malaise | | 1 | | 1 | | |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Nausea | | 1 | | 1 | | |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Overdose | | 4 | | 4 | | |
| Pain in extremity | | 2 | | 2 | | |
| Product preparation issue | | 10 | | 10 | | |
| Pyrexia | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Syncope | | 1 | | | | 1 |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | |
| Underdose | 1 | 5 | 1 | 5 | | |
| | 30 | 71 | 14 | 48 | 16 | 23 |

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Country Where Event Occurred

CHILE

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 2 | | 1 | | 1 |
| Abnormal faeces | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 3 | 1 | 2 | | 1 |
| Arthritis | | 1 | | | | 1 |
| Asthenia | | 1 | | 1 | | |
| Back pain | 1 | 2 | 1 | 2 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Burning sensation | | 1 | | 1 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | | 3 | | 2 | | 1 |
| Choking | 1 | 1 | | | 1 | 1 |
| Complement factor C3 decreased | 1 | 1 | 1 | 1 | | |
| C-reactive protein decreased | 1 | 1 | 1 | 1 | | |
| Crying | | 1 | | | | 1 |
| Diarrhoea | 1 | 5 | 1 | 5 | | |
| Disease recurrence | | 1 | | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dry mouth | | 1 | | | | 1 |
| Dysbiosis | | 1 | | | | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 3 | 3 | 3 | 3 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | | 1 | | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Guillain-Barre syndrome | 1 | 1 | | | 1 | 1 |
| Headache | | 4 | | 3 | | 1 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | | 1 | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypersensitivity | | 1 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypotension | 1 | 1 |
| Joint swelling | | 2 |
| Loss of consciousness | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenopathy | 1 | 4 |
| Lymph node pain | 1 | 3 |
| Malaise | 1 | 4 |
| Maternal exposure timing unspecified | | 1 |
| Monocyte count decreased | 1 | 1 |
| Muscle spasms | | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 2 | 4 |
| Nasal congestion | | 1 |
| Nausea | | 2 |
| Off label use | | 1 |
| Pain | 2 | 4 |
| Pain in extremity | | 1 |
| Pallor | 1 | 1 |
| Pancreatitis | | 1 |
| Paraesthesia | 2 | 3 |
| Photophobia | | 1 |
| Product use issue | | 1 |
| Pyrexia | 1 | 6 |
| Rash | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Respiratory disorder | 1 | 1 |
| Rhabdomyolysis | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| Sensory loss | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | | 1 |
| 1 | 3 | | |
| 1 | 4 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 3 | | 1 |
| | 1 | | |
| | 1 | | 1 |
| 1 | 3 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| 1 | 5 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Synovial cyst | | 1 | | 1 | | |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Urine analysis abnormal | | 1 | | | | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 3 | 1 | 1 | 1 | 2 |
| Venous thrombosis | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 53 | 113 | 26 | 68 | 27 | 45 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | | 1 | | | | 1 |
| Angioedema | | 1 | | | | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Dyspnoea | | 1 | | | | 1 |
| Eye pruritus | | 1 | | | | 1 |
| Eye swelling | | 1 | | | | 1 |
| Fatigue | | 1 | | 1 | | |
| Headache | 1 | 2 | 1 | 2 | | |
| Incorrect route of product administration | | 1 | | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Nausea | | 1 | | 1 | | |
| Ocular hyperaemia | | 1 | | | | 1 |
| Off label use | | 1 | | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Respiratory distress | | 1 | | | | 1 |
| Swelling face | | 1 | | | | 1 |
| Vaccination site pain | | 1 | | 1 | | |
| | 2 | 18 | 2 | 10 | | 8 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Burning sensation | | 1 | | 1 | | |
| Dermatitis allergic | | 4 | | 4 | | |
| Dizziness | | 1 | | 1 | | |
| Erythema | | 1 | | 1 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | | 1 | | 1 | | |
| Headache | | 1 | | 1 | | |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Incomplete course of vaccination | 7 | 7 | 7 | 7 | | |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | | 1 | | 1 | | |
| Mental disorder | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | | 1 | | 1 | | |
| Polydipsia | | 1 | | 1 | | |
| Vaccination site pain | | 1 | | 1 | | |
| | 12 | 26 | 9 | 23 | 3 | 3 |

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Country Where Event Occurred

COLOMBIA

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Candida infection | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Gingivitis | | 1 | | 1 |
| Hypersensitivity | | 1 | | 1 |
| Leukocytosis | | 1 | | 1 |
| Off label use | | 1 | | 1 |
| Oral candidiasis | | 1 | | 1 |
| Product use issue | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| Stomatitis | | 1 | | 1 |
| | | 10 | | 10 |

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Country Where Event Occurred
COSTA RICA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 1 | | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 2 | | 1 | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Depression | 1 | 1 | 1 | 1 | | |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 4 | 4 | 2 | 2 | 2 | 2 |
| Energy increased | | 1 | | 1 | | |
| Euphoric mood | | 1 | | 1 | | |
| Eye allergy | | 1 | | 1 | | |
| Eye inflammation | | 1 | | 1 | | |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Fatigue | 5 | 6 | 4 | 5 | 1 | 1 |
| Feeling abnormal | | 1 | | 1 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | | 1 | | 1 | | |
| Headache | 6 | 9 | 5 | 8 | 1 | 1 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | 1 | 2 | 1 | 2 | | |
| Insomnia | | 1 | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Limb discomfort | | 1 | | 1 | | |
| Loss of personal independence in daily activities | 1 | 1 | | | 1 | 1 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Lymph node pain | | 1 | | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Migraine | 1 | 1 | 1 | 1 | | |
| Miosis | 1 | 1 | | | 1 | 1 |
| Muscle contracture | 1 | 1 | 1 | 1 | | |
| Myalgia | 3 | 3 | 2 | 2 | 1 | 1 |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 3 | 5 | 3 | 5 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Sensation of foreign body | 1 | 1 | 1 | 1 | | |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Tachycardia | 1 | 2 | 1 | 2 | | |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Thirst | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 3 | 6 | 3 | 6 | | |
| | 62 | 85 | 37 | 60 | 25 | 25 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Communication disorder | 1 | 1 | 1 | 1 | | |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 5 | 2 | 5 | | |
| Heart rate irregular | | 1 | | 1 | | |
| Hepatic enzyme increased | | 1 | | | | 1 |
| Joint range of motion decreased | | 1 | | | | 1 |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 3 | 1 | 2 | | 1 |
| Mobility decreased | | 1 | | | | 1 |
| Myalgia | 3 | 5 | 3 | 4 | | 1 |
| Pain | 3 | 4 | 3 | 4 | | |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pleuritic pain | 1 | 1 | 1 | 1 | | |
| Pneumonitis | 1 | 1 | | | 1 | 1 |
| Pruritus | | 1 | | 1 | | |
| Pyrexia | 2 | 5 | 2 | 4 | | 1 |
| Rash | | 1 | | 1 | | |
| Red blood cell sedimentation rate increased | | 1 | | 1 | | |
| Sleep disorder | | 1 | | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|-----------|----------|---|-----------|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Splenomegaly | | 1 | | | | 1 | |
| Suspected COVID-19 | 1 | 1 | 1 | 1 | | | |
| Throat clearing | 1 | 1 | 1 | 1 | | | |
| Tremor | 1 | 1 | 1 | 1 | | | |
| Vaccination site pain | 3 | 4 | 3 | 4 | | | |
| Vasculitis | | 1 | | 1 | | | |
| Vomiting | 1 | 1 | | | 1 | | 1 |
| | 38 | 61 | 31 | 47 | 7 | | 14 |

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Country Where Event Occurred
CROATIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 2 | 1 | 2 | | |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angioedema | 1 | 2 | | | 1 | 2 |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Arthralgia | 7 | 7 | 7 | 7 | | |
| Asthenia | 10 | 10 | 9 | 9 | 1 | 1 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Back pain | 4 | 4 | 3 | 3 | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 3 | 3 | | | 3 | 3 |
| Body temperature increased | 6 | 9 | 5 | 8 | 1 | 1 |
| Bone pain | 4 | 4 | 4 | 4 | | |
| Bronchospasm | 2 | 3 | 1 | 1 | 1 | 2 |
| Burning sensation | 1 | 2 | | | 1 | 2 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 3 | 3 | 1 | 1 | 2 | 2 |
| Chest pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Chills | 17 | 20 | 13 | 16 | 4 | 4 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Conjunctivitis allergic | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | | | 2 | 2 |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diaphragmatic spasm | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Diarrhoea | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 6 | 7 |
| Dry mouth | 1 | 1 |
| Dysgeusia | 1 | 2 |
| Dyskinesia | 1 | 1 |
| Dysphagia | 2 | 2 |
| Dyspnoea | 7 | 8 |
| Encephalitis post immunisation | 1 | 1 |
| Erythema | 12 | 14 |
| Extensive swelling of vaccinated limb | 12 | 12 |
| Extrapyramidal disorder | 1 | 1 |
| Eye haematoma | 1 | 1 |
| Eye haemorrhage | 1 | 1 |
| Eyelid oedema | 2 | 2 |
| Eyelid ptosis | | 1 |
| Eye opacity | 1 | 1 |
| Eye pain | | 1 |
| Facial paresis | 1 | 2 |
| Fatigue | 8 | 12 |
| Fear | 1 | 1 |
| Feeding disorder | 1 | 1 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | | 1 |
| Feeling hot | 6 | 6 |
| Gastrointestinal pain | 1 | 1 |
| Gingival bleeding | 1 | 1 |
| Headache | 31 | 39 |
| Head discomfort | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | | |
| 5 | 6 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 6 | 7 |
| | | 1 | 1 |
| | 1 | 12 | 13 |
| | | 12 | 12 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 2 |
| 6 | 10 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 3 | 3 | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| 23 | 30 | 8 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 3 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoaesthesia oral | | 1 |
| Hypogeusia | 1 | 1 |
| Hypotension | 1 | 1 |
| Illness | 1 | 1 |
| Incorrect dose administered | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Lip disorder | | 1 |
| Lip oedema | 1 | 1 |
| Lip swelling | 1 | 1 |
| Localised oedema | 1 | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 2 | 2 |
| Lymph node pain | 1 | 1 |
| Malaise | 7 | 8 |
| Migraine | 1 | 1 |
| Monoparesis | 1 | 1 |
| Multi-organ disorder | | 1 |
| Muscle spasms | 1 | 1 |
| Muscle tightness | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Myalgia | 19 | 21 |
| Myosclerosis | 1 | 1 |
| Nausea | 13 | 13 |
| Neck pain | 1 | 2 |
| Night sweats | 1 | 1 |
| Nystagmus | 1 | 1 |
| Ocular hyperaemia | 1 | 1 |
| Oedema mouth | 1 | 1 |
| Oral mucosal erythema | 1 | 1 |
| Oral pain | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 6 | 7 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 18 | 20 | 1 | 1 |
| | | 1 | 1 |
| 10 | 10 | 3 | 3 |
| 1 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------|--|--|
| Oropharyngeal pain | 1 | 1 |
| Pain | | 1 |
| Pain in extremity | 9 | 9 |
| Palpitations | 5 | 5 |
| Panic attack | 2 | 2 |
| Paraesthesia | 6 | 7 |
| Paraesthesia oral | 3 | 3 |
| Paresis | 1 | 1 |
| Peripheral swelling | 2 | 3 |
| Pharyngeal paraesthesia | | 1 |
| Pharyngeal swelling | 1 | 1 |
| Presyncope | 1 | 1 |
| Pruritus | 5 | 6 |
| Pulmonary pain | 1 | 1 |
| Pyrexia | 26 | 32 |
| Rales | 1 | 1 |
| Rash | 7 | 9 |
| Rash erythematous | | 1 |
| Rash macular | 1 | 1 |
| Rash maculo-papular | 3 | 3 |
| Respiratory tract oedema | | 1 |
| Retching | 1 | 1 |
| Salivary hypersecretion | 1 | 1 |
| Sensory disturbance | 1 | 1 |
| Sensory loss | 1 | 1 |
| Serum sickness | 1 | 1 |
| Skin oedema | 1 | 1 |
| Sleep paralysis | 1 | 1 |
| Sleep terror | 1 | 1 |
| Somnolence | 2 | 2 |
| Speech disorder | 1 | 1 |
| Stridor | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| 8 | 8 | 1 | 1 |
| 3 | 3 | 2 | 2 |
| | | 2 | 2 |
| 3 | 3 | 3 | 4 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 5 | 6 |
| 1 | 1 | | |
| 19 | 25 | 7 | 7 |
| | | 1 | 1 |
| | 1 | 7 | 8 |
| | | | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 2 | | | 1 | 2 |
| Swollen tongue | 1 | 2 | | | 1 | 2 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 6 | 6 | 4 | 4 | 2 | 2 |
| Tachypnoea | | 1 | | | | 1 |
| Tinnitus | 3 | 3 | 2 | 2 | 1 | 1 |
| Tongue oedema | 2 | 3 | | | 2 | 3 |
| Tremor | 5 | 6 | 4 | 4 | 1 | 2 |
| Type I hypersensitivity | 16 | 17 | | | 16 | 17 |
| Underdose | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Urticaria | 5 | 5 | | | 5 | 5 |
| Vaccination site erythema | 19 | 20 | 14 | 15 | 5 | 5 |
| Vaccination site haematoma | 2 | 2 | 2 | 2 | | |
| Vaccination site hypersensitivity | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site joint erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 4 | 5 | 3 | 3 | 1 | 2 |
| Vaccination site pain | 43 | 52 | 36 | 44 | 7 | 8 |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 10 | 11 | 8 | 9 | 2 | 2 |
| Vertigo | 3 | 3 | 2 | 2 | 1 | 1 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vitreous detachment | 1 | 1 | | | 1 | 1 |
| Vomiting | 3 | 3 | 2 | 2 | 1 | 1 |
| Wheezing | 1 | 2 | | | 1 | 2 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 484 | 558 | 280 | 325 | 204 | 233 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to chemicals | | 1 | | 1 | | |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Blood creatine phosphokinase increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Burning sensation | 1 | 2 | | 1 | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | 4 | 4 | | |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Discomfort | | 1 | | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Ear canal erythema | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Ear pruritus | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 2 | | 1 | 1 | 1 |
| Extensive swelling of vaccinated limb | 2 | 2 | | | 2 | 2 |
| Eyelid function disorder | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 2 | 2 | | | 2 | 2 |
| Fatigue | 4 | 4 | 4 | 4 | | |
| Feeling hot | | 1 | | 1 | | |
| Fibromyalgia | 1 | 1 | | | 1 | 1 |
| Headache | 12 | 12 | 7 | 7 | 5 | 5 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Immune system disorder | 1 | 1 | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Insomnia | 1 | 2 | 1 | 2 | | |
| Lymphadenopathy | 2 | 2 | 2 | 2 | | |
| Lymphopenia | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 2 | 2 | | |
| Muscle contractions involuntary | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 2 | | 1 | 1 | 1 |
| Pain of skin | 1 | 1 | | | 1 | 1 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 2 | | 1 | 1 | 1 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | 1 | 1 | | |
| Psoriasis | 1 | 1 | 1 | 1 | | |
| Pyrexia | 8 | 10 | 6 | 8 | 2 | 2 |
| Rheumatoid factor positive | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Spinal pain | 1 | 1 | 1 | 1 | | |
| Tremor | 2 | 2 | 2 | 2 | | |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 7 | 8 | 5 | 6 | 2 | 2 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Viral infection | 1 | 1 | 1 | 1 | | |
| | 98 | 109 | 55 | 66 | 43 | 43 |

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Country Where Event Occurred
CYPRUS

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 4 | 4 | 4 | 4 | | |
| Asthenia | 3 | 4 | 3 | 4 | | |
| Axillary pain | 2 | 2 | 2 | 2 | | |
| Back pain | | 1 | | 1 | | |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | | 1 | | | | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cervix oedema | | 1 | | 1 | | |
| Chills | 6 | 7 | 6 | 7 | | |
| Condition aggravated | | 1 | | 1 | | |
| Contusion | 1 | 1 | 1 | 1 | | |
| Cough | | 1 | | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 5 | 7 | 5 | 7 | | |
| Dysgeusia | | 1 | | 1 | | |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Eyelid ptosis | | 1 | | 1 | | |
| Face oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Facial paralysis | | 1 | | | | 1 |
| Facial paresis | 2 | 4 | | | 2 | 4 |
| Fatigue | 4 | 4 | 4 | 4 | | |
| Fibrin D dimer increased | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 2 | 2 | 2 | 2 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| Guillain-Barre syndrome | 1 | 1 | 1 | 1 | | |
| Headache | 6 | 8 | 6 | 8 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | | 1 |
| Hypertension | | 1 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | | 1 |
| Hypoaesthesia eye | | 1 |
| Hypoaesthesia oral | | 1 |
| Hyponatraemia | 1 | 1 |
| Hypotension | 1 | 1 |
| Inappropriate schedule of product administration | | 1 |
| Insomnia | 1 | 1 |
| Lymphadenopathy | 4 | 5 |
| Malaise | 1 | 1 |
| Migraine | | 1 |
| Muscle contracture | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 7 | 7 |
| Myelitis | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nausea | 5 | 5 |
| Off label use | 1 | 1 |
| Oropharyngeal pain | | 1 |
| Oxygen saturation decreased | 2 | 2 |
| Pain | 2 | 2 |
| Pain in extremity | 1 | 1 |
| Pallor | 1 | 1 |
| Pharyngeal oedema | 1 | 1 |
| Product use issue | 1 | 1 |
| Pulmonary embolism | 2 | 2 |
| Pyrexia | 4 | 4 |
| Rash | | 1 |
| Respiratory tract oedema | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 4 | 4 | | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 7 | 7 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 5 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 2 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 4 | 4 | | |
| | 1 | | |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| SARS-CoV-2 ant body test negative | | 1 | | | | 1 | |
| Sinus congestion | | 1 | | 1 | | | |
| Sluggishness | 1 | 1 | 1 | 1 | | | |
| Swollen tongue | | 1 | | 1 | | | |
| Syncope | 2 | 2 | | | 2 | 2 | |
| Tachyarrhythmia | | 1 | | | | 1 | |
| Tachycardia | | 1 | | | | 1 | |
| Upper respiratory tract congestion | | 1 | | 1 | | | |
| Vaccination site oedema | 2 | 2 | 2 | 2 | | | |
| Vaccination site pain | 6 | 7 | 6 | 7 | | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | | |
| Vasculitis | 1 | 1 | 1 | 1 | | | |
| Vertigo | 1 | 1 | 1 | 1 | | | |
| Vomiting | 2 | 2 | 2 | 2 | | | |
| | 110 | 143 | 94 | 115 | 16 | 28 | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Confusional state | 1 | 1 | 1 | 1 | | |
| COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| Dermatitis atopic | 1 | 1 | 1 | 1 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | 1 | 2 | | |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Eczema | 1 | 1 | 1 | 1 | | |
| Epistaxis | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Facial paresis | 2 | 2 | | | 2 | 2 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Head titubation | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 2 | 2 | 2 | | |
| Myocardial infarction | 1 | 2 | | | 1 | 2 |
| Overdose | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 1 | 1 | 1 | | |
| Pyrexia | 3 | 4 | 3 | 4 | | |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tremor | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 4 | 3 | 4 | | |
| | 41 | 45 | 28 | 31 | 13 | 14 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 3 | 3 | 3 | 3 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Malaise | 3 | 3 | 3 | 3 | | |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| | 12 | 12 | 11 | 11 | 1 | 1 |

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Country Where Event Occurred
CZECH REPUBLIC

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Acute vestibular syndrome | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | 1 | 3 | | | 1 | 3 |
| Anaesthesia oral | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 3 | 5 | | | 3 | 5 |
| Angioedema | | 1 | | | | 1 |
| Anosmia | 2 | 2 | 2 | 2 | | |
| Anxiety | 3 | 4 | 2 | 3 | 1 | 1 |
| Apathy | 2 | 2 | 1 | 1 | 1 | 1 |
| Application site coldness | 1 | 1 | | | 1 | 1 |
| Arthralgia | 23 | 25 | 21 | 23 | 2 | 2 |
| Asthenia | 13 | 15 | 8 | 10 | 5 | 5 |
| Asthma | | 1 | | | | 1 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 3 | 4 | 3 | 4 | | |
| Bacterial rhinitis | 1 | 1 | | | 1 | 1 |
| Blindness | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 3 | 4 | 3 | 3 | | 1 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 2 | 1 | 2 | | |
| Breast pain | 1 | 1 | | | 1 | 1 |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| Burning sensation mucosal | 2 | 2 | 2 | 2 | | |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 5 | 5 | 2 | 2 | 3 | 3 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 41 | 44 | 38 | 40 | 3 | 4 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 2 | 3 | | | 2 | 3 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Communication disorder | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------|--|--|
| Condition aggravated | 1 | 1 |
| Confusional state | 2 | 2 |
| Cough | 3 | 4 |
| COVID-19 | 9 | 11 |
| COVID-19 pneumonia | 2 | 2 |
| C-reactive protein increased | 1 | 1 |
| Decreased appetite | 2 | 2 |
| Depression | 1 | 1 |
| Dermatitis | 1 | 1 |
| Dermatitis allergic | 1 | 1 |
| Diarrhoea | 8 | 9 |
| Disease recurrence | 1 | 1 |
| Disorientation | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 9 | 11 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 4 | 7 |
| Dry mouth | 2 | 2 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 1 | 1 |
| Dyspepsia | 1 | 1 |
| Dysphagia | | 1 |
| Dyspnoea | 6 | 10 |
| Ear discomfort | 3 | 3 |
| Ear swelling | 1 | 1 |
| Eating disorder | 2 | 2 |
| Epilepsy | 1 | 1 |
| Erythema | 12 | 14 |
| Eye inflammation | 1 | 1 |
| Eye pain | 2 | 2 |
| Eye pruritus | | 1 |
| Facial pain | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 2 | 2 |
| 2 | 3 | 1 | 1 |
| 4 | 4 | 5 | 7 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 7 | 8 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 6 | 7 | 3 | 4 |
| 1 | 1 | | |
| | | 4 | 7 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | 5 | 8 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 7 | 9 | 5 | 5 |
| 1 | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| | | 1 | 1 |

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 * AE=Adverse Event
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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Facial paresis | 1 | 2 |
| Fall | 1 | 1 |
| Fatigue | 39 | 47 |
| Feeling abnormal | 3 | 3 |
| Feeling cold | 1 | 1 |
| Feeling hot | 4 | 4 |
| Flushing | 2 | 2 |
| Formication | 1 | 1 |
| Frequent bowel movements | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 |
| Generalised oedema | 1 | 1 |
| General physical health deterioration | 2 | 2 |
| Hallucination | 1 | 1 |
| Headache | 48 | 52 |
| Head discomfort | 1 | 1 |
| Hot flush | 3 | 3 |
| Hyperglycaemia | 1 | 1 |
| Hyperhidrosis | 4 | 4 |
| Hyperphagia | 1 | 1 |
| Hypersensitivity | 12 | 14 |
| Hypersomnia | 1 | 1 |
| Hypertension | 3 | 4 |
| Hyperventilation | | 1 |
| Hypoaesthesia | 4 | 5 |
| Hypoaesthesia oral | 1 | 1 |
| Hypokalaemia | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hypotension | 3 | 4 |
| Illness | 1 | 1 |
| Illusion | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| 1 | 1 | | |
| 33 | 41 | 6 | 6 |
| 3 | 3 | | |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 41 | 45 | 7 | 7 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 4 | 4 | | |
| 1 | 1 | | |
| 4 | 5 | 8 | 9 |
| | | 1 | 1 |
| | 1 | 3 | 3 |
| | 1 | | |
| 2 | 3 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Incorrect route of product administration | 3 | 3 |
| Influenza | 1 | 1 |
| Influenza like illness | 4 | 4 |
| Injected limb mobility decreased | 1 | 1 |
| Insomnia | 1 | 1 |
| Irritability | 1 | 1 |
| Joint instability | 1 | 1 |
| Joint range of motion decreased | 1 | 1 |
| Joint stiffness | | 1 |
| Joint warmth | 1 | 1 |
| Language disorder | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Limb immobilisation | 1 | 1 |
| Lip swelling | 1 | 2 |
| Localised oedema | 1 | 1 |
| Logorrhoea | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenitis | 1 | 1 |
| Lymphadenopathy | 19 | 20 |
| Lymph node pain | 7 | 7 |
| Malaise | 5 | 6 |
| Maternal exposure during pregnancy | 1 | 1 |
| Memory impairment | 1 | 1 |
| Migraine | 1 | 1 |
| Mobility decreased | | 1 |
| Monoparesis | 1 | 1 |
| Mucosal disorder | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal chest pain | | 1 |
| Musculoskeletal disorder | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | | |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 13 | 14 | 6 | 6 |
| 5 | 5 | 2 | 2 |
| 4 | 5 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Musculoskeletal pain | | 1 |
| Musculoskeletal stiffness | 2 | 4 |
| Myalgia | 18 | 20 |
| Nasal discomfort | 1 | 1 |
| Nausea | 26 | 30 |
| Neck pain | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Ocular hyperaemia | | 1 |
| Oedema | 1 | 1 |
| Oedema mouth | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Off label use | 2 | 2 |
| Oral discomfort | 1 | 1 |
| Oral pruritus | | 1 |
| Oropharyngeal discomfort | 2 | 2 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 5 | 6 |
| Pain in extremity | 18 | 20 |
| Pain of skin | 1 | 1 |
| Pallor | 1 | 1 |
| Palpitations | 6 | 6 |
| Paraesthesia | 15 | 18 |
| Paraesthesia oral | 4 | 4 |
| Peripheral coldness | 4 | 4 |
| Peripheral swelling | 4 | 5 |
| Pharyngeal oedema | 1 | 2 |
| Pharyngeal swelling | 1 | 2 |
| Photophobia | | 1 |
| Photopsia | 1 | 1 |
| Photosensitivity reaction | 1 | 1 |
| Poor quality product administered | 60 | 60 |
| Presyncope | 5 | 5 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 2 | 4 | | |
| 16 | 18 | 2 | 2 |
| | | 1 | 1 |
| 22 | 25 | 4 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 4 | 5 | 1 | 1 |
| 15 | 17 | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 5 | 5 |
| 10 | 11 | 5 | 7 |
| | | 4 | 4 |
| 4 | 4 | | |
| 1 | 1 | 3 | 4 |
| | 1 | 1 | 1 |
| | | 1 | 2 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 60 | 60 | | |
| 1 | 1 | 4 | 4 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------|--|--|
| Product preparation error | 59 | 59 |
| Product preparation issue | 1 | 1 |
| Product use issue | 2 | 2 |
| Pruritus | 13 | 14 |
| Pulmonary embolism | 1 | 1 |
| Pulmonary pain | 1 | 1 |
| Pyrexia | 58 | 61 |
| Rash | 12 | 13 |
| Rash macular | 2 | 2 |
| Rash pruritic | 3 | 3 |
| Rash pustular | 1 | 1 |
| Respiration abnormal | 1 | 1 |
| Respiratory disorder | 1 | 1 |
| Retching | 1 | 1 |
| Rhinitis | | 1 |
| Rhinorrhoea | 1 | 2 |
| SARS-CoV-2 test positive | 2 | 3 |
| Sensation of foreign body | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Skin disorder | 1 | 1 |
| Skin reaction | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Somnolence | 1 | 3 |
| Speech disorder | 1 | 1 |
| Spinal pain | 1 | 1 |
| Swelling | 1 | 2 |
| Swelling face | 6 | 7 |
| Swollen tongue | 1 | 3 |
| Syncope | 3 | 3 |
| Tachycardia | 6 | 7 |
| Tachypnoea | 1 | 2 |
| Tension headache | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 59 | 59 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 4 | 5 | 9 | 9 |
| | | 1 | 1 |
| 1 | 1 | | |
| 42 | 45 | 16 | 16 |
| 5 | 6 | 7 | 7 |
| | | 2 | 2 |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| 2 | 2 | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 5 | 6 |
| | | 1 | 3 |
| | | 3 | 3 |
| 4 | 5 | 2 | 2 |
| 1 | 1 | | 1 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Throat tightness | 1 | 2 | | | 1 | 2 |
| Tongue discomfort | 1 | 1 | 1 | 1 | | |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 4 | 4 | 3 | 3 | 1 | 1 |
| Urticaria | 2 | 2 | 2 | 2 | | |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Vaccination site atrophy | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 23 | 23 | 17 | 17 | 6 | 6 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 1 | 2 | 1 | 2 | | |
| Vaccination site oedema | 10 | 10 | 6 | 6 | 4 | 4 |
| Vaccination site pain | 35 | 38 | 29 | 32 | 6 | 6 |
| Vaccination site papule | 1 | 1 | | | 1 | 1 |
| Vaccination site paraesthesia | 2 | 2 | 2 | 2 | | |
| Vaccination site pruritus | 6 | 6 | 6 | 6 | | |
| Vaccination site reaction | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 6 | 6 | 5 | 5 | 1 | 1 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 5 | 5 | 5 | 5 | | |
| Vertigo | 10 | 11 | 8 | 9 | 2 | 2 |
| Vision blurred | 2 | 3 | 2 | 3 | | |
| Visual field defect | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 18 | 19 | 14 | 14 | 4 | 5 |
| | 925 | 1,030 | 656 | 726 | 269 | 304 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anal incontinence | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Apathy | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 7 | 7 | 4 | 4 | 3 | 3 |
| Asthenia | 10 | 10 | 8 | 8 | 2 | 2 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Blood pressure systolic increased | 2 | 2 | 2 | 2 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 4 | 4 | | | 4 | 4 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 8 | 8 | 6 | 6 | 2 | 2 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Cough | 2 | 2 | 2 | 2 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 4 | 4 | 3 | 3 | 1 | 1 |
| Decreased interest | 1 | 1 | 1 | 1 | | |
| Delirium | 1 | 1 | | | 1 | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 6 | 6 | 3 | 3 | 3 | 3 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Fatigue | 10 | 11 | 9 | 10 | 1 | 1 |
| Feeling hot | 2 | 2 | 2 | 2 | | |
| Grunting | 1 | 1 | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Hallucination | 1 | 1 |
| Headache | 5 | 5 |
| Hyperhidrosis | 1 | 1 |
| Hypertension | 1 | 1 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoglycaemia | 1 | 1 |
| Hypokalaemia | 1 | 1 |
| Hypotension | 5 | 5 |
| Hypoxia | 2 | 2 |
| Influenza like illness | 3 | 3 |
| Insomnia | 2 | 2 |
| Jaundice | 1 | 1 |
| Joint effusion | 1 | 1 |
| Loss of consciousness | 4 | 4 |
| Lymphadenopathy | 1 | 1 |
| Lymphoedema | 1 | 1 |
| Malaise | 1 | 1 |
| Mucosal dryness | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Myalgia | 8 | 9 |
| Myosclerosis | 1 | 1 |
| Nervousness | 1 | 1 |
| Off label use | 2 | 2 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 2 | 2 |
| Pallor | 2 | 2 |
| Palpitations | 1 | 1 |
| Paraesthesia | 2 | 2 |
| Paraesthesia oral | 1 | 1 |
| Peripheral coldness | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 3 | 3 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 3 | 3 |
| | | 2 | 2 |
| 3 | 3 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------------|--|--|
| Pneumonia | 1 | 1 |
| Polyarthritits | 1 | 1 |
| Poor quality product administered | 23 | 23 |
| Presyncope | 4 | 4 |
| Product preparation error | 23 | 23 |
| Product use issue | 2 | 2 |
| Pruritus | 1 | 1 |
| Pyrexia | 13 | 14 |
| Rash | 1 | 1 |
| Rash macular | 1 | 1 |
| Respiratory acidosis | 1 | 1 |
| Respiratory depression | 1 | 1 |
| Respiratory failure | 1 | 1 |
| Respiratory tract oedema | 1 | 1 |
| Restlessness | 1 | 1 |
| Seizure | 1 | 1 |
| Sepsis | 1 | 1 |
| Shock | 2 | 2 |
| Sleep disorder | 1 | 1 |
| Somnolence | 1 | 1 |
| Syncope | 1 | 1 |
| Tachycardia | 1 | 1 |
| Tension headache | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue oedema | 1 | 1 |
| Toothache | 1 | 1 |
| Tremor | 2 | 2 |
| Vaccination site erythema | 2 | 2 |
| Vaccination site mass | 1 | 1 |
| Vaccination site oedema | 1 | 1 |
| Vaccination site pain | 6 | 6 |
| Vaccination site swelling | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 23 | 23 | | |
| 1 | 1 | 3 | 3 |
| 23 | 23 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 9 | 10 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 6 | 6 | | |
| 1 | 1 | 1 | 1 |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-------------------------|--|--|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vertigo | 3 | 3 | 1 | 1 | 2 | 2 |
| Vomiting | 2 | 2 | | | 2 | 2 |
| Wheezing | 1 | 1 | 1 | 1 | | |
| | 244 | 247 | 156 | 159 | 88 | 88 |

Gender

UNKNOWN

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|--------------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Exposure via breast milk | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

DENMARK

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 5 | 7 | 2 | 4 | 3 | 3 |
| Abdominal pain upper | 2 | 2 | 1 | 1 | 1 | 1 |
| Accidental exposure to product | 1 | 1 | 1 | 1 | | |
| Acute leukaemia | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Altered state of consciousness | 2 | 2 | | | 2 | 2 |
| Anaemia | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 5 | 12 | | | 5 | 12 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Angioedema | | 4 | | | | 4 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Anxiety | 2 | 3 | 1 | 1 | 1 | 2 |
| Arthralgia | 12 | 22 | 7 | 17 | 5 | 5 |
| Asthenia | 4 | 7 | 1 | 2 | 3 | 5 |
| Asthma | 2 | 2 | 1 | 1 | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrial flutter | | 1 | | | | 1 |
| Auricular swelling | 1 | 1 | 1 | 1 | | |
| Axillary pain | 3 | 5 | 3 | 5 | | |
| Back pain | 3 | 4 | 2 | 3 | 1 | 1 |
| Blood creatine phosphokinase increased | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | | 1 | | 1 | | |
| Blood lactate dehydrogenase abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | | 1 | | | | 1 |
| Blood pressure decreased | | 2 | | | | 2 |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 3 | 4 | 1 | 1 | 2 | 3 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Blood pressure systolic increased | 1 | 1 |
| Body temperature increased | 1 | 3 |
| Bradycardia | 1 | 1 |
| Breast pain | 1 | 1 |
| Bronchospasm | | 1 |
| Burning sensation | 3 | 3 |
| Cardiogenic shock | 1 | 1 |
| Cerebral thrombosis | 1 | 1 |
| Chest discomfort | 8 | 14 |
| Chest pain | 8 | 8 |
| Chills | 25 | 37 |
| Choking sensation | 1 | 1 |
| Chorioretinitis | 1 | 1 |
| Chronic obstructive pulmonary disease | | 1 |
| Cold sweat | | 1 |
| Condition aggravated | 4 | 6 |
| Confusional state | 2 | 2 |
| Conjunctival haemorrhage | 1 | 1 |
| Coordination abnormal | 2 | 2 |
| Cough | 7 | 15 |
| COVID-19 | 7 | 8 |
| C-reactive protein increased | 4 | 4 |
| Crying | 1 | 1 |
| Cystitis | 1 | 1 |
| Death | 4 | 4 |
| Deep vein thrombosis | 1 | 1 |
| Delusion | 1 | 1 |
| Depressed level of consciousness | 3 | 3 |
| Derealisation | 2 | 3 |
| Dermatitis allergic | 1 | 2 |
| Diarrhoea | 8 | 12 |
| Discomfort | 3 | 6 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 5 | 5 | 9 |
| 4 | 4 | 4 | 4 |
| 18 | 27 | 7 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | 4 | 6 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| 6 | 9 | 1 | 6 |
| | | 7 | 8 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| 2 | 3 | | |
| | | 1 | 2 |
| 3 | 7 | 5 | 5 |
| 1 | 1 | 2 | 5 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Disorientation | 1 | 1 |
| Disturbance in attention | 1 | 2 |
| Dizziness | 54 | 77 |
| Dizziness exertional | 1 | 1 |
| Dizziness postural | | 1 |
| Drug ineffective | 5 | 6 |
| Dry eye | | 1 |
| Dry mouth | 3 | 3 |
| Dry skin | 1 | 1 |
| Dry throat | | 1 |
| Dysaesthesia | 1 | 2 |
| Dysgeusia | | 1 |
| Dysphagia | 2 | 4 |
| Dysphonia | 3 | 5 |
| Dyspnoea | 19 | 35 |
| Dyspnoea at rest | | 1 |
| Dyspnoea exertional | 2 | 2 |
| Dysstasia | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear pruritus | 1 | 1 |
| Electrocardiogram QT prolonged | 1 | 1 |
| Electrocardiogram ST segment depression | 1 | 1 |
| Erythema | 21 | 27 |
| Exposure via skin contact | 1 | 1 |
| Eyelid oedema | 1 | 1 |
| Eye pain | 2 | 5 |
| Eye pruritus | 1 | 3 |
| Face oedema | 1 | 1 |
| Fall | 2 | 2 |
| Fatigue | 55 | 71 |
| Feeling abnormal | 2 | 2 |
| Feeling cold | 7 | 8 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| 30 | 42 | 24 | 35 |
| 1 | 1 | | |
| | | 5 | 6 |
| | 1 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | 1 | 1 |
| | 1 | | |
| | 1 | 2 | 3 |
| 3 | 3 | | 2 |
| 6 | 13 | 13 | 22 |
| | | | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 12 | 16 | 9 | 11 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 5 | | |
| | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 44 | 57 | 11 | 14 |
| 2 | 2 | | |
| 5 | 6 | 2 | 2 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Feeling hot | 11 | 18 |
| Feeling of body temperature change | 1 | 1 |
| Fluid intake reduced | | 1 |
| Flushing | 1 | 6 |
| Foaming at mouth | 1 | 2 |
| General physical health deterioration | 1 | 3 |
| Glossodynia | | 1 |
| Hallucination, visual | 1 | 1 |
| Hand dermatitis | 1 | 1 |
| Headache | 104 | 140 |
| Head discomfort | 3 | 3 |
| Head injury | 1 | 1 |
| Heart rate abnormal | 1 | 1 |
| Heart rate decreased | 2 | 2 |
| Heart rate increased | 2 | 5 |
| Herpes zoster | 1 | 1 |
| Hot flush | 2 | 3 |
| Hyperacusis | 2 | 2 |
| Hyperhidrosis | 7 | 9 |
| Hypersensitivity | 9 | 15 |
| Hypersomnia | 1 | 1 |
| Hypertension | 9 | 11 |
| Hyperventilation | 2 | 4 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Hypoaesthesia oral | 2 | 2 |
| Hypoglycaemia | 1 | 1 |
| Hypokalaemia | 1 | 1 |
| Hypophagia | | 1 |
| Hypotension | 3 | 4 |
| Hypoxia | 1 | 1 |
| Illness | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 7 | 10 | 4 | 8 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 3 | | 3 |
| | 1 | 1 | 1 |
| | | 1 | 3 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 77 | 106 | 27 | 34 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 3 | 1 | 2 |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 1 | 1 | 1 |
| 4 | 5 | 3 | 4 |
| 1 | 2 | 8 | 13 |
| 1 | 1 | | |
| 4 | 5 | 5 | 6 |
| | | 2 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | 1 | | |
| | | 3 | 4 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Inappropriate schedule of product administration | 1 | 1 |
| Incorrect route of product administration | 2 | 3 |
| Infection | 1 | 2 |
| Influenza | 4 | 4 |
| Influenza like illness | 6 | 8 |
| Injected limb mobility decreased | 1 | 1 |
| Injection site pain | | 1 |
| Insomnia | 2 | 2 |
| Joint stiffness | 1 | 1 |
| Joint swelling | 2 | 3 |
| Lacrimation increased | 2 | 2 |
| Lethargy | 2 | 2 |
| Leukopenia | 1 | 1 |
| Limb discomfort | 5 | 5 |
| Lip swelling | 2 | 2 |
| Loss of consciousness | 3 | 3 |
| Loss of control of legs | 1 | 1 |
| Lymphadenitis | 2 | 2 |
| Lymphadenopathy | 10 | 13 |
| Lymph node pain | 2 | 3 |
| Lymphopenia | 1 | 1 |
| Malaise | 48 | 75 |
| Migraine | 2 | 3 |
| Mobility decreased | 1 | 1 |
| Motor dysfunction | 1 | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle fatigue | 1 | 2 |
| Muscle spasms | 3 | 3 |
| Muscle tightness | 1 | 2 |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 4 | 4 |
| Musculoskeletal discomfort | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | 1 |
| 3 | 3 | 1 | 1 |
| 5 | 7 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| 2 | 2 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 3 | 3 | 2 | 2 |
| | | 2 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 5 | 8 | 5 | 5 |
| 2 | 3 | | |
| | | 1 | 1 |
| 31 | 47 | 17 | 28 |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| 2 | 2 | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 33 | 53 |
| Myelitis | 1 | 1 |
| Nasal congestion | 3 | 4 |
| Nasal pruritus | 1 | 2 |
| Nasopharyngitis | 1 | 2 |
| Nausea | 53 | 70 |
| Neck pain | 2 | 3 |
| Neuralgia | 1 | 1 |
| Obliterative bronchiolitis | 1 | 1 |
| Obstructive airways disorder | | 1 |
| Odynophagia | 2 | 2 |
| Oedema peripheral | 1 | 2 |
| Off label use | 4 | 4 |
| Oral fungal infection | 1 | 1 |
| Oral mucosal blistering | 1 | 1 |
| Oral mucosal eruption | 1 | 1 |
| Oral pruritus | 2 | 2 |
| Oropharyngeal discomfort | 1 | 2 |
| Oropharyngeal pain | 9 | 10 |
| Oxygen saturation decreased | | 1 |
| Pain | 8 | 12 |
| Painful respiration | 2 | 2 |
| Pain in extremity | 15 | 21 |
| Pain of skin | 1 | 1 |
| Pallor | 2 | 8 |
| Palpitations | 7 | 17 |
| Panic attack | 1 | 1 |
| Paraesthesia | 20 | 27 |
| Paraesthesia oral | 6 | 7 |
| Periarthritis | 1 | 1 |
| Periorbital swelling | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 29 | 48 | 4 | 5 |
| | | 1 | 1 |
| 3 | 4 | | |
| | 1 | 1 | 1 |
| 1 | 2 | | |
| 32 | 42 | 21 | 28 |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 |
| 4 | 4 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 2 | | |
| 8 | 9 | 1 | 1 |
| | | | 1 |
| 6 | 9 | 2 | 3 |
| 2 | 2 | | |
| 14 | 20 | 1 | 1 |
| 1 | 1 | | |
| | 3 | 2 | 5 |
| 5 | 10 | 2 | 7 |
| | | 1 | 1 |
| 14 | 17 | 6 | 10 |
| 4 | 4 | 2 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Peripheral swelling | 4 | 5 |
| Pharyngeal oedema | | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | 5 | 9 |
| Photophobia | 2 | 2 |
| Photopsia | 2 | 3 |
| Pleural effusion | 1 | 2 |
| Pneumonia | 3 | 4 |
| Pneumonia bacterial | 1 | 1 |
| Postmenopausal haemorrhage | 1 | 1 |
| Presyncope | 6 | 17 |
| Productive cough | 1 | 1 |
| Product use issue | 4 | 4 |
| Prolonged expiration | | 1 |
| Pruritus | 22 | 31 |
| Pulmonary arterial hypertension | 1 | 1 |
| Pulmonary embolism | 1 | 1 |
| Pulmonary fibrosis | | 1 |
| Pulmonary oedema | 1 | 2 |
| Pyrexia | 78 | 107 |
| Rash | 9 | 17 |
| Rash erythematous | 6 | 13 |
| Rash morbilliform | 1 | 1 |
| Rash papular | 1 | 1 |
| Rash pruritic | 4 | 7 |
| Rash vesicular | 1 | 1 |
| Renal colic | 1 | 1 |
| Renal failure | 1 | 1 |
| Renal pain | 1 | 1 |
| Respiratory acidosis | 1 | 1 |
| Respiratory failure | 2 | 3 |
| Respiratory tract infection bacterial | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 4 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 2 | 2 | 3 | 7 |
| 1 | 1 | 1 | 1 |
| | 1 | 2 | 2 |
| | | 1 | 2 |
| | | 3 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 5 | 4 | 12 |
| 1 | 1 | | |
| 4 | 4 | | |
| | | | 1 |
| 15 | 23 | 7 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 2 |
| 54 | 77 | 24 | 30 |
| 6 | 10 | 3 | 7 |
| 5 | 9 | 1 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 6 | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Restlessness | 1 | 5 |
| Rhinalgia | 1 | 1 |
| Rhinorrhoea | 4 | 4 |
| Salivary hypersecretion | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 |
| Seizure | 1 | 1 |
| Sensation of foreign body | 1 | 1 |
| Sensory disturbance | 4 | 5 |
| Sensory loss | 2 | 2 |
| Severe acute respiratory syndrome | | 1 |
| Sinus tachycardia | 1 | 2 |
| Skin lesion | | 1 |
| Sneezing | 4 | 4 |
| Somnolence | 3 | 3 |
| Stomatitis | 1 | 1 |
| Stridor | | 1 |
| Sudden cardiac death | 1 | 1 |
| Sudden death | 2 | 3 |
| Swelling | 1 | 2 |
| Swelling face | 7 | 13 |
| Swelling of eyelid | | 2 |
| Swollen tongue | 3 | 6 |
| Syncope | 6 | 9 |
| Tachycardia | 1 | 5 |
| Tachypnoea | | 1 |
| Taste disorder | 1 | 1 |
| Tenderness | 3 | 3 |
| Throat irritation | 2 | 4 |
| Throat tightness | 2 | 5 |
| Thrombosis | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue pruritus | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 5 | | |
| 1 | 1 | | |
| 4 | 4 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | | |
| | | 2 | 2 |
| | | | 1 |
| 1 | 2 | | |
| | 1 | | |
| 4 | 4 | | |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 2 | | |
| 2 | 4 | 5 | 9 |
| | 1 | | 1 |
| 1 | 1 | 2 | 5 |
| | | 6 | 9 |
| | 1 | 1 | 4 |
| | | | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| | 2 | 2 | 2 |
| 1 | 2 | 1 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Tonic convulsion | 1 | 1 |
| Tremor | 5 | 8 |
| Troponin I increased | 1 | 1 |
| Tunnel vision | 1 | 1 |
| Underdose | 1 | 2 |
| Upper respiratory tract infection | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 |
| Urticaria | 8 | 18 |
| Vaccination complication | 1 | 2 |
| Vaccination site abscess | 1 | 1 |
| Vaccination site discolouration | 1 | 1 |
| Vaccination site discomfort | 1 | 2 |
| Vaccination site erythema | 12 | 20 |
| Vaccination site haematoma | 1 | 2 |
| Vaccination site haemorrhage | | 1 |
| Vaccination site hypoaesthesia | 1 | 1 |
| Vaccination site induration | 1 | 1 |
| Vaccination site inflammation | 1 | 1 |
| Vaccination site irritation | 1 | 2 |
| Vaccination site lymphadenopathy | | 1 |
| Vaccination site mass | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 |
| Vaccination site necrosis | 1 | 1 |
| Vaccination site pain | 59 | 96 |
| Vaccination site paraesthesia | 1 | 2 |
| Vaccination site pruritus | 3 | 5 |
| Vaccination site rash | 1 | 2 |
| Vaccination site reaction | 1 | 1 |
| Vaccination site swelling | 15 | 25 |
| Vaccination site thrombosis | 1 | 1 |
| Vaccination site warmth | 6 | 8 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 2 | 2 | 3 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 6 | 13 | 2 | 5 |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| 10 | 17 | 2 | 3 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 54 | 89 | 5 | 7 |
| 1 | 2 | | |
| 3 | 5 | | |
| 1 | 1 | | 1 |
| 1 | 1 | | |
| 13 | 22 | 2 | 3 |
| | | 1 | 1 |
| 5 | 7 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaginal discharge | 1 | 1 | 1 | 1 | | |
| Vaginal haemorrhage | 1 | 1 | 1 | 1 | | |
| Vasodilatation | | 1 | | | | 1 |
| Vertigo | 1 | 2 | | | 1 | 2 |
| Vision blurred | 1 | 2 | | | 1 | 2 |
| Visual impairment | | 1 | | 1 | | |
| Vomiting | 16 | 22 | 8 | 11 | 8 | 11 |
| Vulvovaginal pain | 1 | 1 | 1 | 1 | | |
| Vulvovaginal pruritus | 1 | 1 | 1 | 1 | | |
| Weight increased | | 1 | | 1 | | |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 1,201 | 1,758 | 745 | 1093 | 456 | 665 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Aggression | | 1 | | | | 1 |
| Anaemia | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Aspiration | | 1 | | | | 1 |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Bacteraemia | | 1 | | | | 1 |
| Blood albumin decreased | 1 | 1 | 1 | 1 | | |
| Blood chloride increased | 1 | 1 | 1 | 1 | | |
| Blood creatinine increased | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure systolic increased | | 1 | | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| Calcium ionised increased | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | | 1 | | | | 1 |
| Chills | 2 | 4 | 1 | 3 | 1 | 1 |
| Chronic obstructive pulmonary disease | 2 | 2 | | | 2 | 2 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Coma | | 1 | | | | 1 |
| Condition aggravated | 2 | 2 | | | 2 | 2 |
| Confusional state | 1 | 2 | 1 | 1 | | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 7 | 7 | | | 7 | 7 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Death | 1 | 2 | | | 1 | 2 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Delirium | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 2 | | | 1 | 2 |
| Diarrhoea | 3 | 4 | 1 | 2 | 2 | 2 |

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Gender

MALE

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|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | | 1 | | 1 | | |
| Dizziness | 3 | 6 | 1 | 3 | 2 | 3 |
| Drug ineffective | 4 | 4 | | | 4 | 4 |
| Drug interaction | | 1 | | | | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 7 | 8 | 1 | 1 | 6 | 7 |
| Dyspnoea exertional | 2 | 2 | 1 | 1 | 1 | 1 |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Facial pain | | 1 | | 1 | | |
| Fatigue | 9 | 13 | 6 | 8 | 3 | 5 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling drunk | | 1 | | 1 | | |
| Feeling hot | 1 | 2 | 1 | 2 | | |
| Flushing | 1 | 3 | 1 | 2 | | 1 |
| Gastroesophageal reflux disease | | 1 | | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 3 | 4 | | | 3 | 4 |
| Glomerular filtration rate decreased | 1 | 1 | | | 1 | 1 |
| Groin pain | 1 | 1 | 1 | 1 | | |
| Haemorrhage intracranial | 1 | 1 | | | 1 | 1 |
| Headache | 11 | 19 | 7 | 14 | 4 | 5 |
| Hemiparesis | | 1 | | | | 1 |
| Hot flush | 2 | 2 | 2 | 2 | | |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypoacusis | 1 | 1 | 1 | 1 | | |
| Hypophagia | 1 | 1 | 1 | 1 | | |
| Hypotension | 1 | 2 | 1 | 1 | | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | | 1 | | 1 | | |
| Influenza | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 2 | 3 | 2 | 3 | | |

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Gender

MALE

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|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Insomnia | 1 | 2 | 1 | 2 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | | 1 | | | | 1 |
| Lymphadenopathy | 4 | 4 | 3 | 3 | 1 | 1 |
| Malaise | 7 | 10 | 2 | 4 | 5 | 6 |
| Micturition urgency | 1 | 1 | | | 1 | 1 |
| Mobility decreased | | 1 | | | | 1 |
| Muscle discomfort | | 1 | | 1 | | |
| Myalgia | 7 | 9 | 3 | 5 | 4 | 4 |
| Nasal obstruction | | 1 | | 1 | | |
| Nausea | 4 | 9 | 1 | 5 | 3 | 4 |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| Odynophagia | | 1 | | 1 | | |
| Off label use | 3 | 3 | 3 | 3 | | |
| Oropharyngeal pain | 2 | 4 | 2 | 4 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 1 | 3 | 1 | 3 | | |
| Periarthritis | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pharyngitis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 3 | 3 | | | 3 | 3 |
| Pneumonia aspiration | | 1 | | | | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pyrexia | 13 | 19 | 8 | 13 | 5 | 6 |
| Rales | | 1 | | | | 1 |
| Rash | 2 | 2 | 2 | 2 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|---|-----|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Respiratory arrest | | 1 | | | | | 1 |
| Respiratory failure | 4 | 5 | | | 4 | | 5 |
| Respiratory rate decreased | 1 | 1 | | | 1 | | 1 |
| Rhinitis | 1 | 1 | 1 | 1 | | | |
| SARS-CoV-2 test positive | 1 | 1 | 1 | 1 | | | |
| Seasonal allergy | 1 | 1 | 1 | 1 | | | |
| Sepsis | | 1 | | | | | 1 |
| Sneezing | 1 | 1 | 1 | 1 | | | |
| Somnolence | 2 | 3 | 2 | 2 | | | 1 |
| Syncope | | 1 | | | | | 1 |
| Tachypnoea | 1 | 1 | | | 1 | | 1 |
| Temporomandibular joint syndrome | 1 | 1 | | | 1 | | 1 |
| Thinking abnormal | | 1 | | | | | 1 |
| Throat irritation | 1 | 2 | 1 | 2 | | | |
| Tinnitus | 1 | 1 | 1 | 1 | | | |
| Tremor | 1 | 1 | 1 | 1 | | | |
| Urinary incontinence | | 1 | | | | | 1 |
| Urticaria | 2 | 2 | 1 | 1 | 1 | | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | | |
| Vaccination site pain | 11 | 19 | 10 | 18 | 1 | | 1 |
| Vaccination site rash | 1 | 1 | 1 | 1 | | | |
| Vaccination site swelling | 3 | 3 | 2 | 2 | 1 | | 1 |
| Vomiting | 2 | 4 | 1 | 1 | 1 | | 3 |
| Wound complication | 1 | 1 | 1 | 1 | | | |
| | 196 | 285 | 99 | 154 | 97 | | 131 |

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Gender

UNKNOWN

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|------------------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Exposure via breast milk | 1 | 1 | 1 | 1 |
| Hypoaesthesia | | 1 | | 1 |
| Product administration error | | 1 | | 1 |
| | 1 | 3 | 1 | 3 |

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Country Where Event Occurred
ECUADOR

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Blood pressure increased | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Laryngitis | 1 | 1 | 1 | 1 |
| Musculoskeletal disorder | 1 | 1 | 1 | 1 |
| Tracheitis | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

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Country Where Event Occurred

ESTONIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 5 | 6 | 5 | 6 | | |
| Asthenia | 9 | 10 | 5 | 6 | 4 | 4 |
| Asymptomatic COVID-19 | | 1 | | | | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood creatine phosphokinase increased | 1 | 1 | 1 | 1 | | |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chills | 6 | 6 | 5 | 5 | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 2 | 2 | | |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 4 | 1 | 1 | 3 | 3 |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Drug ineffective | | 1 | | | | 1 |
| Dysgeusia | 5 | 5 | 4 | 4 | 1 | 1 |
| Dyspnoea | 2 | 2 | 2 | 2 | | |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Facial nerve disorder | | 1 | | 1 | | |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Fall | 1 | 1 | 1 | 1 | | |
| Fatigue | 6 | 6 | 5 | 5 | 1 | 1 |
| Feeling hot | | 1 | | 1 | | |
| Flushing | 1 | 1 | 1 | 1 | | |
| Fracture | | 1 | | | | 1 |
| Headache | 18 | 20 | 14 | 16 | 4 | 4 |
| Hypersensitivity | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypertension | 1 | 2 | 1 | 2 | | |
| Hypoaesthesia | 1 | 3 | 1 | 3 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Hypopnoea | 1 | 1 |
| Hypotension | 2 | 2 |
| Hypothermia | 1 | 1 |
| Immunisation anxiety related reaction | 4 | 6 |
| Immunisation reaction | 1 | 1 |
| Insomnia | 1 | 1 |
| Intranasal paraesthesia | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Lymphadenopathy | | 1 |
| Malaise | 6 | 7 |
| Maternal exposure during pregnancy | | 4 |
| Migraine with aura | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 5 | 6 |
| Nausea | 8 | 8 |
| Neck pain | 1 | 1 |
| Off label use | 1 | 2 |
| Oral herpes | 2 | 2 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 3 | 4 |
| Pallor | 1 | 1 |
| Palpitations | | 1 |
| Paraesthesia | 9 | 13 |
| Paraesthesia oral | 3 | 3 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pneumonia | 1 | 1 |
| Presyncope | 1 | 1 |
| Product use issue | 1 | 2 |
| Pyrexia | 12 | 12 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 4 | 6 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 4 | 5 | 2 | 2 |
| | 4 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 5 | 1 | 1 |
| 4 | 4 | 4 | 4 |
| | | 1 | 1 |
| 1 | 2 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 4 | | |
| | | 1 | 1 |
| | 1 | | |
| 7 | 11 | 2 | 2 |
| 3 | 3 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| 11 | 11 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Restlessness | | 1 | | 1 | | |
| Retching | 1 | 1 | | | 1 | 1 |
| Somnolence | 5 | 5 | 4 | 4 | 1 | 1 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Syringe issue | | 1 | | 1 | | |
| Tachycardia | 1 | 2 | 1 | 2 | | |
| Type I hypersensitivity | 1 | 1 | | | 1 | 1 |
| Underdose | | 1 | | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 18 | 19 | 18 | 19 | | |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| | 188 | 222 | 134 | 165 | 54 | 57 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Immunisation anxiety related reaction | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | | | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 3 | 3 | 3 | | |
| | 11 | 11 | 7 | 7 | 4 | 4 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Chills | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

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Country Where Event Occurred

FINLAND

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 2 | 2 | | | 2 | 2 |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 5 | 5 | 2 | 2 | 3 | 3 |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 4 | 4 | | | 4 | 4 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 8 | 10 | | | 8 | 10 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Aphonia | 3 | 3 | 1 | 1 | 2 | 2 |
| Appendicitis | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 4 | 4 | | | 4 | 4 |
| Arthralgia | 14 | 14 | 4 | 4 | 10 | 10 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Arthritis reactive | 1 | 1 | | | 1 | 1 |
| Asthenia | 18 | 20 | 3 | 5 | 15 | 15 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Axillary pain | 6 | 7 | 3 | 4 | 3 | 3 |
| Back pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure diastolic increased | 1 | 1 | | | 1 | 1 |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 10 | 10 | 1 | 1 | 9 | 9 |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Breast cyst | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 3 | 5 | 1 | 1 | 2 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chest pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Chills | 8 | 8 | 4 | 4 | 4 | 4 |
| Cognitive disorder | 1 | 1 | 1 | 1 | | |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Confusional state | 2 | 2 | | | 2 | 2 |
| Congestive cardiomyopathy | 1 | 1 | | | 1 | 1 |
| Cough | 6 | 7 | | | 6 | 7 |
| C-reactive protein increased | 6 | 7 | | 1 | 6 | 6 |
| Death | 3 | 3 | | | 3 | 3 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Dementia Alzheimer's type | | 1 | | | | 1 |
| Derealisation | | 1 | | 1 | | |
| Diarrhoea | 4 | 4 | 2 | 2 | 2 | 2 |
| Discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dizziness | 11 | 12 | | | 11 | 12 |
| Dry eye | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 4 | 4 | | | 4 | 4 |
| Dysphonia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dyspnoea | 26 | 29 | 3 | 3 | 23 | 26 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Ear pruritus | 1 | 1 | 1 | 1 | | |
| Eczema | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Erythema | 19 | 22 | 4 | 5 | 15 | 17 |
| Erythema multiforme | 1 | 1 | | | 1 | 1 |
| Erythema of eyelid | 1 | 1 | | | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 2 | 2 |
| 4 | 4 | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 6 | 7 |
| | 1 | 6 | 6 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 11 | 12 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 4 | 4 |
| 2 | 2 | 1 | 1 |
| 3 | 3 | 23 | 26 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | 15 | 17 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Extrasystoles | 1 | 2 |
| Eyelid irritation | 1 | 1 |
| Eyelid oedema | 3 | 3 |
| Eye pain | 4 | 4 |
| Face oedema | 5 | 5 |
| Facial pain | 3 | 3 |
| Facial paralysis | 4 | 4 |
| Facial paresis | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 32 | 34 |
| Feeding disorder | 1 | 1 |
| Feeling abnormal | 5 | 5 |
| Feeling cold | 4 | 5 |
| Feeling hot | 8 | 9 |
| Flatulence | 1 | 1 |
| Flushing | 5 | 5 |
| Gait disturbance | 1 | 1 |
| Gastric disorder | 1 | 1 |
| Gaze palsy | 2 | 2 |
| General physical health deterioration | 3 | 3 |
| Gingival swelling | 1 | 1 |
| Grip strength decreased | 1 | 1 |
| Haematoma | 2 | 2 |
| Hallucination, auditory | 1 | 1 |
| Headache | 44 | 47 |
| Head discomfort | 1 | 1 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 11 | 12 |
| Hemianaesthesia | 7 | 7 |
| Hemiparaesthesia | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Hot flush | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | 2 | 2 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 15 | 16 | 17 | 18 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| 1 | 2 | 3 | 3 |
| 1 | 2 | 7 | 7 |
| 1 | 1 | | |
| | | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| 10 | 11 | 34 | 36 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 10 | 11 |
| | | 7 | 7 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Hyperaesthesia | 3 | 3 |
| Hyperhidrosis | 5 | 5 |
| Hypersensitivity | 7 | 8 |
| Hypoaesthesia | 12 | 13 |
| Hypoaesthesia oral | 6 | 7 |
| Hypoaesthesia teeth | 1 | 1 |
| Hypokalaemia | 3 | 5 |
| Hypotension | | 1 |
| Hypotonia | 2 | 2 |
| Impaired work ability | 1 | 1 |
| Incorrect route of product administration | 7 | 7 |
| Increased upper airway secretion | 4 | 4 |
| Inflammatory marker increased | 1 | 1 |
| Insomnia | 3 | 3 |
| Joint range of motion decreased | 1 | 1 |
| Laryngeal pain | 1 | 1 |
| Lip oedema | 1 | 1 |
| Lip pain | 2 | 2 |
| Lip pruritus | 1 | 1 |
| Lip swelling | 2 | 2 |
| Localised oedema | 2 | 2 |
| Loss of consciousness | 1 | 1 |
| Loss of control of legs | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenopathy | 17 | 21 |
| Lymph node pain | 2 | 2 |
| Lymph nodes scan abnormal | 1 | 1 |
| Malaise | 20 | 24 |
| Malignant lymphoid neoplasm | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 1 |
| Memory impairment | 1 | 1 |
| Menstrual disorder | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 3 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | 6 | 7 |
| 2 | 3 | 10 | 10 |
| 1 | 2 | 5 | 5 |
| 1 | 1 | | |
| | | 3 | 5 |
| | | | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 7 | 7 | | |
| | | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 11 | 10 | 10 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 3 | 6 | 17 | 18 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Middle insomnia | 1 | 1 |
| Migraine | 2 | 3 |
| Mobility decreased | 1 | 1 |
| Monoparesis | 1 | 1 |
| Mouth swelling | 2 | 2 |
| Movement disorder | 1 | 1 |
| Muscle fatigue | 1 | 1 |
| Muscle spasms | 2 | 2 |
| Muscle spasticity | 1 | 1 |
| Muscle twitching | 3 | 3 |
| Muscular weakness | 8 | 8 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal pain | 2 | 2 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 25 | 28 |
| Mydriasis | 1 | 1 |
| Myocarditis | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nausea | 23 | 25 |
| Neck pain | 3 | 3 |
| Neuralgia | 3 | 3 |
| Neurological symptom | 1 | 1 |
| Night sweats | 1 | 1 |
| Nodule | | 1 |
| Nuchal rigidity | 1 | 2 |
| Obstruction | 1 | 1 |
| Oedema peripheral | 2 | 2 |
| Off label use | 1 | 1 |
| Opisthotonus | 1 | 1 |
| Oral discomfort | 1 | 1 |
| Oral mucosal blistering | | 1 |
| Oral pruritus | 3 | 4 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 2 | 2 | 6 | 6 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| 3 | 6 | 22 | 22 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 6 | 18 | 19 |
| | | 3 | 3 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 3 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oropharyngeal discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Oropharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 7 | 7 | 3 | 3 | 4 | 4 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 5 | 5 | 1 | 1 | 4 | 4 |
| Pain in extremity | 31 | 34 | 12 | 15 | 19 | 19 |
| Pain of skin | 2 | 2 | 1 | 1 | 1 | 1 |
| Pallor | 2 | 2 | | | 2 | 2 |
| Palpitations | 9 | 10 | 2 | 3 | 7 | 7 |
| Papule | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 16 | 17 | 5 | 5 | 11 | 12 |
| Paraesthesia oral | 9 | 10 | 2 | 3 | 7 | 7 |
| Pharyngeal hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Pharyngeal oedema | 4 | 5 | 1 | 1 | 3 | 4 |
| Pharyngeal paraesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Pharyngeal swelling | 2 | 3 | | | 2 | 3 |
| Photophobia | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 2 | | 1 | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pruritus | 7 | 7 | 5 | 5 | 2 | 2 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | | | 1 | 1 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 38 | 41 | 6 | 9 | 32 | 32 |
| Rash | 3 | 5 | 1 | 1 | 2 | 4 |
| Rash erythematous | | 1 | | 1 | | |
| Rash macular | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| Respiratory tract irritation | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rhinorrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Seizure | | 1 | | | | 1 |
| Self-injurious ideation | 1 | 1 | | | 1 | 1 |
| Sensation of foreign body | 5 | 5 | 1 | 1 | 4 | 4 |
| Sensory disturbance | 1 | 1 | 1 | 1 | | |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 2 | | 1 | 1 | 1 |
| Stiff tongue | 1 | 1 | | | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Swelling | 3 | 3 | 1 | 1 | 2 | 2 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Swelling of eyelid | 1 | 1 | | | 1 | 1 |
| Syncope | 3 | 4 | | | 3 | 4 |
| Synovial fluid white blood cells positive | 1 | 1 | | | 1 | 1 |
| Tachycardia | 4 | 6 | | 1 | 4 | 5 |
| Throat irritation | 8 | 9 | 2 | 2 | 6 | 7 |
| Throat tightness | 2 | 2 | | | 2 | 2 |
| Thrombophlebitis superficial | 1 | 1 | | | 1 | 1 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Toothache | 1 | 1 | 1 | 1 | | |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 4 | | | 3 | 4 |
| Type IV hypersensitivity reaction | | 1 | | 1 | | |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urticaria | 15 | 16 | 6 | 6 | 9 | 10 |
| Vaccination site abscess | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 14 | 16 | 9 | 11 | 5 | 5 |
| Vaccination site haematoma | 3 | 4 | 3 | 4 | | |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 4 |
| | | 1 | 1 |
| | 1 | 4 | 5 |
| 2 | 2 | 6 | 7 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 6 | 6 | 9 | 10 |
| | | 1 | 1 |
| 9 | 11 | 5 | 5 |
| 3 | 4 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site hyperaesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 2 | 2 | 2 | 2 | | |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site macule | | 1 | | 1 | | |
| Vaccination site movement impairment | 4 | 4 | | | 4 | 4 |
| Vaccination site oedema | 8 | 10 | 7 | 9 | 1 | 1 |
| Vaccination site pain | 26 | 28 | 12 | 14 | 14 | 14 |
| Vaccination site plaque | | 1 | | 1 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 6 | 6 | 2 | 2 | 4 | 4 |
| Vaccination site warmth | 5 | 8 | 2 | 5 | 3 | 3 |
| Vertigo | 2 | 2 | | | 2 | 2 |
| Viral infection | 2 | 2 | | | 2 | 2 |
| Vision blurred | 2 | 2 | | | 2 | 2 |
| Vomiting | 6 | 7 | 2 | 2 | 4 | 5 |
| Wheezing | 3 | 3 | 1 | 1 | 2 | 2 |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 895 | 984 | 238 | 290 | 657 | 694 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Ankylosing spondylitis | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Apnoea | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 4 | 1 | 2 | 2 | 2 |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 2 | | 1 | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 2 | 2 | | | 2 | 2 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Dementia Alzheimer's type | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Dizziness | 4 | 4 | | | 4 | 4 |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 6 | 6 | 1 | 1 | 5 | 5 |
| Ear canal erythema | 1 | 1 | 1 | 1 | | |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Eczema | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Eye haematoma | 1 | 1 | | | 1 | 1 |
| Eyelid ptosis | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Facial paralysis | 3 | 3 |
| Fatigue | 8 | 8 |
| Flank pain | 1 | 1 |
| Foaming at mouth | 1 | 1 |
| Gait disturbance | | 1 |
| General physical health deterioration | 4 | 4 |
| Headache | 3 | 3 |
| Head discomfort | 1 | 1 |
| Heart rate increased | 1 | 1 |
| Heart rate irregular | 1 | 1 |
| Herpes zoster | 1 | 1 |
| Herpes zoster cutaneous disseminated | 1 | 1 |
| Hyperventilation | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Irritability postvaccinal | | 1 |
| Loss of consciousness | 1 | 1 |
| Loss of control of legs | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Malaise | 3 | 3 |
| Middle insomnia | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 2 | 2 |
| Nasal congestion | 1 | 1 |
| Nasal oedema | 1 | 1 |
| Nausea | 6 | 6 |
| Oral disorder | 1 | 1 |
| Oral herpes | 1 | 1 |
| Pain in extremity | 3 | 3 |
| Pain of skin | 1 | 1 |
| Pallor | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 3 |
| 1 | 1 | 7 | 7 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Paraesthesia | 1 | 1 |
| Pneumonia | 1 | 1 |
| Pneumonia aspiration | 1 | 1 |
| Productive cough | 1 | 1 |
| Pyrexia | 7 | 7 |
| Rash erythematous | 1 | 1 |
| Rash macular | 1 | 1 |
| Respiratory arrest | 1 | 1 |
| Respiratory tract infection | 1 | 1 |
| Rhonchi | 1 | 1 |
| Rinne tuning fork test abnormal | 1 | 1 |
| Seizure | 1 | 1 |
| Slow speech | 1 | 1 |
| Somnolence | 2 | 2 |
| Speech disorder | 1 | 1 |
| Subcutaneous abscess | 1 | 1 |
| Sudden death | 1 | 1 |
| Swelling face | 1 | 1 |
| Tendon pain | 1 | 1 |
| Tremor | 1 | 1 |
| Tympanic membrane hyperaemia | 1 | 1 |
| Vaccination site erythema | 2 | 2 |
| Vaccination site hyperaesthesia | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 1 |
| Vaccination site movement impairment | 2 | 2 |
| Vaccination site oedema | 2 | 2 |
| Vaccination site pain | 7 | 8 |
| Vertigo | 1 | 1 |
| Visual impairment | 2 | 2 |
| Vomiting | 2 | 2 |
| Weber tuning fork test abnormal | 1 | 1 |
| Wheezing | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 1 | 2 | 6 | 6 |
| | | 1 | 1 |
| | | 2 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 152 | 158 | 24 | 30 | 128 | 128 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Poor quality product administered | 12 | 12 | 12 | 12 |
| Product preparation error | 12 | 12 | 12 | 12 |
| | 24 | 24 | 24 | 24 |

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Country Where Event Occurred

FRANCE

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 19 | 21 | 12 | 13 | 7 | 8 |
| Abdominal pain upper | 6 | 6 | | | 6 | 6 |
| Accidental overdose | 1 | 2 | 1 | 2 | | |
| Acute coronary syndrome | 3 | 3 | | | 3 | 3 |
| Acute febrile neutrophilic dermatosis | 1 | 1 | | | 1 | 1 |
| Acute kidney injury | 4 | 4 | | | 4 | 4 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute pulmonary oedema | 6 | 6 | | | 6 | 6 |
| Acute respiratory distress syndrome | 4 | 4 | | | 4 | 4 |
| Acute respiratory failure | 2 | 3 | | | 2 | 3 |
| Acute vestibular syndrome | 1 | 1 | | | 1 | 1 |
| Aerococcus urinae infection | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Aggression | 2 | 2 | | | 2 | 2 |
| Agitation | 5 | 5 | 1 | 1 | 4 | 4 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | 3 | 3 | 1 | 1 | 2 | 2 |
| Altered state of consciousness | 5 | 5 | | | 5 | 5 |
| Amaurosis fugax | 1 | 1 | | | 1 | 1 |
| Anaesthesia oral | 2 | 2 | | | 2 | 2 |
| Anaphylactic reaction | 14 | 15 | | | 14 | 15 |
| Anaphylactic shock | 5 | 6 | | | 5 | 6 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Angioedema | 8 | 9 | | | 8 | 9 |
| Ankylosing spondylitis | 2 | 2 | | | 2 | 2 |
| Anosmia | 2 | 2 | | | 2 | 2 |
| Anuria | 1 | 1 | | | 1 | 1 |
| Anxiety | 3 | 5 | 1 | 1 | 2 | 4 |
| Anxiety disorder | 1 | 1 | 1 | 1 | | |
| Aortic dissection | | 1 | | | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Apathy | 1 | 1 |
| Aphasia | 5 | 5 |
| Aphonia | 1 | 1 |
| Aphthous ulcer | 2 | 2 |
| Arrhythmia | 6 | 8 |
| Arrhythmia supraventricular | 1 | 2 |
| Arthralgia | 36 | 37 |
| Arthritis | 1 | 1 |
| Aspartate aminotransferase increased | 2 | 2 |
| Asthenia | 128 | 130 |
| Asthma | 4 | 4 |
| Asthmatic crisis | 2 | 2 |
| Asymptomatic COVID-19 | 1 | 1 |
| Atrial f brillation | 5 | 7 |
| Atrial flutter | 1 | 1 |
| Atrioventricular block | 1 | 1 |
| Atrioventricular block complete | 2 | 2 |
| Aura | 1 | 1 |
| Axillary pain | 5 | 5 |
| Back pain | 7 | 7 |
| Balance disorder | 6 | 6 |
| Behaviour disorder | 2 | 2 |
| Benign breast neoplasm | 1 | 1 |
| Bipolar disorder | 1 | 1 |
| Blood alkaline phosphatase increased | 1 | 1 |
| Blood pressure decreased | 7 | 7 |
| Blood pressure increased | 3 | 3 |
| Blood pressure systolic decreased | 1 | 1 |
| Blood pressure systolic increased | | 1 |
| Blood thyroid stimulating hormone increased | 1 | 1 |
| Body temperature decreased | 2 | 2 |
| Body temperature increased | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 6 | 8 |
| | | 1 | 2 |
| 15 | 16 | 21 | 21 |
| | | 1 | 1 |
| 2 | 2 | | |
| 57 | 59 | 71 | 71 |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 5 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 3 | 3 | 2 | 2 |
| 4 | 4 | 3 | 3 |
| 1 | 1 | 5 | 5 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 7 | 7 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |

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|-------------------------------------|------------------------------------|--------------------------------------|
| Bradycardia | 9 | 9 |
| Brain natriuretic peptide increased | 1 | 1 |
| Breast swelling | 1 | 1 |
| Bronchial obstruction | | 1 |
| Bronchiolitis | 1 | 1 |
| Bronchopneumopathy | 1 | 1 |
| Bronchospasm | 4 | 4 |
| Bundle branch block | 1 | 1 |
| Bundle branch block left | 1 | 1 |
| Bundle branch block right | 2 | 2 |
| Burning sensation | 4 | 5 |
| Bursitis | 2 | 2 |
| Cardiac arrest | 1 | 2 |
| Cardiac disorder | 1 | 1 |
| Cardiac failure | 10 | 11 |
| Cardiac failure acute | 2 | 2 |
| Cardiac failure congestive | 1 | 1 |
| Cardiac fibrillation | 1 | 1 |
| Cardiac flutter | 1 | 1 |
| Cardiogenic shock | 3 | 3 |
| Cardiomegaly | 1 | 1 |
| Cardiopulmonary failure | 1 | 1 |
| Cardio-respiratory arrest | 4 | 5 |
| Cardiovascular disorder | 1 | 1 |
| Cellulitis | 1 | 1 |
| Central nervous system lesion | 1 | 1 |
| Cerebral artery stenosis | 1 | 1 |
| Cerebral haematoma | 2 | 2 |
| Cerebral haemorrhage | 1 | 1 |
| Cerebral hyperperfusion syndrome | 1 | 1 |
| Cerebrovascular accident | 7 | 9 |
| Chest discomfort | 14 | 14 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 9 | 9 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 2 | 3 | 3 |
| 1 | 1 | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 10 | 11 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 7 | 9 |
| 8 | 8 | 6 | 6 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chest injury | 1 | 1 | | | 1 | 1 |
| Chest pain | 11 | 12 | 4 | 4 | 7 | 8 |
| Chillblains | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 56 | 59 | 18 | 21 | 38 | 38 |
| Choking | 1 | 1 | | | 1 | 1 |
| Choking sensation | 1 | 1 | 1 | 1 | | |
| Cholecystitis | 1 | 1 | | | 1 | 1 |
| Cholestatic liver injury | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 2 | 2 | | | 2 | 2 |
| Circulatory collapse | 3 | 3 | | | 3 | 3 |
| Clonus | 1 | 1 | | | 1 | 1 |
| Cognitive disorder | 2 | 3 | 2 | 2 | | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Coma | 3 | 3 | | | 3 | 3 |
| Condition aggravated | 4 | 5 | 1 | 1 | 3 | 4 |
| Confusional state | 5 | 6 | | | 5 | 6 |
| Conjunctival haemorrhage | 5 | 5 | | | 5 | 5 |
| Conjunctivitis | 1 | 1 | | | 1 | 1 |
| Constipation | 1 | 2 | 1 | 2 | | |
| Coordination abnormal | 1 | 1 | 1 | 1 | | |
| Coronavirus infection | 2 | 2 | 1 | 1 | 1 | 1 |
| Costovertebral angle tenderness | 1 | 1 | | | 1 | 1 |
| Cough | 16 | 17 | 6 | 7 | 10 | 10 |
| COVID-19 | 56 | 61 | 10 | 10 | 46 | 51 |
| COVID-19 pneumonia | 2 | 2 | | | 2 | 2 |
| C-reactive protein increased | 9 | 9 | 6 | 6 | 3 | 3 |
| Creatinine renal clearance decreased | 1 | 1 | | | 1 | 1 |
| Crepitations | 1 | 1 | | | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 | | | 1 | 1 |
| Cyanosis | 4 | 4 | | | 4 | 4 |
| Cystitis klebsiella | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | 2 | 2 | | | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 4 | 4 | 7 | 8 |
| 1 | 1 | 1 | 1 |
| 18 | 21 | 38 | 38 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| 2 | 2 | | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | 3 | 4 |
| | | 5 | 6 |
| | | 5 | 5 |
| | | 1 | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 6 | 7 | 10 | 10 |
| 10 | 10 | 46 | 51 |
| | | 2 | 2 |
| 6 | 6 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Death | 27 | 30 |
| Decreased appetite | 10 | 10 |
| Deep vein thrombosis | 2 | 2 |
| Dehydration | 2 | 2 |
| Dementia | 1 | 1 |
| Depressed level of consciousness | 7 | 8 |
| Dermo-hypodermatitis | 2 | 2 |
| Diabetes mellitus | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 |
| Diabetic ketosis | 1 | 1 |
| Diabetic metabolic decompensation | 1 | 1 |
| Diarrhoea | 37 | 41 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplopia | 2 | 2 |
| Discomfort | 12 | 12 |
| Disease recurrence | 10 | 10 |
| Disinhibition | 1 | 1 |
| Disorientation | 4 | 4 |
| Disturbance in attention | 5 | 5 |
| Dizziness | 29 | 31 |
| Dizziness postural | 1 | 1 |
| Droling | 1 | 1 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 38 | 44 |
| Dry mouth | 2 | 2 |
| Dry throat | 2 | 2 |
| Dysaesthesia | 3 | 3 |
| Dysarthria | 4 | 5 |
| Dysgeusia | 8 | 8 |
| Dysphagia | 7 | 9 |
| Dysphemia | 2 | 2 |
| Dysphonia | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 27 | 30 |
| 4 | 4 | 6 | 6 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 7 | 8 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 14 | 16 | 23 | 25 |
| | | 1 | 1 |
| | | 2 | 2 |
| 2 | 2 | 10 | 10 |
| | | 10 | 10 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 4 | 4 |
| 9 | 10 | 20 | 21 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 38 | 44 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 3 | 3 | | |
| 1 | 1 | 3 | 4 |
| 3 | 3 | 5 | 5 |
| 2 | 2 | 5 | 7 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |

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Gender

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dyspnoea | 36 | 39 |
| Dyspnoea exertional | 1 | 1 |
| Dysstasia | 1 | 1 |
| Dysuria | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear disorder | 1 | 1 |
| Ear pain | 3 | 3 |
| Eating disorder | 1 | 1 |
| Electrocardiogram T wave inversion | 1 | 1 |
| Encephalitis | 1 | 1 |
| Eosinophil count increased | 1 | 1 |
| Epilepsy | 3 | 3 |
| Epistaxis | 1 | 1 |
| Epstein-Barr virus infection | 1 | 1 |
| Epstein-Barr virus test positive | 1 | 1 |
| Erectile dysfunction | 1 | 1 |
| Eructation | 3 | 3 |
| Erysipelas | 1 | 1 |
| Erythema | 27 | 29 |
| Erythema of eyelid | 1 | 1 |
| Escherichia urinary tract infection | 1 | 1 |
| Exposure via breast milk | | 1 |
| Extensive swelling of vaccinated limb | 3 | 3 |
| Extensor plantar response | 1 | 1 |
| Extradural haematoma | 1 | 1 |
| Eye disorder | 1 | 1 |
| Eye injury | 1 | 1 |
| Eye irritation | 1 | 1 |
| Eyelid irritation | | 1 |
| Eyelid oedema | 4 | 4 |
| Eyelid ptosis | 1 | 1 |
| Eye pain | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 6 | 6 | 30 | 33 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 10 | 12 | 17 | 17 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 2 | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |

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FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Face oedema | 9 | 9 |
| Facial pain | 2 | 2 |
| Facial paralysis | 18 | 18 |
| Facial paresis | 1 | 1 |
| Faecal vomiting | 2 | 2 |
| Fall | 14 | 15 |
| Fatigue | 71 | 73 |
| Fear | | 1 |
| Feeling abnormal | 4 | 4 |
| Feeling cold | 7 | 7 |
| Feeling drunk | 4 | 4 |
| Feeling hot | 6 | 6 |
| Feeling of body temperature change | 1 | 1 |
| Flushing | 7 | 7 |
| Foaming at mouth | 1 | 1 |
| Food aversion | 1 | 1 |
| Formication | 3 | 4 |
| Frostbite | 1 | 1 |
| Gait disturbance | 7 | 7 |
| Gait inability | 2 | 2 |
| Gamma-glutamyltransferase increased | 1 | 1 |
| Gastric volvulus | 1 | 1 |
| Gastrointestinal disorder | 2 | 2 |
| Gastrointestinal haemorrhage | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 |
| Gastrointestinal motility disorder | 1 | 1 |
| Gastrointestinal pain | 3 | 3 |
| Generalised oedema | 1 | 1 |
| General physical health deterioration | 9 | 9 |
| Gingival discomfort | 1 | 1 |
| Glomerular filtration rate decreased | 2 | 2 |
| Gout | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 8 | 8 |
| | | 2 | 2 |
| | | 18 | 18 |
| | | 1 | 1 |
| | | 2 | 2 |
| 3 | 3 | 11 | 12 |
| 35 | 37 | 36 | 36 |
| | | | 1 |
| 3 | 3 | 1 | 1 |
| 4 | 4 | 3 | 3 |
| 3 | 3 | 1 | 1 |
| 2 | 2 | 4 | 4 |
| 1 | 1 | | |
| 2 | 2 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 1 | 2 |
| 1 | 1 | | |
| 3 | 3 | 4 | 4 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 9 | 9 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haemarthrosis | 1 | 1 | | | 1 | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haematochezia | 2 | 2 | | | 2 | 2 |
| Haematoma | 3 | 3 | | | 3 | 3 |
| Haemodynamic instability | 1 | 1 | 1 | 1 | | |
| Haemoglobin decreased | 2 | 2 | 2 | 2 | | |
| Haemorrhagic stroke | 3 | 4 | | | 3 | 4 |
| Haemothorax | 1 | 1 | | | 1 | 1 |
| Hair colour changes | 1 | 1 | 1 | 1 | | |
| Hallucination, auditory | 1 | 1 | | | 1 | 1 |
| Hallucinations, mixed | 1 | 1 | | | 1 | 1 |
| Headache | 152 | 158 | 64 | 70 | 88 | 88 |
| Head discomfort | 3 | 3 | 2 | 2 | 1 | 1 |
| Head injury | 3 | 3 | | | 3 | 3 |
| Heart rate increased | 5 | 5 | 2 | 2 | 3 | 3 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Heart sounds abnormal | 1 | 1 | | | 1 | 1 |
| Hemianopia homonymous | 1 | 1 | | | 1 | 1 |
| Hemiparaesthesia | 1 | 1 | | | 1 | 1 |
| Hemiparesis | 5 | 5 | | | 5 | 5 |
| Hemiplegia | 4 | 4 | | | 4 | 4 |
| Hepatic function abnormal | 1 | 1 | 1 | 1 | | |
| Hepatitis cholestatic | 1 | 1 | | | 1 | 1 |
| Hepatitis infectious mononucleosis | 1 | 1 | | | 1 | 1 |
| Hepatocellular injury | 3 | 3 | | | 3 | 3 |
| Herpes zoster | 7 | 7 | | | 7 | 7 |
| High-pitched crying | 1 | 1 | 1 | 1 | | |
| Hot flush | 15 | 16 | 7 | 8 | 8 | 8 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 15 | 16 | 4 | 5 | 11 | 11 |
| Hyperkalaemia | 3 | 3 | | | 3 | 3 |
| Hyperleukocytosis | 3 | 3 | | | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 3 | 3 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 3 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 64 | 70 | 88 | 88 |
| 2 | 2 | 1 | 1 |
| | | 3 | 3 |
| 2 | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 7 | 7 |
| 1 | 1 | | |
| 7 | 8 | 8 | 8 |
| | | 1 | 1 |
| 4 | 5 | 11 | 11 |
| | | 3 | 3 |
| | | 3 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypernatraemia | 2 | 2 |
| Hypersensitivity | 27 | 28 |
| Hypersensitivity vasculitis | 1 | 1 |
| Hypersomnia | 2 | 2 |
| Hypertension | 71 | 73 |
| Hypertensive crisis | 6 | 6 |
| Hyperthermia | 11 | 11 |
| Hyperthyroidism | 1 | 1 |
| Hypertonia | | 1 |
| Hyperventilation | 2 | 2 |
| Hypoacusis | 2 | 2 |
| Hypoaesthesia | 7 | 7 |
| Hypoaesthesia oral | 3 | 3 |
| Hypocalcaemia | 1 | 1 |
| Hypoglycaemia | 4 | 4 |
| Hypokalaemia | 2 | 2 |
| Hypokinesia | 2 | 2 |
| Hypoperfusion | 2 | 2 |
| Hypotension | 39 | 40 |
| Hypothermia | 5 | 5 |
| Hypotonia | 1 | 1 |
| Hypoventilation | 1 | 1 |
| Hypoxia | 7 | 7 |
| Illrd nerve paralysis | 1 | 1 |
| Ill-defined disorder | 1 | 1 |
| Illness | 1 | 1 |
| Impaired work ability | 2 | 2 |
| Inappropriate schedule of product administration | 2 | 4 |
| Incorrect dose administered | 1 | 1 |
| Incorrect route of product administration | 6 | 7 |
| Increased bronchial secretion | 1 | 2 |
| Infarction | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 12 | 12 | 15 | 16 |
| | | 1 | 1 |
| | | 2 | 2 |
| 9 | 11 | 62 | 62 |
| | | 6 | 6 |
| 4 | 4 | 7 | 7 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| | | 2 | 2 |
| 5 | 5 | 2 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 11 | 11 | 28 | 29 |
| | | 5 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 3 | 1 | 1 |
| 1 | 1 | | |
| 6 | 7 | | |
| | | 1 | 2 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Infection | 2 | 2 |
| Inflammation | 6 | 6 |
| Inflammatory pain | 1 | 1 |
| Influenza | 4 | 4 |
| Influenza like illness | 25 | 25 |
| Initial insomnia | 1 | 1 |
| Injected limb mobility decreased | 7 | 7 |
| Injection site erythema | | 1 |
| Injection site pain | | 1 |
| Injection site rash | 1 | 1 |
| Insomnia | 9 | 10 |
| Insulin-requiring type 2 diabetes mellitus | 1 | 1 |
| Intercostal neuralgia | 1 | 1 |
| International normalised ratio abnormal | 1 | 1 |
| Interstitial lung disease | 1 | 1 |
| Intracardiac thrombus | 1 | 1 |
| Intracranial haematoma | 1 | 1 |
| Iron deficiency anaemia | 1 | 1 |
| Ischaemic cardiomyopathy | 1 | 1 |
| Ischaemic stroke | 7 | 8 |
| Jaundice | 1 | 1 |
| Joint effusion | 1 | 1 |
| Joint stiffness | 1 | 1 |
| Jugular vein thrombosis | 1 | 1 |
| Lacrimation increased | 3 | 3 |
| Lactic acidosis | 1 | 1 |
| Language disorder | 2 | 2 |
| Laryngeal discomfort | 3 | 3 |
| Laryngeal dyspnoea | 2 | 2 |
| Laryngeal oedema | 3 | 3 |
| Laryngitis | 1 | 1 |
| Left ventricular failure | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| 2 | 2 | 4 | 4 |
| | | 1 | 1 |
| | | 4 | 4 |
| 4 | 4 | 21 | 21 |
| | | 1 | 1 |
| 2 | 2 | 5 | 5 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 3 | 4 | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 7 | 8 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Left ventricular hypertrophy | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Leukopenia | 1 | 1 |
| Lichen planus | 1 | 1 |
| Limb discomfort | 3 | 3 |
| Lip oedema | 3 | 4 |
| Lip pruritus | 1 | 1 |
| Lip swelling | 3 | 3 |
| Listless | 1 | 1 |
| Livedo reticularis | 3 | 3 |
| Liver injury | 1 | 1 |
| Lividity | 1 | 1 |
| Localised oedema | 2 | 2 |
| Logorrhoea | 1 | 1 |
| Loss of consciousness | 15 | 17 |
| Lower respiratory tract infection | 1 | 1 |
| Lung disorder | 4 | 4 |
| Lymphadenitis | 2 | 2 |
| Lymphadenopathy | 25 | 25 |
| Lymph node pain | 1 | 1 |
| Lymphocyte count decreased | 1 | 1 |
| Lymphopenia | 2 | 3 |
| Macroglossia | 1 | 1 |
| Malaise | 73 | 82 |
| Melaena | 1 | 1 |
| Memory impairment | 2 | 2 |
| Mental fatigue | 1 | 1 |
| Metamorphopsia | 1 | 1 |
| Metastases to peritoneum | 1 | 1 |
| Microembolism | 1 | 1 |
| Middle insomnia | 1 | 1 |
| Migraine | 11 | 11 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | | |
| 1 | 1 | 2 | 3 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 15 | 17 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 2 | 2 | | |
| 15 | 15 | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| 23 | 27 | 50 | 55 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 5 | 6 | 6 |

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|----------------------------|------------------------------------|--------------------------------------|
| Migraine with aura | 3 | 3 |
| Miosis | 1 | 1 |
| Mitral valve disease | 1 | 1 |
| Mobility decreased | 3 | 3 |
| Mononucleosis syndrome | 1 | 1 |
| Monoplegia | 1 | 1 |
| Motor dysfunction | 1 | 1 |
| Movement disorder | 1 | 1 |
| Mucosal pain | 1 | 1 |
| Muscle contracture | 3 | 3 |
| Muscle spasms | 6 | 6 |
| Muscle tightness | 1 | 1 |
| Muscular weakness | 3 | 3 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal disorder | 2 | 2 |
| Musculoskeletal stiffness | 23 | 24 |
| Myalgia | 73 | 75 |
| Myalgia intercostal | 1 | 1 |
| Mydriasis | 1 | 1 |
| Myocardial infarction | 10 | 10 |
| Myocardial necrosis | 1 | 1 |
| Myoclonus | 2 | 2 |
| Myokymia | 1 | 1 |
| Myositis | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 76 | 84 |
| Neck pain | 9 | 10 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 11 | 11 |
| Neuromuscular pain | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 2 | 2 | 4 | 4 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 4 | 5 | 19 | 19 |
| 33 | 35 | 40 | 40 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 10 | 10 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 28 | 34 | 48 | 50 |
| 2 | 3 | 7 | 7 |
| | | 1 | 1 |
| 4 | 4 | 7 | 7 |
| 1 | 1 | | |

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Gender

FEMALE

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|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Neutropenia | 2 | 2 | | | 2 | 2 |
| Neutrophil count abnormal | 1 | 1 | | | 1 | 1 |
| Neutrophil count decreased | 1 | 1 | | | 1 | 1 |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| Neutrophilic dermatosis | 1 | 1 | | | 1 | 1 |
| Nightmare | 1 | 1 | 1 | 1 | | |
| N-terminal prohormone brain natriuretic peptide increased | 1 | 1 | | | 1 | 1 |
| Nystagmus | 1 | 1 | | | 1 | 1 |
| Obstructive airways disorder | 1 | 1 | 1 | 1 | | |
| Occupational exposure to product | 1 | 2 | 1 | 2 | | |
| Ocular discomfort | 2 | 3 | 2 | 3 | | |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Odynophagia | 1 | 1 | | | 1 | 1 |
| Oedema | 2 | 2 | | | 2 | 2 |
| Oedema peripheral | 8 | 8 | 1 | 1 | 7 | 7 |
| Oesophageal pain | 1 | 1 | | | 1 | 1 |
| Off label use | 7 | 7 | 7 | 7 | | |
| Ophthalmic herpes zoster | 3 | 3 | | | 3 | 3 |
| Optic ischaemic neuropathy | 1 | 1 | | | 1 | 1 |
| Oral discomfort | | 1 | | 1 | | |
| Oral dysaesthesia | 1 | 1 | 1 | 1 | | |
| Oral pain | 2 | 2 | 2 | 2 | | |
| Oral pruritus | 2 | 2 | | | 2 | 2 |
| Oropharyngeal discomfort | 1 | 2 | 1 | 1 | | 1 |
| Oropharyngeal pain | 5 | 5 | 5 | 5 | | |
| Oropharyngeal swelling | 1 | 1 | | | 1 | 1 |
| Overdose | | 4 | | 4 | | |
| Oxygen saturation decreased | 34 | 35 | 2 | 2 | 32 | 33 |
| Pain | 31 | 32 | 15 | 16 | 16 | 16 |
| Pain in extremity | 22 | 23 | 7 | 8 | 15 | 15 |

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FEMALE

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|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pain in jaw | 2 | 2 | 2 | 2 | | |
| Palatal oedema | 1 | 1 | | | 1 | 1 |
| Pallor | 5 | 5 | | | 5 | 5 |
| Palpitations | 7 | 8 | 3 | 4 | 4 | 4 |
| Pancreatitis acute | 2 | 2 | | | 2 | 2 |
| Pancytopenia | 2 | 2 | | | 2 | 2 |
| Papule | 1 | 2 | | 1 | 1 | 1 |
| Paraesthesia | 38 | 39 | 12 | 13 | 26 | 26 |
| Paraesthesia oral | 8 | 8 | 3 | 3 | 5 | 5 |
| Paralysis | 3 | 3 | | | 3 | 3 |
| Parosmia | 2 | 2 | 2 | 2 | | |
| Partial seizures | 1 | 1 | | | 1 | 1 |
| Peau d'orange | 1 | 1 | 1 | 1 | | |
| Periarthritis | 1 | 1 | | | 1 | 1 |
| Pericarditis | 5 | 5 | | | 5 | 5 |
| Peripheral coldness | 2 | 2 | 1 | 1 | 1 | 1 |
| Peripheral swelling | 4 | 4 | 2 | 2 | 2 | 2 |
| Pernio-like erythema | 1 | 1 | 1 | 1 | | |
| Persistent depressive disorder | 1 | 1 | | | 1 | 1 |
| Petechiae | 1 | 1 | 1 | 1 | | |
| Petit mal epilepsy | | 1 | | | | 1 |
| Phaeochromocytoma | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorder | 1 | 1 | | | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Phonophobia | 2 | 2 | 1 | 1 | 1 | 1 |
| Photophobia | 3 | 3 | | | 3 | 3 |
| Photopsia | 1 | 1 | | | 1 | 1 |
| Photosensitivity reaction | 1 | 1 | 1 | 1 | | |
| Piloerection | 1 | 1 | | | 1 | 1 |
| Platelet count decreased | 1 | 1 | 1 | 1 | | |
| Pneumonia | 5 | 5 | | | 5 | 5 |
| Pneumonia aspiration | 6 | 6 | | | 6 | 6 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 5 | 5 |
| 3 | 4 | 4 | 4 |
| | | 2 | 2 |
| | | 2 | 2 |
| | 1 | 1 | 1 |
| 12 | 13 | 26 | 26 |
| 3 | 3 | 5 | 5 |
| | | 3 | 3 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 5 | 5 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 6 | 6 |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Pneumonitis | 1 | 1 |
| Pneumoperitoneum | 1 | 1 |
| Polyarthritits | 1 | 1 |
| Polydipsia | 1 | 1 |
| Poor quality product administered | 69 | 69 |
| Presyncope | 12 | 12 |
| Product administration error | 1 | 1 |
| Productive cough | 3 | 4 |
| Product preparation error | 1 | 2 |
| Product preparation issue | 2 | 6 |
| Product temperature excursion issue | 69 | 69 |
| Product use issue | 7 | 7 |
| Pruritus | 18 | 20 |
| Psychomotor hyperactivity | 1 | 1 |
| Psychomotor skills impaired | 2 | 2 |
| Pulmonary arterial hypertension | 1 | 1 |
| Pulmonary congestion | 1 | 1 |
| Pulmonary embolism | 10 | 10 |
| Pulmonary infarction | 1 | 1 |
| Pyrexia | 120 | 127 |
| Rales | 1 | 1 |
| Rash | 13 | 14 |
| Rash erythematous | 5 | 5 |
| Rash macular | 2 | 2 |
| Rash maculo-papular | 2 | 2 |
| Rash papular | 1 | 1 |
| Rash pruritic | 4 | 4 |
| Red blood cell sedimentation rate increased | 1 | 1 |
| Renal failure | 2 | 3 |
| Renal impairment | 1 | 1 |
| Respiration abnormal | 1 | 1 |
| Respiratory a kalosis | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 69 | 69 | | |
| 7 | 7 | 5 | 5 |
| | | 1 | 1 |
| 2 | 2 | 1 | 2 |
| 1 | 2 | | |
| 2 | 6 | | |
| 69 | 69 | | |
| 7 | 7 | | |
| 8 | 10 | 10 | 10 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 10 | 10 |
| | | 1 | 1 |
| 42 | 48 | 78 | 79 |
| | | 1 | 1 |
| 9 | 10 | 4 | 4 |
| 1 | 1 | 4 | 4 |
| | | 2 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| 3 | 3 | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |

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Gender

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|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 9 | 9 | | | 9 | 9 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Restlessness | 4 | 4 | 2 | 2 | 2 | 2 |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Rhinitis | 4 | 4 | 2 | 2 | 2 | 2 |
| Rhinorrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Rhonchi | 1 | 1 | | | 1 | 1 |
| Rib fracture | 1 | 1 | | | 1 | 1 |
| Salivary hypersecretion | 3 | 3 | 1 | 1 | 2 | 2 |
| SARS-CoV-2 ant body test negative | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | 5 | 5 | 2 | 2 | 3 | 3 |
| Seizure | 3 | 3 | | | 3 | 3 |
| Sensorimotor disorder | 1 | 1 | | | 1 | 1 |
| Sensory loss | 2 | 2 | | | 2 | 2 |
| Septic shock | 1 | 1 | | | 1 | 1 |
| Serum ferritin increased | 1 | 1 | 1 | 1 | | |
| Shock | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 4 | 4 | 1 | 1 | 3 | 3 |
| Skin plaque | 3 | 3 | 2 | 2 | 1 | 1 |
| Skin warm | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 2 | 2 | | | 2 | 2 |
| Sleep disorder due to general medical condition, insomnia type | 1 | 1 | 1 | 1 | | |
| Sleep talking | 1 | 1 | 1 | 1 | | |
| Sluggishness | 1 | 1 | 1 | 1 | | |
| Somnolence | 8 | 8 | 3 | 3 | 5 | 5 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Spinal osteoarthritis | 1 | 1 | 1 | 1 | | |
| Spinal pain | 1 | 1 | | | 1 | 1 |
| Spondylitis | 1 | 1 | | | 1 | 1 |

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|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Status epilepticus | 1 | 1 | | | 1 | 1 |
| Stomatitis | 1 | 1 | | | 1 | 1 |
| Stress | 2 | 2 | 1 | 1 | 1 | 1 |
| Subileus | 1 | 1 | | | 1 | 1 |
| Sudden death | 13 | 17 | | | 13 | 17 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Suicidal ideation | 1 | 1 | | | 1 | 1 |
| Supraventricular tachycardia | 5 | 5 | | | 5 | 5 |
| Suspected COVID-19 | 1 | 2 | | | 1 | 2 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 3 | 4 | 1 | 2 | 2 | 2 |
| Syncope | 9 | 9 | | | 9 | 9 |
| Synovial cyst | 1 | 1 | | | 1 | 1 |
| Systemic lupus erythematosus | 1 | 1 | | | 1 | 1 |
| Tachyarrhythmia | 2 | 2 | 1 | 1 | 1 | 1 |
| Tachycardia | 59 | 62 | 16 | 18 | 43 | 44 |
| Tachypnoea | 6 | 6 | | | 6 | 6 |
| Tendonitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Tendon pain | 2 | 2 | 2 | 2 | | |
| Tension | 2 | 2 | 1 | 1 | 1 | 1 |
| Tension headache | 1 | 1 | | | 1 | 1 |
| Thermohypoaesthesia | 1 | 1 | 1 | 1 | | |
| Thirst | 3 | 3 | 2 | 2 | 1 | 1 |
| Throat irritation | 2 | 2 | 1 | 1 | 1 | 1 |
| Thrombocytopenia | 2 | 3 | | | 2 | 3 |
| Thrombophlebitis superficial | 1 | 1 | 1 | 1 | | |
| Thyroid mass | 1 | 1 | 1 | 1 | | |
| Tinnitus | 4 | 4 | 1 | 1 | 3 | 3 |
| Tongue coated | 1 | 1 | | | 1 | 1 |
| Tongue discolouration | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 13 | 17 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | 2 | 2 |
| | | 9 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 16 | 18 | 43 | 44 |
| | | 6 | 6 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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|-----------------------------------|------------------------------------|--------------------------------------|
| Tongue dry | 1 | 1 |
| Tongue movement disturbance | 1 | 1 |
| Tongue oedema | 2 | 2 |
| Tonic clonic movements | 1 | 1 |
| Toothache | 1 | 1 |
| Tooth infection | 1 | 1 |
| Transcription medication error | 1 | 1 |
| Transient ischaemic attack | 7 | 7 |
| Tremor | 13 | 13 |
| Trismus | 1 | 1 |
| Tumour perforation | 1 | 1 |
| Type I hypersensitivity | 1 | 1 |
| Type II hypersensitivity | 1 | 1 |
| Underdose | | 3 |
| Unresponsive to stimuli | 2 | 2 |
| Urinary tract candidiasis | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 |
| Urosepsis | 1 | 1 |
| Urticaria | 19 | 21 |
| Vaccination complication | 2 | 2 |
| Vaccination site abscess | 1 | 1 |
| Vaccination site bruising | 1 | 1 |
| Vaccination site coldness | 1 | 1 |
| Vaccination site discolouration | 1 | 1 |
| Vaccination site discomfort | 1 | 1 |
| Vaccination site erythema | 12 | 14 |
| Vaccination site exfoliation | 1 | 1 |
| Vaccination site haematoma | 5 | 5 |
| Vaccination site haemorrhage | 2 | 2 |
| Vaccination site hypersensitivity | 9 | 9 |
| Vaccination site hypoaesthesia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 7 | 7 |
| 4 | 4 | 9 | 9 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 3 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 9 | 9 | 10 | 12 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 11 | 13 | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 9 | 9 | | |
| | | 1 | 1 |

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site induration | 3 | 5 | 3 | 5 | | |
| Vaccination site inflammation | 7 | 7 | 4 | 4 | 3 | 3 |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 6 | 6 | 5 | 5 | 1 | 1 |
| Vaccination site nodule | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site oedema | 4 | 4 | 1 | 1 | 3 | 3 |
| Vaccination site pain | 100 | 101 | 63 | 64 | 37 | 37 |
| Vaccination site papule | 1 | 1 | 1 | 1 | | |
| Vaccination site paraesthesia | 7 | 7 | 4 | 4 | 3 | 3 |
| Vaccination site pruritus | 5 | 7 | 2 | 4 | 3 | 3 |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 2 | 3 | 2 | 3 | | |
| Vaccination site recall reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 6 | 7 | 3 | 4 | 3 | 3 |
| Vaccination site thrombosis | 1 | 1 | | | 1 | 1 |
| Vaccination site urticaria | | 1 | | 1 | | |
| Vaccination site warmth | 5 | 5 | 4 | 4 | 1 | 1 |
| Vascular purpura | 1 | 1 | | | 1 | 1 |
| Vasculitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Vasodilatation | 1 | 1 | 1 | 1 | | |
| Venous oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Vertigo | 21 | 21 | 6 | 6 | 15 | 15 |
| Vertigo positional | 2 | 2 | | | 2 | 2 |
| Vestibular disorder | 1 | 1 | | | 1 | 1 |
| Vestibular neuritis | 2 | 2 | | | 2 | 2 |
| Vision blurred | 3 | 3 | 2 | 2 | 1 | 1 |
| Visual acuity reduced | 1 | 1 | | | 1 | 1 |
| Visual impairment | 3 | 3 | 1 | 1 | 2 | 2 |
| Vomiting | 42 | 44 | 14 | 14 | 28 | 30 |
| Walking disability | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Wrong technique in product usage process | 1 | 2 | 1 | 2 | | |
| | 3,240 | 3,418 | 1131 | 1225 | 2109 | 2193 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 6 | 6 | 1 | 1 | 5 | 5 |
| Abdominal pain upper | 4 | 4 | 3 | 3 | 1 | 1 |
| Abdominal rigidity | 1 | 1 | | | 1 | 1 |
| Abnormal behaviour | 1 | 1 | | | 1 | 1 |
| Acute abdomen | 1 | 1 | | | 1 | 1 |
| Acute coronary syndrome | 2 | 2 | | | 2 | 2 |
| Acute kidney injury | 3 | 3 | | | 3 | 3 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Acute respiratory distress syndrome | 1 | 2 | | | 1 | 2 |
| Acute respiratory failure | 2 | 2 | | | 2 | 2 |
| Acute vestibular syndrome | 1 | 1 | | | 1 | 1 |
| Adult failure to thrive | 1 | 1 | | | 1 | 1 |
| Ageusia | | 1 | | 1 | | |
| Agitation | 4 | 4 | 2 | 2 | 2 | 2 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Anaemia | 2 | 2 | | | 2 | 2 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Anosmia | | 1 | | 1 | | |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Aortic dissection | | 1 | | | | 1 |
| Apathy | 2 | 2 | 2 | 2 | | |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Aphthous ulcer | | 1 | | 1 | | |
| Arrhythmia | 5 | 5 | | | 5 | 5 |
| Arthralgia | 7 | 8 | 5 | 6 | 2 | 2 |
| Asthenia | 35 | 35 | 15 | 15 | 20 | 20 |
| Asymptomatic COVID-19 | 2 | 2 | | | 2 | 2 |

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Gender

MALE

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 9 | 9 | | | 9 | 9 |
| Atrial flutter | 2 | 2 | | | 2 | 2 |
| Atrioventricular block | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bacterial infection | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood alkaline phosphatase increased | 1 | 1 | 1 | 1 | | |
| Blood glucose increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 8 | 8 | 1 | 1 | 7 | 7 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Blood uric acid increased | | 1 | | 1 | | |
| Bradycardia | 2 | 2 | | | 2 | 2 |
| Bradyphrenia | 1 | 1 | | | 1 | 1 |
| Bronchitis | 1 | 2 | | | 1 | 2 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Bursal fluid accumulation | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 5 | 5 | | | 5 | 5 |
| Cardiac failure | 9 | 10 | | | 9 | 10 |
| Cardio-respiratory arrest | 2 | 3 | | | 2 | 3 |
| Cerebellar syndrome | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 6 | 6 | 4 | 4 | 2 | 2 |
| Chest pain | 8 | 8 | 1 | 1 | 7 | 7 |
| Chills | 15 | 16 | 8 | 9 | 7 | 7 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Colitis | 1 | 1 | 1 | 1 | | |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 9 | 9 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 5 | 5 |
| | | 9 | 10 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 2 | 2 |
| 1 | 1 | 7 | 7 |
| 8 | 9 | 7 | 7 |
| | | 1 | 1 |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # | Cumulative Total # |
|------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Coma | 1 | 1 |
| Condition aggravated | 1 | 1 |
| Confusional state | 4 | 4 |
| Conjunctival haemorrhage | 1 | 1 |
| Coronary artery disease | 1 | 1 |
| Coronary artery stenosis | 1 | 1 |
| Cough | 7 | 7 |
| COVID-19 | 41 | 41 |
| COVID-19 pneumonia | 1 | 1 |
| C-reactive protein increased | 5 | 7 |
| Cyanosis | 1 | 1 |
| Cytomegalovirus infection | 1 | 1 |
| Death | 13 | 14 |
| Decreased appetite | 6 | 7 |
| Dehydration | 4 | 4 |
| Delirium | 1 | 1 |
| Depression | 1 | 1 |
| Dermatitis bullous | 1 | 1 |
| Diabetes mellitus | 1 | 1 |
| Diabetic ketoacidosis | 2 | 2 |
| Diarrhoea | 13 | 13 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplopia | 1 | 1 |
| Discomfort | 6 | 6 |
| Disease progression | 1 | 1 |
| Disease recurrence | 3 | 3 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 13 | 13 |
| Drooling | 1 | 1 |
| Drug ineffective | 30 | 31 |
| Dysaesthesia | 2 | 2 |
| Dysarthria | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 3 | 3 |
| 6 | 6 | 35 | 35 |
| | | 1 | 1 |
| 1 | 2 | 4 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 13 | 14 |
| 4 | 5 | 2 | 2 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 5 | 5 | 8 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| 5 | 5 | 8 | 8 |
| 1 | 1 | | |
| 1 | 1 | 29 | 30 |
| | | 2 | 2 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dysgeusia | 2 | 2 | 2 | 2 | | |
| Dyslipidaemia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 2 | 2 | | | 2 | 2 |
| Dysphemia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 17 | 17 | 4 | 4 | 13 | 13 |
| Dyspnoea at rest | 1 | 1 | | | 1 | 1 |
| Dyspnoea exertional | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Dysuria | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Eczema | 2 | 2 | 1 | 1 | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | 1 | | | 1 | 1 |
| Electroencephalogram abnormal | 1 | 1 | | | 1 | 1 |
| Eosinophilia | 1 | 1 | | | 1 | 1 |
| Epilepsy | 5 | 5 | | | 5 | 5 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Erysipelas | 2 | 2 | | | 2 | 2 |
| Erythema | 10 | 11 | 5 | 6 | 5 | 5 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Eyelid function disorder | 1 | 1 | | | 1 | 1 |
| Eyelid haematoma | 1 | 1 | 1 | 1 | | |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Eye swelling | 1 | 1 | | | 1 | 1 |
| Face oedema | 2 | 2 | | | 2 | 2 |
| Facial pain | 2 | 2 | | | 2 | 2 |
| Facial paralysis | 10 | 10 | | | 10 | 10 |
| Facial paresis | 2 | 2 | | | 2 | 2 |
| Faeces soft | 1 | 1 | 1 | 1 | | |
| Fall | 6 | 6 | 1 | 1 | 5 | 5 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 13 | 13 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 5 | 5 | 5 |
| 1 | 1 | | |
| | | 2 | 2 |
| 5 | 6 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 10 | 10 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 5 | 5 |

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Gender

MALE

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fatigue | 22 | 25 | 16 | 19 | 6 | 6 |
| Fat tissue increased | 1 | 1 | 1 | 1 | | |
| Feeling cold | 2 | 2 | 1 | 1 | 1 | 1 |
| Feeling hot | 2 | 2 | 1 | 1 | 1 | 1 |
| Flushing | 2 | 2 | 1 | 1 | 1 | 1 |
| Gait disturbance | 3 | 3 | 1 | 1 | 2 | 2 |
| Gait inability | 1 | 1 | | | 1 | 1 |
| Gamma-glutamyltransferase increased | 1 | 1 | 1 | 1 | | |
| Gastroesophageal reflux disease | 1 | 1 | 1 | 1 | | |
| Gaze palsy | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 3 | 3 | 1 | 1 | 2 | 2 |
| Glomerulonephritis | 1 | 1 | | | 1 | 1 |
| Glycosylated haemoglobin increased | | 1 | | 1 | | |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Haemoptysis | | 1 | | | | 1 |
| Headache | 22 | 25 | 12 | 15 | 10 | 10 |
| Head injury | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 3 | 3 | 1 | 1 | 2 | 2 |
| Hemianopia homonymous | 1 | 1 | | | 1 | 1 |
| Hemiplegia | 2 | 2 | | | 2 | 2 |
| Herpes ophthalmic | 1 | 1 | | | 1 | 1 |
| Herpes simplex | 1 | 1 | 1 | 1 | | |
| Herpes zoster | 5 | 5 | 1 | 1 | 4 | 4 |
| Hoffmann's sign | 1 | 1 | 1 | 1 | | |
| Horner's syndrome | 1 | 1 | | | 1 | 1 |
| Hot flush | 2 | 2 | 2 | 2 | | |
| Hyperaesthesia | 1 | 1 | 1 | 1 | | |
| Hyperglycaemia | 1 | 1 | 1 | 1 | | |
| Hyperglycinaemia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 8 | 8 | 2 | 2 | 6 | 6 |
| Hyperleukocytosis | 2 | 3 | | | 2 | 3 |

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MALE

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|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypersensitivity | 9 | 9 | 4 | 4 | 5 | 5 |
| Hypersomnia | 1 | 1 | 1 | 1 | | |
| Hypertension | 14 | 14 | 2 | 2 | 12 | 12 |
| Hypertensive crisis | 3 | 4 | | | 3 | 4 |
| Hypertensive urgency | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 3 | 3 | 1 | 1 | 2 | 2 |
| Hyperventilation | 1 | 1 | 1 | 1 | | |
| Hypervitaminosis B12 | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Hypotension | 5 | 5 | 1 | 1 | 4 | 4 |
| Hypothermia | 2 | 2 | | | 2 | 2 |
| Inappropriate schedule of product administration | 1 | 2 | 1 | 2 | | |
| Incorrect dose administered | 2 | 2 | 2 | 2 | | |
| Incorrect route of product administration | 3 | 6 | 3 | 6 | | |
| Infection | 1 | 1 | | | 1 | 1 |
| Inflammation | 2 | 2 | | | 2 | 2 |
| Influenza | 2 | 2 | | | 2 | 2 |
| Influenza like illness | 10 | 10 | 6 | 6 | 4 | 4 |
| Injected limb mobility decreased | 2 | 2 | | | 2 | 2 |
| Injection site erythema | | 1 | | 1 | | |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Insomnia | 6 | 7 | 4 | 5 | 2 | 2 |
| International normalised ratio abnormal | | 1 | | | | 1 |
| Irritability | 1 | 1 | 1 | 1 | | |
| Ischaemic stroke | 6 | 6 | | | 6 | 6 |
| Jaundice | 1 | 1 | | | 1 | 1 |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Laryngeal oedema | 1 | 1 | | | 1 | 1 |
| Larynx irritation | 1 | 1 | | | 1 | 1 |
| Leukoencephalopathy | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 4 | 5 | 5 |
| 1 | 1 | | |
| 2 | 2 | 12 | 12 |
| | | 3 | 4 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| | | 2 | 2 |
| 1 | 2 | | |
| 2 | 2 | | |
| 3 | 6 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| 6 | 6 | 4 | 4 |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | | |
| 4 | 5 | 2 | 2 |
| | | | 1 |
| 1 | 1 | | |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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|--------------------------------------|------------------------------------|--------------------------------------|
| Lip oedema | 1 | 1 |
| Lip swelling | 1 | 1 |
| Livedo reticularis | 1 | 1 |
| Localised oedema | 1 | 1 |
| Loss of consciousness | 5 | 5 |
| Lower respiratory tract congestion | 1 | 1 |
| Lung abscess | 1 | 1 |
| Lung disorder | 1 | 1 |
| Lymphadenopathy | 4 | 6 |
| Lymphopenia | 2 | 2 |
| Malaise | 30 | 31 |
| Malignant hypertension | 1 | 1 |
| Malnutrition | 1 | 1 |
| Mass | 1 | 1 |
| Medication error | 1 | 1 |
| Migraine | 1 | 1 |
| Migraine with aura | 1 | 1 |
| Monoparesis | 1 | 1 |
| Motor dysfunction | 1 | 1 |
| Mouth haemorrhage | 1 | 1 |
| Mucous stools | 1 | 1 |
| Muscle fatigue | 1 | 1 |
| Muscle rigidity | 1 | 1 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | 5 | 5 |
| Myalgia | 19 | 19 |
| Mydriasis | 1 | 1 |
| Myelitis | 1 | 1 |
| Myocardial infarction | 5 | 5 |
| Myocardial necrosis marker increased | 1 | 1 |
| Myocarditis | 1 | 1 |
| Myoclonus | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 6 | | |
| | | 2 | 2 |
| 8 | 9 | 22 | 22 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 3 | 3 |
| 9 | 9 | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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|------------------------------|------------------------------------|--------------------------------------|
| Nasal congestion | 1 | 2 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 16 | 17 |
| Needle issue | | 1 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 2 | 2 |
| Neutropenia | 1 | 1 |
| Noninfective chorioretinitis | 1 | 1 |
| Obstruction gastric | 1 | 1 |
| Oedema peripheral | 1 | 2 |
| Off label use | 3 | 4 |
| Ophthalmic herpes zoster | 1 | 1 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 2 | 2 |
| Otitis externa | | 1 |
| Overdose | 2 | 4 |
| Oxygen saturation decreased | 7 | 7 |
| Pain | 21 | 21 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 3 | 4 |
| Palatal oedema | 1 | 1 |
| Pallor | 4 | 4 |
| Palpitations | 5 | 5 |
| Paraesthesia | 11 | 11 |
| Paraesthesia oral | | 1 |
| Paresis | 1 | 1 |
| Parkinsonism | 1 | 1 |
| Parosmia | 1 | 1 |
| Pericardial effusion | 1 | 1 |
| Pericarditis | 1 | 1 |
| Periorbital oedema | 1 | 1 |
| Peripheral coldness | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 8 | 9 | 8 | 8 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 3 | 4 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 2 | 4 | | |
| 2 | 2 | 5 | 5 |
| 13 | 13 | 8 | 8 |
| | | 1 | 1 |
| 2 | 3 | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| 2 | 2 | 3 | 3 |
| 3 | 3 | 8 | 8 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |

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MALE

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|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Petechiae | 1 | 1 | 1 | 1 | | |
| Photophobia | 1 | 1 | | | 1 | 1 |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 3 | 3 | | | 3 | 3 |
| Pneumonia aspiration | 5 | 5 | | | 5 | 5 |
| Pneumonia bacterial | 1 | 1 | | | 1 | 1 |
| Pneumonia moraxella | 1 | 1 | | | 1 | 1 |
| Polydipsia | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | 31 | 31 | 31 | 31 | | |
| Presyncope | 2 | 2 | 1 | 1 | 1 | 1 |
| Product preparation issue | | 7 | | 7 | | |
| Product temperature excursion issue | 28 | 28 | 28 | 28 | | |
| Product use issue | 2 | 3 | 2 | 3 | | |
| Pruritus | 7 | 8 | 4 | 5 | 3 | 3 |
| Pseudodementia | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 3 | 3 | | | 3 | 3 |
| Pulmonary oedema | 2 | 2 | | | 2 | 2 |
| Purpura | 2 | 2 | | | 2 | 2 |
| Pyrexia | 33 | 35 | 13 | 15 | 20 | 20 |
| Rales | 1 | 2 | | | 1 | 2 |
| Rash | 8 | 8 | 3 | 3 | 5 | 5 |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 1 | 2 | 1 | 2 | | |
| Rash papular | 3 | 3 | 2 | 2 | 1 | 1 |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Renal failure | 2 | 2 | | | 2 | 2 |
| Renal impairment | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 3 | 3 | | | 3 | 3 |
| Respiratory distress | 3 | 3 | | | 3 | 3 |
| Respiratory failure | 3 | 3 | | | 3 | 3 |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 31 | 31 | | |
| 1 | 1 | 1 | 1 |
| | 7 | | |
| 28 | 28 | | |
| 2 | 3 | | |
| 4 | 5 | 3 | 3 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 2 | 2 |
| | | 2 | 2 |
| 13 | 15 | 20 | 20 |
| | | 1 | 2 |
| 3 | 3 | 5 | 5 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| 2 | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 3 | 3 |
| | | 3 | 3 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory tract oedema | 1 | 1 | | | 1 | 1 |
| Retinal artery occlusion | 1 | 1 | | | 1 | 1 |
| Rhabdomyolysis | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 3 | 3 | 1 | 1 | 2 | 2 |
| SARS-CoV-2 ant body test negative | 6 | 6 | 5 | 5 | 1 | 1 |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 3 | 3 | 1 | 1 | 2 | 2 |
| Seizure | 6 | 6 | | | 6 | 6 |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Septic shock | 2 | 2 | | | 2 | 2 |
| Sinus arrest | 1 | 1 | | | 1 | 1 |
| Sinus bradycardia | 1 | 1 | | | 1 | 1 |
| Sinus disorder | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Skin lesion | 1 | 1 | | | 1 | 1 |
| Skin mass | 2 | 2 | 1 | 1 | 1 | 1 |
| Skin warm | 1 | 1 | 1 | 1 | | |
| Sleep apnoea syndrome | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Somnolence | 3 | 3 | 2 | 2 | 1 | 1 |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Staring | 1 | 1 | | | 1 | 1 |
| Status epilepticus | 1 | 1 | | | 1 | 1 |
| Subileus | 1 | 1 | | | 1 | 1 |
| Sudden death | 8 | 10 | | | 8 | 10 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Supraventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Suspected COVID-19 | 1 | 2 | | | 1 | 2 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Syncope | 5 | 5 | | | 5 | 5 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 5 | 5 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 8 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 5 | 5 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Tachyarrhythmia | 2 | 2 |
| Tachycardia | 16 | 16 |
| Tachypnoea | 3 | 3 |
| Taste disorder | 1 | 1 |
| Tension | 1 | 1 |
| Thrombocytopenia | 1 | 1 |
| Thrombocytopenic purpura | 1 | 1 |
| Thrombophlebitis superficial | 2 | 2 |
| Thrombosis | 2 | 2 |
| Tinnitus | 1 | 1 |
| Tongue biting | 1 | 1 |
| Tongue haematoma | | 2 |
| Tongue oedema | 1 | 1 |
| Tonic clonic movements | 2 | 2 |
| Tonsillar hypertrophy | 1 | 1 |
| Transaminases increased | 1 | 1 |
| Transient ischaemic attack | 1 | 1 |
| Tremor | 3 | 4 |
| Troponin increased | 1 | 1 |
| Type 2 diabetes mellitus | 1 | 1 |
| Type I hypersensitivity | 1 | 1 |
| Underdose | 2 | 8 |
| Urticaria | 5 | 5 |
| Vaccination complication | | 1 |
| Vaccination failure | 1 | 1 |
| Vaccination site erythema | 5 | 5 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site hypersensitivity | 9 | 9 |
| Vaccination site induration | 1 | 1 |
| Vaccination site inflammation | 1 | 1 |
| Vaccination site movement impairment | 2 | 2 |
| Vaccination site oedema | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| 2 | 2 | 14 | 14 |
| | | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 8 | | |
| 1 | 1 | 4 | 4 |
| | 1 | | |
| | | 1 | 1 |
| 5 | 5 | | |
| | | 1 | 1 |
| 9 | 9 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 31 | 37 | 22 | 28 | 9 | 9 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| Vascular purpura | 1 | 1 | | | 1 | 1 |
| Venous thrombosis | 2 | 2 | | | 2 | 2 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Ventricular fibrillation | 1 | 1 | | | 1 | 1 |
| Ventricular tachycardia | 2 | 2 | | | 2 | 2 |
| Vertigo | 10 | 10 | 4 | 4 | 6 | 6 |
| Vestibular disorder | 1 | 1 | | | 1 | 1 |
| Vestibular neuritis | 1 | 1 | | | 1 | 1 |
| Vision blurred | 3 | 3 | | | 3 | 3 |
| Vomiting | 15 | 15 | 5 | 5 | 10 | 10 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | | | 1 | 1 |
| Yellow skin | | 1 | | 1 | | |
| | 1,162 | 1,242 | 425 | 488 | 737 | 754 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Autoimmune thyroiditis | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| COVID-19 | 33 | 33 | 1 | 1 | 32 | 32 |
| Death | | 5 | | | | 5 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 32 | 32 | | | 32 | 32 |
| Dyspnoea exertional | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | | 1 | | 1 | | |
| Eyelid ptosis | 1 | 1 | 1 | 1 | | |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Herpes zoster | 1 | 2 | 1 | 2 | | |
| Hypertension | 4 | 4 | 4 | 4 | | |
| Hyperthermia | 1 | 1 | 1 | 1 | | |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Intercepted product preparation error | | 1 | | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myocardial ischaemia | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 2 | 2 | 2 | 2 | | |
| Pancreatitis acute | 1 | 1 | | | 1 | 1 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Poor quality product administered | 19 | 21 | 19 | 21 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product packaging quantity issue | 1 | 1 | 1 | 1 | | |
| Product preparation issue | | 6 | | 6 | | |
| Product temperature excursion issue | 18 | 19 | 18 | 19 | | |
| Rash | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Underdose | | 5 | | 5 | | |
| Vaccination site dysaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 135 | 159 | 59 | 78 | 76 | 81 |

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Country Where Event Occurred

FRENCH POLYNESIA

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dermatitis bullous | 1 | 1 | 1 | 1 |
| Dermatosis | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

GERMANY

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | 6 | 8 | 1 | 1 | 3 | 5 | 3 | 3 |
| Abdominal pain lower | 2 | 5 | | | 1 | 4 | 1 | 1 |
| Abdominal pain upper | 7 | 8 | | | 5 | 6 | 2 | 2 |
| Abnormal faeces | 1 | 3 | | | 1 | 3 | | |
| Abortion missed | 1 | 1 | | | | | 1 | 1 |
| Abortion spontaneous | 2 | 2 | | | | | 2 | 2 |
| Abscess | | 1 | | | | | | 1 |
| Accidental overdose | | 11 | | | | 9 | | 2 |
| Acidosis | 1 | 1 | | | | | 1 | 1 |
| Acute coronary syndrome | 3 | 3 | | | | | 3 | 3 |
| Acute kidney injury | 3 | 6 | | | | | 3 | 6 |
| Acute myocardial infarction | 2 | 6 | | | | | 2 | 6 |
| Acute respiratory distress syndrome | 1 | 1 | | | | | 1 | 1 |
| Acute respiratory failure | | 1 | | | | | | 1 |
| Ageusia | 2 | 3 | | | 2 | 3 | | |
| Agitation | 2 | 3 | | | | 1 | 2 | 2 |
| Agranulocytosis | 1 | 1 | | | | | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | | | | | 1 | 1 |
| Allergic oedema | | 1 | | | | 1 | | |
| Allergy to vaccine | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Altered state of consciousness | | | 1 | 1 | | | | |
| Amnesia | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Anaphylactic reaction | 38 | 48 | | | | | 38 | 48 |
| Anaphylactic shock | 6 | 8 | 1 | 1 | | | 6 | 8 |
| Anaphylactoid reaction | | 1 | | | | | | 1 |
| Angina pectoris | 6 | 8 | | | | | 6 | 8 |
| Angioedema | 10 | 12 | | | | | 10 | 12 |
| Anosmia | 1 | 2 | | | 1 | 2 | | |
| Anxiety | 1 | 2 | | | | 1 | 1 | 1 |
| Apathy | 1 | 2 | | | | | 1 | 2 |
| Aphasia | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Appendicitis | | | 1 | 1 | | | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Application site vesicles | 1 | 1 |
| Arrhythmia | 9 | 12 |
| Arterial occlusive disease | 1 | 1 |
| Arteriosclerosis | 1 | 1 |
| Arthralgia | 19 | 33 |
| Arthropathy | 1 | 1 |
| Aspartate aminotransferase increased | 1 | 1 |
| Asthenia | 25 | 52 |
| Asthenopia | | 1 |
| Asthma | 5 | 7 |
| Asymptomatic COVID-19 | 1 | 1 |
| Ataxia | 3 | 3 |
| Atrial fibrillation | 5 | 6 |
| Atrial flutter | 1 | 1 |
| Atrioventricular block complete | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 |
| Autonomic nervous system imbalance | 1 | 1 |
| Axillary pain | 3 | 3 |
| Back pain | 4 | 6 |
| Basal ganglia infarction | 1 | 1 |
| Bedridden | | 1 |
| Bladder discomfort | | 1 |
| Bladder pain | | 1 |
| Blepharitis | 1 | 1 |
| Blood glucose fluctuation | | 1 |
| Blood lactate dehydrogenase increased | 2 | 2 |
| Blood pressure abnormal | 1 | 1 |
| Blood pressure decreased | 4 | 6 |
| Blood pressure fluctuation | | 1 |
| Blood pressure immeasurable | 1 | 1 |
| Blood pressure increased | 5 | 8 |
| Blood urine present | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| 1 | 1 | | | 9 | 12 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 17 | 17 | 18 | 32 | 1 | 1 |
| | | | | 1 | 1 |
| | | 20 | 44 | 5 | 8 |
| | | | 1 | | |
| | | 2 | 3 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 5 | 6 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 3 | | |
| | | 4 | 6 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| 1 | 1 | | 1 | 4 | 5 |
| | | | 1 | | |
| | | | | 1 | 1 |
| 2 | 2 | 2 | 4 | 3 | 4 |
| | | | | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Body temperature increased | 17 | 27 |
| Bone pain | 8 | 8 |
| Bradycardia | 1 | 2 |
| Breast pain | | |
| Bronchial disorder | | 1 |
| Bronchitis | 2 | 3 |
| Bronchospasm | 1 | 2 |
| Burning sensation | 3 | 4 |
| Bursitis | | |
| Capillary nail refill test abnormal | 1 | 1 |
| Cardiac aneurysm | 1 | 1 |
| Cardiac arrest | 3 | 4 |
| Cardiac failure | 6 | 9 |
| Cardiac failure acute | 1 | 1 |
| Cardiac failure congestive | 1 | 2 |
| Cardiogenic shock | 2 | 3 |
| Cardio-respiratory arrest | 1 | 1 |
| Cardiovascular disorder | 9 | 15 |
| Cardiovascular insufficiency | 2 | 3 |
| Cerebellar ataxia | 1 | 1 |
| Cerebellar syndrome | 1 | 1 |
| Cerebral haemorrhage | | 1 |
| Cerebral infarction | 3 | 4 |
| Cerebral ischaemia | 1 | 1 |
| Cerebrovascular accident | 8 | 8 |
| Cerebrovascular disorder | 1 | 1 |
| Chest discomfort | 1 | 4 |
| Chest pain | 7 | 7 |
| Chills | 33 | 58 |
| Chronic obstructive pulmonary disease | 3 | 3 |
| Circulatory collapse | 11 | 13 |
| Cold sweat | 3 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 15 | 23 | 2 | 4 |
| | | 6 | 6 | 2 | 2 |
| | | | | 1 | 2 |
| 1 | 1 | | | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | 1 | 2 |
| 1 | 1 | | | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | | | 6 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 6 | 11 | 3 | 4 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 8 | 8 |
| | | | | 1 | 1 |
| | | 1 | 4 | | |
| | | 5 | 5 | 2 | 2 |
| 20 | 20 | 29 | 52 | 4 | 6 |
| | | | | 3 | 3 |
| 1 | 1 | | | 11 | 13 |
| | | 1 | 1 | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Condition aggravated | 2 | 4 |
| Confusional state | 4 | 5 |
| Conjunctival haemorrhage | 2 | 2 |
| Conjunctivitis | 1 | 1 |
| Constipation | | 1 |
| Coronavirus infection | 2 | 2 |
| Coronavirus test positive | 3 | 3 |
| Cor pulmonale | 1 | 1 |
| Cough | 17 | 25 |
| COVID-19 | 60 | 90 |
| COVID-19 pneumonia | 3 | 3 |
| Cranial nerve disorder | 1 | 1 |
| C-reactive protein increased | 2 | 2 |
| Crepitations | | 1 |
| Cyanosis | 1 | 1 |
| Deafness | 1 | 1 |
| Deafness transitory | 1 | 1 |
| Deafness unilateral | 1 | 1 |
| Death | 21 | 38 |
| Decreased appetite | 2 | 2 |
| Deep vein thrombosis | 1 | 1 |
| Dehydration | 1 | 1 |
| Dementia | | 1 |
| Depressed level of consciousness | 2 | 2 |
| Depression | 1 | 1 |
| Dermatitis allergic | 1 | 4 |
| Diabetes mellitus | | 1 |
| Diaphragmalgia | 1 | 1 |
| Diarrhoea | 24 | 38 |
| Diet refusal | 2 | 3 |
| Discomfort | | |
| Disease recurrence | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 2 | | 2 |
| | | 2 | 3 | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | 11 | 18 | 6 | 7 |
| 1 | 1 | 13 | 14 | 47 | 76 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 21 | 38 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 3 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| 10 | 10 | 17 | 30 | 7 | 8 |
| | | | | 2 | 3 |
| 1 | 1 | | | | |
| | | 2 | 3 | | |

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Gender

FEMALE

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|---------------------------|------------------------------------|--------------------------------------|
| Disorientation | 3 | 3 |
| Disturbance in attention | 10 | 15 |
| Dizziness | 65 | 112 |
| Drug ineffective | 57 | 91 |
| Dry eye | | 1 |
| Dry mouth | 4 | 5 |
| Dry skin | | 1 |
| Dysaesthesia | 3 | 4 |
| Dysarthria | 2 | 2 |
| Dysgeusia | 3 | 3 |
| Dyspepsia | | 1 |
| Dysphagia | 5 | 9 |
| Dysphonia | 4 | 6 |
| Dyspnoea | 35 | 51 |
| Dyspnoea at rest | 1 | 1 |
| Dyspnoea exertional | 5 | 6 |
| Dysstasia | | 1 |
| Ear discomfort | 1 | 1 |
| Ear pain | 2 | 3 |
| Eczema | 1 | 2 |
| Embolism arterial | 1 | 1 |
| Enanthema | 1 | 1 |
| Enteritis | 1 | 1 |
| Epilepsy | 14 | 17 |
| Epistaxis | | 3 |
| Erysipelas | 1 | 1 |
| Erythema | 20 | 26 |
| Erythema multiforme | 1 | 1 |
| Exposure during pregnancy | | 1 |
| Exposure via breast milk | 1 | 1 |
| Eye haemorrhage | 1 | 2 |
| Eye irritation | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 2 | 2 |
| | | 6 | 10 | 4 | 5 |
| 36 | 36 | 37 | 75 | 28 | 37 |
| | | | | 57 | 91 |
| | | | 1 | | |
| | | 2 | 3 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | 2 | 3 |
| | | | | 2 | 2 |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | 4 | 4 | 1 | 5 |
| | | 4 | 6 | | |
| 2 | 2 | 13 | 22 | 22 | 29 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 4 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 14 | 17 |
| | | | 3 | | |
| | | | | 1 | 1 |
| | | 15 | 20 | 5 | 6 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | 2 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Eyelid oedema | 1 | 1 |
| Eye pain | 2 | 2 |
| Eye pruritus | 4 | 6 |
| Eye swelling | 2 | 4 |
| Facial pain | | 1 |
| Facial paralysis | 3 | 3 |
| Facial paresis | 4 | 4 |
| Fall | 2 | 4 |
| Fatigue | 65 | 155 |
| Febrile infection | | 1 |
| Feeling abnormal | 3 | 3 |
| Feeling cold | 5 | 13 |
| Feeling hot | 12 | 14 |
| Feeling of body temperature change | 1 | 2 |
| Femoral artery embolism | 1 | 1 |
| Flank pain | 1 | 1 |
| Flatulence | | 1 |
| Flushing | 13 | 18 |
| Food refusal | | 2 |
| Fracture | 1 | 1 |
| Gait disturbance | 3 | 5 |
| Gastrointestinal disorder | 1 | 1 |
| Generalised tonic-clonic seizure | 2 | 2 |
| General physical condition abnormal | 5 | 5 |
| General physical health deterioration | 9 | 16 |
| Gingival swelling | 1 | 1 |
| Gout | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematemesis | 1 | 1 |
| Haematoma | 6 | 7 |
| Haematuria | | 1 |
| Haemoptysis | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 2 | 3 | 4 |
| | | 2 | 3 | | 1 |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | 1 | 3 |
| 43 | 43 | 61 | 147 | 4 | 8 |
| | | | | | 1 |
| | | 3 | 3 | | |
| | | 3 | 10 | 2 | 3 |
| | | 8 | 10 | 4 | 4 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 6 | 7 | 7 | 11 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | 1 | 3 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 5 | 5 |
| | | 2 | 3 | 7 | 13 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 3 | 4 | 4 |
| | | | 1 | | |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Headache | 106 | 200 |
| Head discomfort | | 2 |
| Heart rate increased | 4 | 5 |
| Hemiparesis | 3 | 3 |
| Herpes simplex | 1 | 1 |
| Herpes zoster | 9 | 12 |
| Herpes zoster infection neurological | 1 | 1 |
| Herpes zoster meningitis | 1 | 1 |
| Herpes zoster oticus | 1 | 1 |
| Herpes zoster reactivation | 1 | 1 |
| Hordeolum | | 1 |
| Hot flush | 4 | 5 |
| Huntington's disease | | 3 |
| Hyperaesthesia | 1 | 1 |
| Hypercalcaemia | 1 | 2 |
| Hyperhidrosis | 7 | 12 |
| Hyperkalaemia | 1 | 1 |
| Hypersensitivity | 24 | 35 |
| Hypersensitivity vasculitis | 1 | 1 |
| Hypersomnia | 2 | 3 |
| Hypertension | 18 | 28 |
| Hypertensive crisis | 6 | 6 |
| Hypertensive emergency | 1 | 1 |
| Hyperventilation | 6 | 6 |
| Hypoaesthesia | 8 | 12 |
| Hypoaesthesia oral | 3 | 5 |
| Hypokinesia | 1 | 1 |
| Hyponatraemia | 1 | 1 |
| Hypophagia | 1 | 1 |
| Hyporesponsive to stimuli | 1 | 1 |
| Hypotension | 8 | 15 |
| Hypotonia | 4 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 46 | 46 | 88 | 177 | 18 | 23 |
| | | | 1 | | 1 |
| | | 2 | 3 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 6 | 9 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 4 | 5 | | |
| | | | | | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | 5 | 10 | 2 | 2 |
| | | | | 1 | 1 |
| 3 | 3 | 7 | 10 | 17 | 25 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| 2 | 2 | 5 | 9 | 13 | 19 |
| | | | | 6 | 6 |
| | | | | 1 | 1 |
| | | 2 | 2 | 4 | 4 |
| 2 | 2 | 7 | 11 | 1 | 1 |
| | | 3 | 4 | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 8 | 13 |
| | | 2 | 3 | 2 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypoxia | 1 | 1 |
| Idiopathic intracranial hypertension | 1 | 1 |
| Ileus paralytic | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Impaired work ability | 1 | 1 |
| Inappropriate schedule of product administration | 5 | 6 |
| Incorrect route of product administration | 3 | 10 |
| Increased upper airway secretion | | 1 |
| Infarction | 1 | 1 |
| Infection | 2 | 2 |
| Infective exacerbation of chronic obstructive airways disease | | 1 |
| Inflammatory marker increased | 1 | 1 |
| Influenza like illness | 11 | 24 |
| Injection site pain | | 1 |
| Insomnia | 3 | 4 |
| Irregular breathing | 1 | 2 |
| Ischaemic cerebral infarction | 1 | 1 |
| Jaundice | | 1 |
| Jaw clicking | | 1 |
| Joint range of motion decreased | 2 | 2 |
| Joint swelling | 1 | 1 |
| Lacrimation increased | 5 | 5 |
| Language disorder | | 1 |
| Laryngeal oedema | 1 | 3 |
| Laryngospasm | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Leukopenia | | 1 |
| Limb discomfort | 3 | 8 |
| Lipase increased | 1 | 1 |
| Lip oedema | 1 | 2 |
| Lip swelling | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 5 | 6 | | |
| | | 3 | 9 | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 10 | 23 | 1 | 1 |
| | | | | | 1 |
| | | 3 | 4 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 3 | 3 | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 3 | 8 | | |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Livedo reticularis | | 1 |
| Liver function test increased | 2 | 2 |
| Localised infection | 1 | 1 |
| Local reaction | 4 | 7 |
| Loss of consciousness | 6 | 8 |
| Lower respiratory tract congestion | 1 | 1 |
| Lung disorder | 1 | 1 |
| Lymphadenopathy | 13 | 23 |
| Lymph node pain | 7 | 11 |
| Lymphopenia | 1 | 1 |
| Malaise | 17 | 29 |
| Maternal exposure during pregnancy | 11 | 24 |
| Memory impairment | 1 | 1 |
| Menorrhagia | 1 | 1 |
| Menstrual disorder | 5 | 5 |
| Mental disorder | 1 | 1 |
| Microcytic anaemia | 1 | 1 |
| Microembolism | 1 | 1 |
| Middle insomnia | 1 | 1 |
| Migraine | 1 | 2 |
| Mobility decreased | 3 | 5 |
| Monocytosis | 1 | 1 |
| Monoplegia | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Movement disorder | 1 | 3 |
| Multimorbidity | | 1 |
| Multiple organ dysfunction syndrome | 3 | 3 |
| Multiple sclerosis | 1 | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle spasms | 3 | 3 |
| Muscle spasticity | 1 | 1 |
| Muscle strain | | |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 2 | 5 | 2 | 2 |
| | | | | 6 | 8 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| 1 | 1 | 13 | 23 | | |
| | | 7 | 11 | | |
| | | | | 1 | 1 |
| 37 | 37 | 11 | 19 | 6 | 10 |
| | | 10 | 23 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 5 | 5 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | 3 | 5 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Muscle swelling | | 1 |
| Muscle tightness | | |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 5 | 9 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal stiffness | 1 | 2 |
| Myalgia | 40 | 76 |
| Myocardial infarction | 2 | 3 |
| Myocarditis | 1 | 1 |
| Myoclonus | 2 | 2 |
| Myosclerosis | 1 | 1 |
| Nasal congestion | | 3 |
| Nasopharyngitis | 7 | 12 |
| Nausea | 42 | 69 |
| Neck pain | 1 | 5 |
| Nervousness | 1 | 1 |
| Nervous system disorder | 3 | 3 |
| Neuralgia | 2 | 3 |
| Neuralgic amyotrophy | 1 | 2 |
| Neurodermatitis | 2 | 2 |
| Neutropenia | 1 | 1 |
| Night sweats | 4 | 4 |
| Nodule | 1 | 1 |
| Nystagmus | 1 | 1 |
| Occipital neuralgia | 1 | 1 |
| Occupational exposure to product | | 1 |
| Ocular discomfort | 2 | 2 |
| Ocular hyperaemia | 3 | 4 |
| Odynophagia | | |
| Oedema | | 1 |
| Oedema peripheral | 1 | 1 |
| Off label use | 8 | 14 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| 1 | 1 | | | | |
| | | 1 | 1 | | |
| | | 3 | 7 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| 28 | 28 | 34 | 70 | 6 | 6 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 3 | | |
| 1 | 1 | 6 | 11 | 1 | 1 |
| 29 | 29 | 32 | 57 | 10 | 12 |
| | | 1 | 5 | | |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | 2 | 3 | | |
| | | | | 1 | 2 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | 4 | 4 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | 2 | 3 | 1 | 1 |
| 1 | 1 | | | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 8 | 14 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Oligoarthritis | 1 | 1 |
| Ophthalmic herpes zoster | 2 | 2 |
| Optic neuritis | 1 | 1 |
| Optic neuropathy | 1 | 1 |
| Oral discomfort | 1 | 1 |
| Oral herpes | 2 | 2 |
| Oral mucosa erosion | | 1 |
| Oropharyngeal blistering | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 6 | 12 |
| Orthopnoea | | 1 |
| Orthostatic intolerance | | 1 |
| Otitis media | | 1 |
| Oxygen saturation decreased | 3 | 7 |
| Pain | 7 | 20 |
| Pain in extremity | 68 | 110 |
| Pain in jaw | 2 | 2 |
| Pallor | 1 | 1 |
| Palpitations | 13 | 29 |
| Pancreatitis acute | 1 | 1 |
| Paraesthesia | 23 | 31 |
| Paraesthesia oral | 4 | 6 |
| Paresis | | 1 |
| Pathogen resistance | | 1 |
| Pelvic pain | 1 | 1 |
| Performance status decreased | | 1 |
| Peripheral embolism | | 1 |
| Peripheral swelling | 5 | 8 |
| Peripheral vascular disorder | 9 | 13 |
| Personality change | 5 | 6 |
| Petechiae | 2 | 2 |
| Pharyngeal hypoesthesia | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| 1 | 1 | 5 | 11 | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 3 | 7 |
| | | 5 | 16 | 2 | 4 |
| | | 64 | 105 | 4 | 5 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| 1 | 1 | 7 | 21 | 6 | 8 |
| | | | | 1 | 1 |
| 3 | 3 | 14 | 21 | 9 | 10 |
| | | 2 | 3 | 2 | 3 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 4 | 5 | 1 | 3 |
| 1 | 1 | 3 | 5 | 6 | 8 |
| | | 1 | 1 | 4 | 5 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pharyngeal inflammation | | 1 |
| Pharyngeal oedema | 1 | 1 |
| Pharyngeal swelling | 4 | 6 |
| Pharyngitis | 1 | 1 |
| Photopsia | 2 | 2 |
| Photosensitivity reaction | | 1 |
| Platelet count decreased | 1 | 1 |
| Pneumonia | 9 | 11 |
| Pneumonia aspiration | | 3 |
| Polyarthritis | 1 | 1 |
| Poor quality product administered | 17 | 17 |
| Poor quality sleep | 1 | 3 |
| Presyncope | 5 | 6 |
| Product administered at inappropriate site | | 1 |
| Product preparation issue | | 1 |
| Product temperature excursion issue | 17 | 17 |
| Product use issue | 8 | 15 |
| Protein urine present | | 1 |
| Pruritus | 17 | 27 |
| Pruritus allergic | 1 | 2 |
| Psoriasis | 1 | 2 |
| Psychological factor affecting medical condition | | 1 |
| Psychomotor hyperactivity | 1 | 1 |
| Pulmonary embolism | | 2 |
| Pulmonary oedema | 1 | 1 |
| Pulse waveform abnormal | 1 | 1 |
| Pustule | 3 | 3 |
| Pyrexia | 52 | 85 |
| Quadripareisis | 1 | 1 |
| Rash | 19 | 33 |
| Rash erythematous | 1 | 1 |
| Rash macular | 2 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | 3 | 3 | 1 | 3 |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 9 | 11 |
| | | | | | 3 |
| | | | | 1 | 1 |
| | | 16 | 16 | 1 | 1 |
| | | 1 | 2 | | 1 |
| | | 3 | 4 | 2 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | 16 | 16 | 1 | 1 |
| | | 8 | 15 | | |
| | | | 1 | | |
| 1 | 1 | 12 | 18 | 5 | 9 |
| | | | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| 19 | 19 | 42 | 70 | 10 | 15 |
| | | | | 1 | 1 |
| 4 | 4 | 6 | 14 | 13 | 19 |
| | | 1 | 1 | | |
| | | 2 | 3 | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Rash maculo-papular | 1 | 2 |
| Rash pruritic | | 2 |
| Rash vesicular | 1 | 1 |
| Reaction to excipient | | 1 |
| Renal failure | 4 | 6 |
| Renal pain | | 1 |
| Respiratory distress | 24 | 31 |
| Respiratory failure | 4 | 4 |
| Respiratory symptom | | 1 |
| Respiratory tract infection | 1 | 3 |
| Resting tremor | 1 | 1 |
| Restlessness | 2 | 4 |
| Retching | | 1 |
| Retinal tear | 2 | 2 |
| Retinopathy | 1 | 1 |
| Retrograde amnesia | 1 | 1 |
| Reversible cerebral vasoconstriction syndrome | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 |
| Rhinalgia | | 2 |
| Rhinitis allergic | 1 | 1 |
| Rhinorrhoea | 9 | 16 |
| Rhonchi | | 2 |
| Rosacea | | 1 |
| SARS-CoV-2 ant body test negative | 5 | 5 |
| SARS-CoV-2 ant body test positive | 15 | 15 |
| SARS-CoV-2 sepsis | 1 | 1 |
| SARS-CoV-2 test positive | 9 | 17 |
| Scratch | | 1 |
| Seizure | 10 | 13 |
| Sensation of foreign body | 7 | 10 |
| Sense of oppression | | 1 |
| Sensitive skin | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 4 | 6 |
| | | | 1 | | |
| | | | | 24 | 31 |
| | | | | 4 | 4 |
| | | | 1 | | |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | 2 | 4 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 9 | 15 | | 1 |
| | | | | | 2 |
| | | | | | 1 |
| | | 5 | 5 | | |
| | | 15 | 15 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | 7 | 15 |
| | | | 1 | | |
| | | | | 10 | 13 |
| | | 1 | 1 | 6 | 9 |
| | | | 1 | | |
| | | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Sensory disturbance | 1 | 3 |
| Sensory loss | | 1 |
| Sepsis | 1 | 2 |
| Septic shock | | 1 |
| Shock | 1 | 1 |
| Sialoadenitis | 1 | 1 |
| Sinus congestion | 2 | 2 |
| Sinusitis | 1 | 1 |
| Sinus tachycardia | 1 | 2 |
| Skin abrasion | 1 | 1 |
| Skin burning sensation | 1 | 1 |
| Skin discolouration | 1 | 2 |
| Skin swelling | 1 | 1 |
| Sleep disorder | 1 | 2 |
| Sneezing | 3 | 5 |
| Soft tissue infection | 1 | 1 |
| Somatic symptom disorder | 1 | 1 |
| Somnolence | 6 | 10 |
| Speech disorder | 1 | 2 |
| Spinal pain | 1 | 1 |
| Status epilepticus | 2 | 3 |
| Stomatitis | 1 | 1 |
| Stress | | 2 |
| Stridor | 2 | 2 |
| Stupor | 1 | 1 |
| Sudden cardiac death | | 1 |
| Sudden death | 9 | 15 |
| Sudden visual loss | 1 | 1 |
| Supraventricular extrasystoles | 2 | 2 |
| Supraventricular tachycardia | 2 | 2 |
| Suspected COVID-19 | | 2 |
| Swelling | 3 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 3 | 5 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 5 | 4 | 5 |
| | | 1 | 1 | | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | | 2 |
| | | 2 | 6 | 1 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Swelling face | 6 | 10 |
| Swelling of eyelid | 1 | 1 |
| Swollen tongue | 6 | 9 |
| Syncope | 20 | 23 |
| Systemic inflammatory response syndrome | 1 | 1 |
| Tachyarrhythmia | 1 | 2 |
| Tachycardia | 25 | 40 |
| Tachypnoea | 1 | 1 |
| Temporomandibular joint syndrome | 1 | 1 |
| Tension headache | | 1 |
| Thirst | | |
| Throat irritation | 4 | 5 |
| Throat tightness | 6 | 10 |
| Thrombocytopenia | 2 | 2 |
| Tinnitus | 1 | 1 |
| Tongue discomfort | 1 | 1 |
| Tongue disorder | | 1 |
| Tongue oedema | 1 | 1 |
| Tongue pruritus | 1 | 1 |
| Transaminases increased | 1 | 1 |
| Transient ischaemic attack | | 1 |
| Tremor | 9 | 16 |
| Trichoglossia | 1 | 1 |
| Underdose | 1 | 3 |
| Unresponsive to stimuli | 2 | 3 |
| Upper respiratory tract infection | 2 | 2 |
| Urinary tract infection bacterial | 1 | 1 |
| Urticaria | 12 | 16 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | 1 | 1 |
| Vaccination site dermatitis | | 1 |
| Vaccination site discomfort | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 3 | 3 | 3 | 3 | 3 | 7 |
| | | 1 | 1 | | |
| | | 1 | 2 | 5 | 7 |
| 1 | 1 | | | 20 | 23 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| 5 | 5 | 7 | 14 | 18 | 26 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| 1 | 1 | | | | |
| 1 | 1 | 4 | 5 | | |
| | | 3 | 4 | 3 | 6 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 6 | 7 | 10 |
| | | 1 | 1 | | |
| | | 1 | 3 | | |
| | | | | 2 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 6 | 8 | 6 | 8 |
| 1 | 1 | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 2 | 3 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Vaccination site erythema | 10 | 21 |
| Vaccination site haematoma | 2 | 4 |
| Vaccination site haemorrhage | 2 | 2 |
| Vaccination site hyperaesthesia | 1 | 3 |
| Vaccination site induration | 1 | 4 |
| Vaccination site inflammation | | |
| Vaccination site irritation | | 1 |
| Vaccination site joint movement impairment | 1 | 3 |
| Vaccination site joint pain | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 |
| Vaccination site movement impairment | 2 | 8 |
| Vaccination site pain | 85 | 206 |
| Vaccination site paraesthesia | 2 | 3 |
| Vaccination site pruritus | 5 | 9 |
| Vaccination site rash | 1 | 2 |
| Vaccination site reaction | 1 | 4 |
| Vaccination site swelling | 10 | 31 |
| Vaccination site urticaria | 1 | 1 |
| Vaccination site warmth | 11 | 16 |
| Varicella zoster virus infection | 1 | 1 |
| Vascular dementia | 1 | 1 |
| Venous thrombosis limb | 1 | 1 |
| Ventricular fibrillation | 1 | 2 |
| Vertigo | 2 | 5 |
| Vision blurred | 4 | 6 |
| Visual impairment | 5 | 7 |
| Vitreous disorder | 1 | 1 |
| Vomiting | 26 | 34 |
| Wheezing | 3 | 3 |
| White blood cell count increased | 1 | 1 |
| Wrong technique in product usage process | | 1 |
| | 2,164 | 3,535 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|------------|-------------|-------------|------------|-------------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 8 | 19 | 2 | 2 |
| | | 1 | 3 | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 3 | | |
| | | 1 | 4 | | |
| 1 | 1 | | | | |
| | | | 1 | | |
| | | 1 | 2 | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 8 | | |
| 41 | 41 | 82 | 201 | 3 | 5 |
| | | 2 | 3 | | |
| | | 5 | 9 | | |
| | | 1 | 2 | | |
| | | 1 | 4 | | |
| 8 | 8 | 7 | 28 | 3 | 3 |
| | | 1 | 1 | | |
| 1 | 1 | 10 | 15 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 2 | 5 | | |
| | | 3 | 4 | 1 | 2 |
| | | 3 | 4 | 2 | 3 |
| | | | | 1 | 1 |
| 6 | 6 | 14 | 18 | 12 | 16 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| 396 | 396 | 1185 | 2172 | 979 | 1363 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | | 3 | | | | 3 | | |
| Abdominal pain upper | | 2 | | | | 2 | | |
| Abnormal faeces | 1 | 4 | | | 1 | 4 | | |
| Accidental overdose | | 2 | | | | 1 | | 1 |
| Acne | | 1 | | | | 1 | | |
| Acute abdomen | 1 | 1 | | | | | 1 | 1 |
| Acute kidney injury | 2 | 4 | | | | | 2 | 4 |
| Acute myocardial infarction | | 2 | | | | | | 2 |
| Acute respiratory distress syndrome | 1 | 1 | | | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Ageusia | 1 | 2 | | | 1 | 2 | | |
| Aggression | 1 | 1 | | | | | 1 | 1 |
| Agitation | 1 | 1 | | | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | | | 1 | 1 |
| Amaurosis fugax | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 7 | 8 | | | | | 7 | 8 |
| Anaphylactic shock | 1 | 2 | | | | | 1 | 2 |
| Anosmia | 1 | 2 | | | 1 | 2 | | |
| Anxiety | 1 | 1 | | | 1 | 1 | | |
| Aortic aneurysm | 1 | 1 | | | | | 1 | 1 |
| Apathy | 1 | 2 | | | 1 | 1 | | 1 |
| Aphasia | 1 | 1 | | | | | 1 | 1 |
| Arrhythmia | 3 | 4 | | | | | 3 | 4 |
| Arthralgia | 5 | 9 | 5 | 5 | 4 | 8 | 1 | 1 |
| Arthritis reactive | 1 | 1 | | | | | 1 | 1 |
| Aspiration | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 12 | 21 | | | 7 | 14 | 5 | 7 |
| Asthma | 1 | 1 | | | 1 | 1 | | |
| Ataxia | 2 | 2 | | | | | 2 | 2 |
| Atrial fibrillation | | 1 | | | | | | 1 |
| Atypical pneumonia | | 1 | | | | | | 1 |
| Automatism | 1 | 1 | | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Back pain | | 1 |
| Blister | | 1 |
| Blood calcium decreased | | 1 |
| Blood cholesterol increased | 1 | 1 |
| Blood creatine phosphokinase increased | | 1 |
| Blood creatine phosphokinase MB increased | | 1 |
| Blood creatinine increased | | 1 |
| Blood potassium decreased | | 1 |
| Blood pressure decreased | | 1 |
| Blood pressure increased | 1 | 1 |
| Body temperature increased | 2 | 3 |
| Bone pain | | 1 |
| Bradycardia | 1 | 2 |
| Bronchitis bacterial | | 1 |
| Burning sensation | | 1 |
| Cardiac arrest | 1 | 1 |
| Cardiac failure | 4 | 8 |
| Cardiac fibrillation | | 1 |
| Cardiopulmonary failure | | 1 |
| Cardiovascular disorder | 3 | 3 |
| Cellulitis | 1 | 1 |
| Cerebellar syndrome | 1 | 1 |
| Cerebral atrophy | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 |
| Cerebrovascular accident | 3 | 5 |
| Chest discomfort | 1 | 2 |
| Chest X-ray abnormal | 1 | 1 |
| Chills | 19 | 31 |
| Cholelithiasis | | 1 |
| Chronic kidney disease | | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Circulatory collapse | 4 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 8 |
| | | | | | 1 |
| | | | | | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| 5 | 5 | 15 | 27 | 4 | 4 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 6 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Cold sweat | 2 | 3 |
| Communication disorder | 1 | 1 |
| Confusional state | 3 | 3 |
| Conjunctivitis | | 1 |
| Contusion | 2 | 2 |
| Coronavirus infection | | 1 |
| Cough | 3 | 5 |
| COVID-19 | 45 | 65 |
| COVID-19 pneumonia | 3 | 8 |
| Cranial nerve disorder | | 1 |
| C-reactive protein increased | 1 | 1 |
| Cyanosis | 2 | 3 |
| Death | 12 | 22 |
| Decreased appetite | 1 | 2 |
| Deep vein thrombosis | 2 | 2 |
| Dehydration | 1 | 1 |
| Delirium | 2 | 2 |
| Dementia of the Alzheimer's type, with delirium | | 1 |
| Depressed level of consciousness | 1 | 2 |
| Dermatitis atopic | 1 | 1 |
| Diabetes mellitus | | 1 |
| Diarrhoea | 3 | 10 |
| Diet refusal | 1 | 1 |
| Diplopia | | 1 |
| Discomfort | | |
| Disease recurrence | 1 | 2 |
| Disorientation | 1 | 2 |
| Disturbance in attention | 3 | 3 |
| Dizziness | 10 | 17 |
| Dizziness postural | 1 | 2 |
| Drug ineffective | 39 | 74 |
| Drug interaction | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 2 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 3 | 2 | 2 |
| | | 4 | 4 | 41 | 61 |
| | | | | 3 | 8 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | 12 | 22 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | | | | 1 |
| 1 | 1 | 3 | 10 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| 2 | 2 | | | | |
| | | | | 1 | 2 |
| | | 1 | 2 | | |
| | | 2 | 2 | 1 | 1 |
| 5 | 5 | 5 | 11 | 5 | 6 |
| | | | 1 | 1 | 1 |
| | | | | 39 | 74 |
| | | | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Dysgeusia | 1 | 3 |
| Dysphagia | 2 | 2 |
| Dyspnoea | 10 | 15 |
| Ear pain | | 2 |
| Eating disorder | 1 | 1 |
| Eczema | 1 | 1 |
| Encephalitis | 1 | 1 |
| Epilepsy | 2 | 2 |
| Episcleritis | | 1 |
| Epistaxis | 1 | 1 |
| Erythema | 2 | 5 |
| Escherichia infection | 1 | 1 |
| Exercise tolerance decreased | | |
| Extrapyramidal disorder | 1 | 1 |
| Eye haemorrhage | 1 | 1 |
| Eye irritation | | 1 |
| Eye pain | 1 | 2 |
| Eye swelling | 1 | 1 |
| Face oedema | | 1 |
| Facial paralysis | 5 | 7 |
| Facial paresis | 1 | 1 |
| Fall | 3 | 5 |
| Fatigue | 29 | 59 |
| Febrile infection | | 1 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | 2 | 2 |
| Feeling hot | 4 | 6 |
| Feeling jittery | | |
| Femoral neck fracture | | 1 |
| Femur fracture | 1 | 1 |
| Flatulence | 1 | 2 |
| Flushing | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | 1 | 1 |
| | | | | 2 | 2 |
| | | 3 | 5 | 7 | 10 |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| 1 | 1 | | | 1 | 1 |
| 2 | 2 | 1 | 4 | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 5 | 7 |
| | | | | 1 | 1 |
| | | | | 3 | 5 |
| 11 | 12 | 27 | 57 | 2 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | 2 | 4 | 2 | 2 |
| 1 | 1 | | | | |
| | | | | | 1 |
| 1 | 1 | 1 | 2 | 1 | 1 |
| | | 1 | 2 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Gait disturbance | 3 | 3 |
| Gastrointestinal pain | | |
| General physical condition abnormal | 2 | 3 |
| General physical health deterioration | 9 | 13 |
| Genital herpes | | 1 |
| Glomerular filtration rate decreased | 1 | 1 |
| Glomerulonephritis minimal lesion | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematemesis | 2 | 2 |
| Haematochezia | 1 | 1 |
| Haematocrit decreased | | 1 |
| Haemoglobin decreased | | 1 |
| Hallucination, auditory | 1 | 1 |
| Hallucinations, mixed | 1 | 1 |
| Headache | 32 | 56 |
| Head discomfort | 1 | 1 |
| Head injury | | 1 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 1 | 2 |
| Hemiparesis | 2 | 3 |
| Hepatic pain | 1 | 1 |
| Herpes zoster | 2 | 2 |
| Hunger | | 1 |
| Hyperaesthesia | | 1 |
| Hyperhidrosis | 4 | 7 |
| Hyperpyrexia | | 1 |
| Hypersensitivity | 6 | 10 |
| Hypersomnia | | 1 |
| Hypertension | 3 | 7 |
| Hypertensive crisis | 2 | 2 |
| Hypertonia | 1 | 1 |
| Hyperventilation | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| 1 | 1 | | | | |
| | | | | 2 | 3 |
| | | | 1 | 9 | 12 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 9 | 10 | 32 | 55 | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| 1 | 1 | 4 | 7 | | |
| | | | | | 1 |
| 1 | 1 | 1 | 3 | 5 | 7 |
| | | | 1 | | |
| 1 | 1 | 1 | 2 | 2 | 5 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hypoaesthesia | 2 | 6 |
| Hypoaesthesia oral | | 1 |
| Hypoglycaemia | 1 | 1 |
| Hyponatraemia | 1 | 1 |
| Hypotension | 4 | 5 |
| Illness | 1 | 2 |
| Immune thrombocytopenia | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 3 |
| Incorrect route of product administration | 3 | 5 |
| Induration | | 1 |
| Infective exacerbation of chronic obstructive airways disease | 1 | 1 |
| Influenza like illness | 3 | 10 |
| Initial insomnia | 2 | 2 |
| Injection site discomfort | | 1 |
| Injection site pain | 1 | 2 |
| Intestinal ischaemia | 1 | 1 |
| Ischaemic stroke | | 1 |
| IVth nerve paresis | 1 | 1 |
| Lacrimation increased | | 1 |
| Language disorder | 1 | 1 |
| Left ventricular failure | 1 | 1 |
| Limb discomfort | 3 | 6 |
| Lip swelling | 1 | 2 |
| Loss of consciousness | 2 | 2 |
| Low density lipoprotein increased | 1 | 1 |
| Lung infiltration | 1 | 1 |
| Lymphadenopathy | 7 | 8 |
| Lymph node pain | 1 | 1 |
| Malaise | 7 | 13 |
| Mesenteric vein thrombosis | | 1 |
| Middle insomnia | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 5 | | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 4 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 2 | 3 | | |
| | | 3 | 5 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 8 | 1 | 2 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 6 | | |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 12 | 13 | 6 | 10 | 1 | 3 |
| | | | | | 1 |
| | | | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Mobility decreased | 2 | 4 |
| Motor dysfunction | | 1 |
| Mouth swelling | 1 | 1 |
| Movement disorder | | 2 |
| Multi-organ disorder | 1 | 1 |
| Multiple organ dysfunction syndrome | | 2 |
| Muscle spasms | 1 | 1 |
| Muscle tightness | | 1 |
| Muscle twitching | | 1 |
| Muscular weakness | 1 | 3 |
| Myalgia | 13 | 32 |
| Myelitis | 1 | 1 |
| Myocardial infarction | 1 | 1 |
| Myocarditis | 4 | 4 |
| Myocarditis infectious | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nasopharyngitis | 3 | 5 |
| Nausea | 12 | 22 |
| Neck pain | 1 | 6 |
| Nephrotic syndrome | 1 | 1 |
| Neurodermatitis | 1 | 1 |
| Obstructive airways disorder | 1 | 1 |
| Oedema | 1 | 1 |
| Off label use | 1 | 1 |
| Oropharyngeal pain | 3 | 4 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 5 | 9 |
| Pain in extremity | 17 | 35 |
| Pain of skin | 1 | 1 |
| Palatal swelling | 1 | 1 |
| Pallor | 2 | 2 |
| Palpitations | 3 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| 6 | 7 | 12 | 31 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 4 | 1 | 1 |
| 6 | 6 | 9 | 17 | 3 | 5 |
| | | 1 | 6 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 4 | | |
| | | | | 1 | 1 |
| | | 5 | 8 | | 1 |
| | | 17 | 34 | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| 3 | 3 | 2 | 3 | 1 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Paraesthesia | 2 | 3 |
| Paresis | 1 | 1 |
| Performance status decreased | 1 | 1 |
| Pericarditis | 1 | 1 |
| Peripheral circulatory failure | 1 | 1 |
| Peripheral coldness | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Peripheral vascular disorder | 4 | 6 |
| Personality change | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal swelling | 1 | 2 |
| Pleurisy | 1 | 1 |
| Pneumonia | 6 | 8 |
| Pollakiuria | | 1 |
| Poor quality product administered | 6 | 6 |
| Poor quality sleep | 1 | 1 |
| Presyncope | 1 | 1 |
| Product temperature excursion issue | 6 | 6 |
| Product use issue | 1 | 1 |
| Proteinuria | 1 | 1 |
| Pruritus | 2 | 3 |
| Pulmonary embolism | 4 | 5 |
| Pulmonary oedema | 1 | 1 |
| Pulmonary sepsis | 1 | 2 |
| Pustule | | |
| Pyramidal tract syndrome | 1 | 1 |
| Pyrexia | 36 | 57 |
| Rash | 3 | 7 |
| Rash maculo-papular | 2 | 2 |
| Rash pruritic | | 1 |
| Red blood cell count decreased | | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 6 | 8 |
| | | | 1 | | |
| | | 6 | 6 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 6 | 6 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | | 1 | 2 | 2 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| 1 | 1 | | | | |
| | | | | 1 | 1 |
| 6 | 7 | 24 | 40 | 12 | 17 |
| | | 1 | 3 | 2 | 4 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Renal failure | 1 | 1 |
| Respiratory distress | 6 | 8 |
| Respiratory failure | 6 | 8 |
| Respiratory tract infection | 1 | 1 |
| Restlessness | 3 | 3 |
| Retching | 2 | 2 |
| Rhinitis | | 1 |
| Rhinorrhoea | | 2 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| SARS-CoV-2 ant body test positive | 5 | 7 |
| SARS-CoV-2 test positive | 3 | 13 |
| Seizure | 5 | 7 |
| Sensory disturbance | | 1 |
| Septic shock | 1 | 1 |
| Shock | 1 | 1 |
| Sinusitis | | 1 |
| Skin burning sensation | 1 | 1 |
| Sleep disorder | 4 | 5 |
| Sneezing | | 1 |
| Somnolence | 2 | 3 |
| Staphylococcal sepsis | | 1 |
| Stridor | | 1 |
| Subclavian artery thrombosis | 1 | 1 |
| Sudden death | 6 | 7 |
| Sudden hearing loss | 3 | 4 |
| Sudden onset of sleep | 1 | 1 |
| Superinfection bacterial | 1 | 1 |
| Suspected COVID-19 | | 2 |
| Swelling | 1 | 3 |
| Swelling face | 1 | 1 |
| Syncope | 3 | 4 |
| Tachyarrhythmia | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 6 | 8 |
| | | | | 6 | 8 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 5 | 6 | | 1 |
| | | 1 | 1 | 2 | 12 |
| | | | | 5 | 7 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 5 | | |
| | | | 1 | | |
| | | 2 | 3 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 7 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | | | 3 | 4 |
| | | | | | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Tachycardia | 7 | 10 |
| Tachypnoea | 1 | 1 |
| Taste disorder | | 1 |
| Tenosynovitis | 1 | 1 |
| Tension | 1 | 1 |
| Tetany | 1 | 1 |
| Therapeutic response unexpected | 4 | 4 |
| Thirst | | 1 |
| Throat irritation | | 3 |
| Thrombosis | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue discomfort | | 1 |
| Toxicity to various agents | 1 | 1 |
| Transient ischaemic attack | 1 | 1 |
| Tremor | 1 | 1 |
| Unresponsive to stimuli | | 1 |
| Upper gastrointestinal haemorrhage | 2 | 2 |
| Urinary tract infection | 1 | 1 |
| Urosepsis | 1 | 1 |
| Urticaria | 1 | 2 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | | 2 |
| Vaccination site discomfort | | 1 |
| Vaccination site dysaesthesia | 1 | 1 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site joint pain | 1 | 1 |
| Vaccination site pain | 42 | 92 |
| Vaccination site swelling | 2 | 5 |
| Vaccination site warmth | 1 | 2 |
| Vascular encephalopathy | 1 | 1 |
| Ventricular fibrillation | | 1 |
| Ventricular tachycardia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 2 | 3 | 5 | 7 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 4 | | |
| | | | 1 | | |
| | | | 3 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| 12 | 12 | 41 | 91 | 1 | 1 |
| 4 | 4 | 2 | 5 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vertigo | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Vision blurred | 1 | 1 | | | | | 1 | 1 |
| Visual acuity reduced | 1 | 1 | | | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | | | 1 | 1 |
| Vomiting | 5 | 11 | 2 | 2 | 4 | 9 | 1 | 2 |
| Weight bearing difficulty | | 1 | | | | | | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 | | |
| White blood cell count increased | 1 | 1 | | | | | 1 | 1 |
| | 757 | 1,295 | 103 | 108 | 364 | 707 | 393 | 588 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain lower | | 1 | | 1 | | |
| Ageusia | | 1 | | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Chills | 10 | 11 | 10 | 11 | | |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Coronavirus infection | 3 | 3 | | | 3 | 3 |
| COVID-19 | 62 | 91 | 8 | 8 | 54 | 83 |
| Death | 13 | 17 | | | 13 | 17 |
| Decreased appetite | | 1 | | | | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Diet refusal | | 1 | | | | 1 |
| Dizziness | 1 | 2 | | 1 | 1 | 1 |
| Drug ineffective | 50 | 86 | 1 | 1 | 49 | 85 |
| Dysphagia | 3 | 3 | 3 | 3 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Eczema | 4 | 4 | 4 | 4 | | |
| Erythema | 1 | 3 | 1 | 3 | | |
| Exposure via breast milk | 1 | 2 | 1 | 2 | | |
| Fatigue | 9 | 12 | 9 | 12 | | |
| Headache | 10 | 12 | 9 | 11 | 1 | 1 |
| Hepatitis cholestatic | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 1 | 2 | | 1 | 1 | 1 |
| Hypoaesthesia | | 1 | | 1 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Influenza like illness | | 1 | | 1 | | |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Local reaction | | 1 |
| Lymphadenopathy | | 2 |
| Malaise | 1 | 2 |
| Myalgia | 2 | 2 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 1 | 3 |
| Necrosis | 1 | 1 |
| Neuralgia | 1 | 1 |
| No adverse event | 2 | 3 |
| Off label use | 2 | 3 |
| Pain in extremity | 4 | 8 |
| Paraesthesia | 1 | 2 |
| Paraesthesia oral | | 1 |
| Peripheral swelling | | 1 |
| Poor quality product administered | 3 | 4 |
| Product administered to patient of inappropriate age | 1 | 1 |
| Product complaint | 1 | 1 |
| Product leakage | | 1 |
| Product preparation error | | 2 |
| Product preparation issue | 8 | 8 |
| Product storage error | 1 | 1 |
| Product temperature excursion issue | 2 | 2 |
| Product use issue | 1 | 2 |
| Pyrexia | 5 | 6 |
| Rales | 1 | 1 |
| Rash | 1 | 1 |
| SARS-CoV-2 ant body test negative | 3 | 3 |
| SARS-CoV-2 ant body test positive | 2 | 4 |
| SARS-CoV-2 test false positive | 1 | 4 |
| SARS-CoV-2 test positive | 7 | 20 |
| Stridor | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 2 | | |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 3 | | |
| 2 | 3 | | |
| 4 | 8 | | |
| | 1 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 3 | 4 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | |
| 8 | 8 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 2 | | |
| 3 | 4 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| 2 | 4 | | |
| 1 | 4 | | |
| 5 | 11 | 2 | 9 |
| | | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Suspected COVID-19 | | 1 | | | | 1 | |
| Swelling | | 1 | | 1 | | | |
| Syncope | 1 | 1 | | | 1 | | 1 |
| Tremor | 1 | 1 | 1 | 1 | | | |
| Type IV hypersensitivity reaction | 4 | 4 | 4 | 4 | | | |
| Underdose | 8 | 15 | 8 | 15 | | | |
| Vaccination site hyperaesthesia | | 1 | | 1 | | | |
| Vaccination site pain | 1 | 6 | 1 | 6 | | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | | |
| Visual impairment | 1 | 1 | 1 | 1 | | | |
| Vomiting | 3 | 4 | 1 | 2 | 2 | 2 | |
| Wound | 1 | 1 | 1 | 1 | | | |
| | 254 | 397 | 112 | 176 | 142 | 221 | |

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Country Where Event Occurred

GIBRALTAR

Gender

UNKNOWN

Preferred Term

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Death | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

GREECE

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 6 | 7 | 3 | 4 | 3 | 3 |
| Abdominal pain upper | 2 | 3 | 2 | 3 | | |
| Acute respiratory failure | | 1 | | | | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Allergy to vaccine | 2 | 3 | 1 | 1 | 1 | 2 |
| Anaphylactic reaction | 4 | 6 | | | 4 | 6 |
| Anaphylactic shock | 2 | 5 | | | 2 | 5 |
| Anaphylactoid reaction | 1 | 2 | | | 1 | 2 |
| Angioedema | 9 | 10 | | | 9 | 10 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Antibody test abnormal | | 1 | | 1 | | |
| Anxiety | | 1 | | 1 | | |
| Arrhythmia | 4 | 4 | | | 4 | 4 |
| Arthralgia | 34 | 35 | 13 | 14 | 21 | 21 |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Arthritis enteropathic | 1 | 1 | | | 1 | 1 |
| Aspartate aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Asthenia | 9 | 11 | 4 | 6 | 5 | 5 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | | 1 | | | | 1 |
| Auscultation | | 1 | | 1 | | |
| Back pain | 2 | 2 | 2 | 2 | | |
| Balance disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Blepharospasm | 1 | 1 | 1 | 1 | | |
| Blister | 1 | 2 | 1 | 2 | | |
| Blood glucose abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 3 | 4 | | 1 | 3 | 3 |
| Blood pressure diastolic increased | 1 | 1 | 1 | 1 | | |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 17 | 18 | 11 | 11 | 6 | 7 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------------|--|--|
| Blood pressure systolic increased | 2 | 2 |
| Body dysmorphic disorder | 1 | 1 |
| Bone pain | 2 | 2 |
| Breast pain | 1 | 1 |
| Bronchospasm | 6 | 8 |
| Burning sensation | 8 | 9 |
| Cardiac arrest | | 2 |
| Cardiac discomfort | 1 | 1 |
| Chest discomfort | 4 | 4 |
| Chest pain | 7 | 9 |
| Chills | 34 | 36 |
| Cholinergic syndrome | 3 | 3 |
| Complex regional pain syndrome | 3 | 3 |
| Condition aggravated | 1 | 1 |
| Confusional state | 4 | 4 |
| Cough | 9 | 12 |
| COVID-19 | 7 | 7 |
| C-reactive protein increased | 2 | 2 |
| Deafness | 1 | 1 |
| Defaecation urgency | | 1 |
| Dermatitis allergic | 1 | 1 |
| Diarrhoea | 11 | 13 |
| Diastolic hypertension | | 1 |
| Dizziness | 26 | 34 |
| Drowning | 1 | 1 |
| Drug ineffective | 7 | 7 |
| Drug interaction | | 1 |
| Dry mouth | 2 | 3 |
| Dry throat | 2 | 3 |
| Dysarthria | 2 | 2 |
| Dysgeusia | 4 | 8 |
| Dyskinesia | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 6 | 8 |
| 6 | 7 | 2 | 2 |
| | | | 2 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| 2 | 3 | 5 | 6 |
| 11 | 13 | 23 | 23 |
| | | 3 | 3 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 1 | 1 | 8 | 11 |
| | | 7 | 7 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 5 | 6 | 6 | 7 |
| | | | 1 |
| 16 | 22 | 10 | 12 |
| | | 1 | 1 |
| | | 7 | 7 |
| | | | 1 |
| 1 | 2 | 1 | 1 |
| | 1 | 2 | 2 |
| | | 2 | 2 |
| 2 | 4 | 2 | 4 |
| 1 | 1 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Dyspepsia | 2 | 2 |
| Dysphagia | 4 | 7 |
| Dysphonia | 8 | 11 |
| Dysphoria | | 1 |
| Dyspnoea | 14 | 19 |
| Ear pain | 2 | 2 |
| Enlarged uvula | 1 | 1 |
| Eructation | 1 | 1 |
| Erythema | 35 | 37 |
| Extrasystoles | 1 | 1 |
| Eyelid oedema | 2 | 2 |
| Eyelid ptosis | 1 | 2 |
| Eyelids pruritus | 1 | 1 |
| Eye oedema | | 1 |
| Eye pruritus | | 1 |
| Face oedema | 2 | 2 |
| Facial paresis | 1 | 1 |
| Fatigue | 41 | 46 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | | 1 |
| Feeling hot | 1 | 2 |
| Fibrin D dimer increased | 2 | 2 |
| Flatulence | 1 | 2 |
| Flushing | 14 | 16 |
| Gait disturbance | 1 | 3 |
| Gamma-glutamyltransferase increased | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| Gastrointestinal disorder | 4 | 5 |
| Gastrointestinal hypermotility | | 1 |
| Guillain-Barre syndrome | 2 | 2 |
| Headache | 51 | 60 |
| Head discomfort | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 3 | 6 |
| 1 | 1 | 7 | 10 |
| | | | 1 |
| 4 | 6 | 10 | 13 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 25 | 26 | 10 | 11 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 18 | 22 | 23 | 24 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 2 |
| 10 | 10 | 4 | 6 |
| | 2 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | | |
| | | | 1 |
| | | 2 | 2 |
| 29 | 37 | 22 | 23 |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Heart rate increased | 16 | 16 | 12 | 12 | 4 | 4 |
| Herpes dermatitis | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 8 | 10 | 3 | 5 | 5 | 5 |
| Hypersensitivity | 16 | 23 | 6 | 10 | 10 | 13 |
| Hypertension | 14 | 17 | 9 | 11 | 5 | 6 |
| Hypertensive crisis | 5 | 5 | | | 5 | 5 |
| Hypertensive emergency | | 1 | | | | 1 |
| Hypoacusis | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 33 | 38 | 20 | 24 | 13 | 14 |
| Hypoaesthesia oral | 13 | 17 | 5 | 6 | 8 | 11 |
| Hypotension | 9 | 10 | 2 | 3 | 7 | 7 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Incomplete course of vaccination | | 1 | | 1 | | |
| Incorrect route of product administration | 2 | 2 | 2 | 2 | | |
| Inflammation | 2 | 2 | | | 2 | 2 |
| Injury | | 1 | | 1 | | |
| Irritability | 1 | 1 | 1 | 1 | | |
| Joint range of motion decreased | | 1 | | 1 | | |
| Laryngeal oedema | 3 | 4 | | | 3 | 4 |
| Laryngeal pain | 1 | 1 | | | 1 | 1 |
| Laryngospasm | 4 | 4 | | | 4 | 4 |
| Lethargy | 2 | 2 | 2 | 2 | | |
| Limb discomfort | 1 | 2 | | 1 | 1 | 1 |
| Lip oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Lip swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Liquid product physical issue | 1 | 1 | 1 | 1 | | |
| Livedo reticularis | 1 | 1 | 1 | 1 | | |
| Localised oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Local reaction | 1 | 2 | 1 | 2 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 10 | 10 | 2 | 2 | 8 | 8 |

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FEMALE

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|------------------------------------|------------------------------------|--------------------------------------|
| Lymphadenopathy | 11 | 12 |
| Lymph node pain | 3 | 4 |
| Lymphoedema | 1 | 1 |
| Lymphopenia | 1 | 1 |
| Malaise | 9 | 9 |
| Maternal exposure during pregnancy | | 1 |
| Meningism | 1 | 1 |
| Migraine | 2 | 3 |
| Mucosal dryness | | 1 |
| Muscle discomfort | 1 | 1 |
| Muscle spasms | 3 | 4 |
| Muscle tightness | 1 | 1 |
| Muscular weakness | 1 | 2 |
| Myalgia | 56 | 58 |
| Myelitis | 1 | 1 |
| Nasal congestion | | 1 |
| Nasal pruritus | | 1 |
| Nausea | 20 | 24 |
| Neck pain | 2 | 2 |
| Nervousness | 1 | 1 |
| Ocular hyperaemia | 1 | 1 |
| Oedema | 3 | 3 |
| Oedema peripheral | 1 | 1 |
| Off label use | 2 | 3 |
| Oral herpes | 2 | 3 |
| Oropharyngeal pain | 4 | 4 |
| Orthostatic hypotension | | 1 |
| Oxygen saturation decreased | 3 | 3 |
| Pain | 19 | 19 |
| Pain in extremity | 10 | 13 |
| Pain in jaw | 1 | 1 |
| Palpitations | 12 | 13 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 5 | 7 | 7 |
| 2 | 3 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | 6 | 6 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | 3 | 3 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| 30 | 31 | 26 | 27 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 14 | 17 | 6 | 7 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 2 | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | 1 | | |
| 1 | 1 | 2 | 2 |
| 8 | 8 | 11 | 11 |
| 9 | 12 | 1 | 1 |
| 1 | 1 | | |
| 9 | 10 | 3 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Panic reaction | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Polydipsia | 1 | 1 | 1 | 1 | | |
| Polyneuropathy | 1 | 1 | | | 1 | 1 |
| Polyuria | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | 1 | 1 | 1 | 1 | | |
| Post herpetic neuralgia | 1 | 1 | | | 1 | 1 |
| Presyncope | 5 | 8 | 3 | 4 | 2 | 4 |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Pruritus | 35 | 37 | 21 | 22 | 14 | 15 |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pulmonary thrombosis | 1 | 2 | | | 1 | 2 |
| Pyrexia | 57 | 62 | 27 | 31 | 30 | 31 |
| Rash | 31 | 36 | 12 | 16 | 19 | 20 |
| Rash erythematous | 2 | 2 | 2 | 2 | | |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash maculo-papular | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash pruritic | 7 | 8 | 3 | 4 | 4 | 4 |
| Rheumatoid arthritis | 1 | 2 | | | 1 | 2 |
| Rhinitis allergic | | 1 | | 1 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| Seizure | | 1 | | | | 1 |
| Skin burning sensation | | 1 | | 1 | | |
| Skin reaction | 1 | 1 | | | 1 | 1 |
| Somnolence | 12 | 13 | 7 | 8 | 5 | 5 |
| Spinal pain | 2 | 2 | | | 2 | 2 |
| Stress | 1 | 1 | 1 | 1 | | |
| Sudden death | | 1 | | | | 1 |
| Suspected COVID-19 | 1 | 1 | 1 | 1 | | |
| Swelling face | 2 | 2 | | | 2 | 2 |

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Gender

FEMALE

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Syncope | 4 | 4 | | | 4 | 4 |
| Tachycardia | 26 | 31 | 13 | 15 | 13 | 16 |
| Tachypnoea | 1 | 2 | 1 | 2 | | |
| Taste disorder | 2 | 2 | | | 2 | 2 |
| Temporomandibular joint syndrome | 1 | 1 | 1 | 1 | | |
| Tension | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | | 1 | | 1 | | |
| Throat irritation | 5 | 8 | 3 | 6 | 2 | 2 |
| Tinnitus | 4 | 5 | 2 | 3 | 2 | 2 |
| Tongue discomfort | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Tongue ulceration | | 1 | | 1 | | |
| Tremor | 7 | 9 | 5 | 5 | 2 | 4 |
| Trigeminal neuralgia | 1 | 1 | | | 1 | 1 |
| Trismus | 1 | 1 | 1 | 1 | | |
| Urticaria | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site irritation | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 3 | 3 | 3 | 3 | | |
| Vaccination site pain | 38 | 50 | 29 | 41 | 9 | 9 |
| Vaccination site pruritus | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 2 | 1 | 2 | | |
| Vertigo | 6 | 6 | 5 | 5 | 1 | 1 |
| Viral infection | 2 | 2 | 2 | 2 | | |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 4 | 4 |
| 13 | 15 | 13 | 16 |
| 1 | 2 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 3 | 6 | 2 | 2 |
| 2 | 3 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 5 | 5 | 2 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| 29 | 41 | 9 | 9 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 5 | 5 | 1 | 1 |
| 2 | 2 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vision blurred | 2 | 2 | 2 | 2 | | |
| Vomiting | 8 | 9 | 2 | 3 | 6 | 6 |
| | 1,091 | 1,287 | 530 | 652 | 561 | 635 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Abdominal pain upper | 2 | 2 | 2 | 2 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Acute respiratory distress syndrome | | 1 | | | | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Angioedema | 1 | 2 | | | 1 | 2 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arthralgia | 9 | 9 | 2 | 2 | 7 | 7 |
| Asthenia | 6 | 8 | 4 | 6 | 2 | 2 |
| Blister | 2 | 2 | 2 | 2 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | | 1 | | 1 | | |
| Blood pressure diastolic increased | | 1 | | 1 | | |
| Blood pressure inadequately controlled | | 1 | | 1 | | |
| Blood pressure increased | 4 | 4 | 3 | 3 | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Burning sensation | | 1 | | 1 | | |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Cachexia | 2 | 2 | | | 2 | 2 |
| Capillary disorder | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | | 1 | | | | 1 |
| Cardiac valve disease | | 1 | | | | 1 |
| Central nervous system stimulation | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest pain | | 1 | | | | 1 |
| Chills | 14 | 17 | 5 | 7 | 9 | 10 |
| Condition aggravated | | 1 | | | | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |

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Gender

MALE

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|--------------------------------------|------------------------------------|--------------------------------------|
| Cough | 4 | 4 |
| COVID-19 | 9 | 10 |
| Cyanosis | 1 | 2 |
| Deafness unilateral | | 1 |
| Death | 2 | 2 |
| Decreased appetite | 2 | 2 |
| Diabetes mellitus inadequate control | 1 | 1 |
| Diarrhoea | 4 | 5 |
| Discomfort | 2 | 3 |
| Disorientation | 1 | 1 |
| Dizziness | 13 | 15 |
| Drug ineffective | 7 | 8 |
| Dry mouth | 2 | 3 |
| Dry throat | | 1 |
| Dyskinesia | 1 | 1 |
| Dysphagia | 2 | 3 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 5 | 6 |
| Eructation | 2 | 2 |
| Erythema | 6 | 6 |
| Extrasystoles | 1 | 1 |
| Eye pruritus | 1 | 1 |
| Facial paralysis | 1 | 1 |
| Fall | 1 | 2 |
| Fatigue | 7 | 12 |
| Feeling cold | 1 | 1 |
| Flushing | 2 | 3 |
| Gastrointestinal disorder | 3 | 4 |
| Haematuria | 1 | 1 |
| Headache | 10 | 13 |
| Head discomfort | 1 | 1 |
| Heart rate increased | 2 | 2 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | 1 | 1 |
| 2 | 2 | 7 | 8 |
| 1 | 2 | | |
| | | | 1 |
| | | 2 | 2 |
| 2 | 2 | | |
| | | 1 | 1 |
| 3 | 4 | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| 9 | 10 | 4 | 5 |
| | | 7 | 8 |
| 1 | 2 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 3 | 4 |
| 1 | 1 | 1 | 1 |
| 4 | 4 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 3 | 7 | 4 | 5 |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| 3 | 4 | | |
| | | 1 | 1 |
| 6 | 9 | 4 | 4 |
| 1 | 1 | | |
| 2 | 2 | | |

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MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 5 | 6 | 2 | 2 | 3 | 4 |
| Hypersensitivity | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypertension | 3 | 4 | 1 | 2 | 2 | 2 |
| Hypertensive crisis | 1 | 2 | | | 1 | 2 |
| Hypoaesthesia | 8 | 9 | 7 | 8 | 1 | 1 |
| Hypoaesthesia oral | | 1 | | 1 | | |
| Hypotension | 2 | 2 | 1 | 1 | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Insulin resistance | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | | | 1 | 1 |
| Leukocytosis | | 1 | | | | 1 |
| Lip oedema | 1 | 1 | 1 | 1 | | |
| Liquid product physical issue | | 1 | | 1 | | |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 2 | 3 | | | 2 | 3 |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 2 | 2 | 1 | 1 | 1 | 1 |
| Malaise | 5 | 6 | 3 | 4 | 2 | 2 |
| Mechanical urticaria | 1 | 1 | 1 | 1 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Musculoskeletal discomfort | 1 | 1 | 1 | 1 | | |
| Myalgia | 10 | 11 | 5 | 6 | 5 | 5 |
| Myocardial infarction | | 1 | | | | 1 |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Nausea | 3 | 5 | 2 | 3 | 1 | 2 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Orthostatic hypotension | 1 | 1 | | | 1 | 1 |
| Pain | 3 | 4 | 2 | 3 | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 1 | 1 |
| 2 | 2 | 3 | 4 |
| 1 | 1 | 2 | 2 |
| 1 | 2 | 2 | 2 |
| | | 1 | 2 |
| 7 | 8 | 1 | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 3 | 4 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 5 | 6 | 5 | 5 |
| | | | 1 |
| 1 | 1 | | |
| 2 | 3 | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 3 | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # | Cumulative Total # |
|-----------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Pain in extremity | 2 | 4 |
| Pallor | 1 | 1 |
| Palpitations | 4 | 4 |
| Pancreatitis | 1 | 1 |
| Periorbital oedema | 1 | 1 |
| Pneumonia | | 1 |
| Pollakiuria | 1 | 1 |
| Poor quality product administered | | 1 |
| Poor quality sleep | | 1 |
| Presyncope | 2 | 2 |
| Product use issue | 1 | 1 |
| Pruritus | 5 | 5 |
| Pulmonary oedema | 1 | 1 |
| Pyrexia | 21 | 28 |
| Rash | 7 | 10 |
| Rash maculo-papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Respiratory tract infection | | 1 |
| SARS-CoV-2 ant body test positive | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 |
| Shock | 1 | 1 |
| Skin lesion | 1 | 1 |
| Somnolence | | 1 |
| Sudden death | 1 | 2 |
| Swelling | 1 | 1 |
| Syncope | 3 | 3 |
| Tachycardia | 3 | 6 |
| Tinnitus | | 1 |
| Tongue oedema | 1 | 1 |
| Tonsillar hypertrophy | 1 | 1 |
| Tremor | 2 | 2 |
| Vaccination site discomfort | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 3 | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 4 | 4 | 1 | 1 |
| | | 1 | 1 |
| 10 | 16 | 11 | 12 |
| 4 | 6 | 3 | 4 |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 3 | 2 | 3 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site hyperaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 2 | 2 | 2 | 2 | | |
| Vaccination site oedema | 1 | 2 | 1 | 2 | | |
| Vaccination site pain | 9 | 13 | 8 | 12 | 1 | 1 |
| Vomiting | 1 | 3 | | 2 | 1 | 1 |
| Wheezing | 1 | 1 | 1 | 1 | | |
| | 298 | 381 | 149 | 205 | 149 | 176 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Antibody test abnormal | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | | 1 | | 1 | | |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Circumstance or information capable of leading to medication error | 2 | 2 | 2 | 2 | | |
| Cough | 3 | 3 | 3 | 3 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Dizziness | 3 | 3 | 2 | 2 | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 2 | | 1 | 1 | 1 |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Eye irritation | | 1 | | 1 | | |
| Headache | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypersensitivity | | 2 | | 2 | | |
| Hypertension | 1 | 2 | | 1 | 1 | 1 |
| Hypoaesthesia oral | 2 | 4 | 1 | 3 | 1 | 1 |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Liquid product physical issue | | 2 | | 2 | | |
| No adverse event | 5 | 7 | 5 | 7 | | |
| Oedema | 1 | 1 | 1 | 1 | | |
| Oral discomfort | | 1 | | 1 | | |
| Oropharyngeal discomfort | 2 | 2 | 2 | 2 | | |
| Pain in extremity | | 1 | | 1 | | |
| Palpitations | | 1 | | 1 | | |
| Periorbital oedema | | 1 | | 1 | | |
| Poor quality product administered | | 2 | | 2 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash macular | | 1 | | 1 | | |
| Reaction to excipient | 1 | 1 | | | 1 | 1 |
| Tachycardia | | 2 | | 2 | | |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vomiting | | 1 | | 1 | | |
| Wrong technique in product usage process | 1 | 1 | 1 | 1 | | |
| | 39 | 61 | 27 | 49 | 12 | 12 |

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Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenia | 1 | 1 | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 |
| Oedema peripheral | 2 | 2 | 2 | 2 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| Periorbital oedema | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 8 | 8 | 8 | 8 |

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Country Where Event Occurred

HUNGARY

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 2 | 2 | 2 | 2 | | |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Ageusia | | 2 | | 2 | | |
| Allergy to vaccine | | 1 | | | | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 2 | 1 | 2 | | |
| Arthralgia | 5 | 7 | 5 | 6 | | 1 |
| Asphyxia | 2 | 2 | | | 2 | 2 |
| Asthenia | 22 | 31 | 20 | 28 | 2 | 3 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Axillary pain | | 1 | | 1 | | |
| Back pain | 1 | 4 | 1 | 4 | | |
| Blister | | 1 | | 1 | | |
| Blood glucose increased | | 1 | | 1 | | |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 5 | 3 | 3 | 1 | 2 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | | 2 | | 2 | | |
| Burning sensation | 2 | 4 | 2 | 4 | | |
| Cartilage injury | 1 | 1 | | | 1 | 1 |
| Cervical neuritis | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 4 | 5 | 4 | 5 | | |
| Chills | 14 | 21 | 14 | 20 | | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | 1 | 1 | | |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Confusional state | | 1 | | 1 | | |
| COVID-19 | 4 | 5 | 2 | 2 | 2 | 3 |
| Craniofacial fracture | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Decreased appetite | 2 | 2 |
| Depressed mood | 1 | 1 |
| Depression | | 1 |
| Diarrhoea | 4 | 4 |
| Dizziness | 13 | 19 |
| Drug hypersensitivity | 2 | 2 |
| Drug ineffective | 3 | 5 |
| Dry mouth | | 1 |
| Dysgeusia | 4 | 5 |
| Dysphagia | 6 | 6 |
| Dyspnoea | 5 | 5 |
| Ear discomfort | | 1 |
| Ear pain | 1 | 2 |
| Ear pruritus | | 2 |
| Eczema | | 1 |
| Erythema | 5 | 7 |
| Exposure during pregnancy | 1 | 1 |
| Exposure via breast milk | | 1 |
| Extrasystoles | 1 | 1 |
| Eye haemorrhage | 1 | 1 |
| Eye oedema | 1 | 1 |
| Face oedema | 1 | 1 |
| Facial paralysis | 2 | 2 |
| Facial paresis | 2 | 2 |
| Fall | 2 | 2 |
| Fatigue | 9 | 12 |
| Feeling abnormal | 3 | 6 |
| Feeling cold | 1 | 1 |
| Feeling hot | | 4 |
| Flushing | 2 | 2 |
| Gait disturbance | | 2 |
| Glossodynia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| 4 | 4 | | |
| 10 | 15 | 3 | 4 |
| 2 | 2 | | |
| | | 3 | 5 |
| | | | 1 |
| 4 | 5 | | |
| 2 | 2 | 4 | 4 |
| 4 | 4 | 1 | 1 |
| | 1 | | |
| 1 | 2 | | |
| | 2 | | |
| | 1 | | |
| 5 | 7 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 9 | 12 | | |
| 3 | 6 | | |
| 1 | 1 | | |
| | 3 | | 1 |
| 2 | 2 | | |
| | 2 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Haemorrhage | | 1 |
| Headache | 21 | 34 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 1 | 3 |
| Herpes virus infection | | 1 |
| Herpes zoster | 1 | 1 |
| Hyperaemia | 1 | 1 |
| Hyperaesthesia | | 1 |
| Hyperhidrosis | 2 | 3 |
| Hypersensitivity | 1 | 1 |
| Hypertensive crisis | 1 | 1 |
| Hypoaesthesia | 3 | 6 |
| Hypoaesthesia oral | 1 | 3 |
| Hypoglycaemia | | 1 |
| Hypokinesia | 1 | 1 |
| Hypotension | 2 | 2 |
| Illness | 1 | 1 |
| Incorrect route of product administration | | 1 |
| Influenza like illness | 1 | 1 |
| Injection site discomfort | 1 | 1 |
| Lacrimation increased | 1 | 2 |
| Lethargy | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Lip swelling | 1 | 1 |
| Localised oedema | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenitis | 2 | 2 |
| Lymphadenopathy | 15 | 18 |
| Lymph node pain | 5 | 6 |
| Malaise | 9 | 17 |
| Maternal exposure during pregnancy | 1 | 1 |
| Micturition urgency | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| 20 | 30 | 1 | 4 |
| 1 | 1 | | |
| 1 | 3 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 5 | 1 | 1 |
| 1 | 3 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 12 | 14 | 3 | 4 |
| 4 | 5 | 1 | 1 |
| 9 | 15 | | 2 |
| 1 | 1 | | |
| | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # | Cumulative Total # |
|-----------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Migraine | 2 | 2 |
| Mood altered | 2 | 2 |
| Muscle fatigue | | 1 |
| Muscle strain | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal stiffness | 2 | 3 |
| Myalgia | 12 | 20 |
| Nasopharyngitis | | 1 |
| Nausea | 13 | 19 |
| Neoplasm progression | 1 | 1 |
| Neuralgia | 1 | 1 |
| Night sweats | 1 | 1 |
| Nipple pain | 1 | 1 |
| No adverse event | | 1 |
| Odynophagia | 1 | 1 |
| Off label use | 1 | 3 |
| Oropharyngeal pain | 2 | 4 |
| Oxygen saturation decreased | | 1 |
| Pain | 1 | 3 |
| Pain in extremity | 13 | 24 |
| Pallor | | 1 |
| Palpitations | 2 | 3 |
| Panic attack | | 1 |
| Paraesthesia | 1 | 3 |
| Peripheral nerve paresis | 1 | 1 |
| Peripheral swelling | 2 | 4 |
| Pneumonia | 1 | 1 |
| Polyarthritis | 1 | 1 |
| Poor quality sleep | 1 | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 3 | 7 |
| Pulpitis dental | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | | |
| 2 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | 1 | 1 |
| 12 | 19 | | 1 |
| | 1 | | |
| 12 | 17 | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 3 | | |
| 2 | 4 | | |
| | 1 | | |
| 1 | 3 | | |
| 13 | 24 | | |
| | 1 | | |
| 1 | 2 | 1 | 1 |
| | 1 | | |
| 1 | 2 | | 1 |
| | | 1 | 1 |
| 2 | 4 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 6 | 1 | 1 |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pyrexia | 26 | 35 | 26 | 33 | | 2 |
| Rash | 3 | 4 | 2 | 3 | 1 | 1 |
| Rash erythematous | 3 | 3 | 3 | 3 | | |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash maculo-papular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 3 | 3 | 3 | 3 | | |
| Retching | 2 | 2 | 2 | 2 | | |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 2 | 3 | 1 | 1 | 1 | 2 |
| Sensation of foreign body | 2 | 2 | | | 2 | 2 |
| Sensitive skin | 2 | 2 | 2 | 2 | | |
| Skin burning sensation | 3 | 3 | 2 | 2 | 1 | 1 |
| Skin disorder | 1 | 1 | 1 | 1 | | |
| Somnolence | 2 | 3 | 2 | 3 | | |
| Stress | 1 | 1 | 1 | 1 | | |
| Swelling face | | 1 | | 1 | | |
| Syncope | 2 | 2 | | | 2 | 2 |
| Tachycardia | 6 | 6 | 4 | 4 | 2 | 2 |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Thirst | | 1 | | | | 1 |
| Throat irritation | | 1 | | 1 | | |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 4 | 2 | 3 | | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site erythema | 3 | 11 | 3 | 11 | | |
| Vaccination site hypoaesthesia | | 1 | | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | | 1 | | 1 | | |
| Vaccination site movement impairment | | 2 | | 2 | | |
| Vaccination site nodule | | 2 | | 2 | | |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 26 | 33 | | 2 |
| 2 | 3 | 1 | 1 |
| 3 | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 2 |
| | | 2 | 2 |
| 2 | 2 | | |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 2 | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 2 | 2 |
| 4 | 4 | 2 | 2 |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| 3 | 11 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | |
| | 2 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site oedema | | 1 | | 1 | | |
| Vaccination site pain | 12 | 21 | 11 | 20 | 1 | 1 |
| Vaccination site pruritus | | 2 | | 2 | | |
| Vaccination site swelling | 4 | 8 | 4 | 8 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Vaginal discharge | | 1 | | 1 | | |
| Vasculitis | 1 | 1 | 1 | 1 | | |
| Vision blurred | | 1 | | 1 | | |
| Vomiting | 3 | 7 | 3 | 6 | | 1 |
| White coat hypertension | 1 | 1 | 1 | 1 | | |
| | 386 | 595 | 321 | 503 | 65 | 92 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Blood pressure increased | 1 | 3 | | 2 | 1 | 1 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Chest discomfort | | 1 | | 1 | | |
| Chest pain | | 1 | | 1 | | |
| Chills | 2 | 2 | 2 | 2 | | |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cold sweat | | 1 | | 1 | | |
| COVID-19 | 1 | 2 | | | 1 | 2 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Dizziness | | 2 | | 2 | | |
| Drug ineffective | | 1 | | | | 1 |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Ear pruritus | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Eye haemorrhage | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 5 | 7 | 4 | 6 | 1 | 1 |
| Feeding disorder | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Flushing | 1 | 1 | 1 | 1 | | |
| Headache | 3 | 9 | 3 | 9 | | |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Hyperaesthesia | | 1 | | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypersensitivity | 3 | 4 | 3 | 4 | | |
| Hypoaesthesia | | 1 | | 1 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Insomnia | 2 | 2 | 2 | 2 | | |
| Laryngeal oedema | | 1 | | | | 1 |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 2 | 1 | 2 | | |
| Lymph node pain | | 1 | | 1 | | |
| Malaise | 3 | 4 | 3 | 4 | | |
| Metabolic acidosis | 1 | 1 | | | 1 | 1 |
| Mobility decreased | | 1 | | 1 | | |
| Muscle strain | 1 | 1 | 1 | 1 | | |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | | 1 | | | | 1 |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Pain of skin | | 1 | | 1 | | |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pulseless electrical activity | 1 | 1 | | | 1 | 1 |
| Pyrexia | 5 | 9 | 4 | 8 | 1 | 1 |
| Rash | | 1 | | 1 | | |
| Rash erythematous | 2 | 2 | 2 | 2 | | |
| Rash maculo-papular | | 1 | | | | 1 |
| Rash pruritic | | 1 | | 1 | | |
| Rash vesicular | | 1 | | 1 | | |
| Rhinorrhoea | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 ant body test positive | 3 | 3 | 3 | 3 | | |
| SARS-CoV-2 test positive | 1 | 1 | 1 | 1 | | |
| Sensation of foreign body | | 1 | | | | 1 |
| Sinusitis | 1 | 1 | 1 | 1 | | |
| Skin lesion | | 1 | | 1 | | |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 4 | | |
| | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| 3 | 4 | | |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 8 | 1 | 1 |
| | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| | 1 | | |
| 2 | 2 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Somnolence | 1 | 2 | 1 | 2 | | |
| Stress | | 1 | | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Swelling face | | 1 | | 1 | | |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Tension | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | |
| Throat irritation | 1 | 1 | 1 | 1 | | |
| Tinnitus | 1 | 2 | 1 | 2 | | |
| Urticaria | 1 | 3 | 1 | 3 | | |
| Vaccination site coldness | | 1 | | 1 | | |
| Vaccination site pain | 2 | 3 | 2 | 3 | | |
| | 78 | 127 | 58 | 99 | 20 | 28 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Herpes zoster | 2 | 5 | 2 | 5 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Lymphoedema | | 1 | | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | | 1 | | 1 | | |
| | 7 | 13 | 5 | 11 | 2 | 2 |

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Country Where Event Occurred

ICELAND

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anal incontinence | 1 | 1 | 1 | 1 | | |
| Aortic aneurysm | | 1 | | | | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arthralgia | 2 | 3 | 2 | 3 | | |
| Asthenia | 2 | 5 | 2 | 5 | | |
| Asthma | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Back pain | | 1 | | 1 | | |
| Blood pressure increased | | 1 | | 1 | | |
| Bone pain | | 1 | | 1 | | |
| Bradycardia | | 1 | | | | 1 |
| Breast inflammation | 1 | 1 | 1 | 1 | | |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Cardiac failure | | 1 | | | | 1 |
| Chest discomfort | 1 | 2 | 1 | 2 | | |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 4 | 5 | 4 | 5 | | |
| Cold sweat | | 1 | | 1 | | |
| Cough | 1 | 4 | 1 | 3 | | 1 |
| Death | | 1 | | | | 1 |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Disease progression | | 1 | | | | 1 |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 8 | 4 | 8 | | |
| Dry mouth | | 1 | | 1 | | |
| Dry throat | | 1 | | 1 | | |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 2 | 1 | 2 | | |
| Ear pain | | 1 | | 1 | | |
| Erythema | 1 | 2 | 1 | 2 | | |
| Fatigue | 6 | 12 | 6 | 12 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Feeling cold | | 1 | | 1 | | |
| Fluid overload | 1 | 1 | | | 1 | 1 |
| Gastrointestinal pain | 1 | 1 | 1 | 1 | | |
| Headache | 8 | 20 | 8 | 20 | | |
| Head discomfort | | 1 | | 1 | | |
| Heart rate increased | 1 | 2 | 1 | 2 | | |
| Hepatic enzyme increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Hot flush | | 1 | | 1 | | |
| Hypercapnia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | 1 | 5 | 1 | 5 | | |
| Hypoperfusion | 1 | 1 | | | 1 | 1 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Limb discomfort | | 1 | | 1 | | |
| Lung infiltration | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 2 | 2 | 2 | 2 | | |
| Malaise | 8 | 13 | 6 | 10 | 2 | 3 |
| Migraine | | 1 | | 1 | | |
| Muscle twitching | 2 | 2 | 2 | 2 | | |
| Myalgia | 8 | 10 | 8 | 10 | | |
| Nasopharyngitis | | 5 | | 5 | | |
| Nausea | 1 | 6 | 1 | 6 | | |
| Ocular discomfort | | 1 | | 1 | | |
| Oropharyngeal pain | 3 | 5 | 3 | 5 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 4 | 4 | 4 | 4 | | |
| Pallor | | 1 | | 1 | | |
| Periorbital swelling | 1 | 1 | 1 | 1 | | |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 8 | 20 | | |
| | 1 | | |
| 1 | 2 | | |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 5 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 6 | 10 | 2 | 3 |
| | 1 | | |
| 2 | 2 | | |
| 8 | 10 | | |
| | 5 | | |
| 1 | 6 | | |
| | 1 | | |
| 3 | 5 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 4 | | |
| | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

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|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral artery thrombosis | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | | 1 | | 1 | | |
| Pneumonia | 2 | 3 | | | 2 | 3 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Pruritus | 3 | 4 | 3 | 4 | | |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | 1 | 1 | | |
| Pyrexia | 8 | 19 | 7 | 17 | 1 | 2 |
| Rash | 1 | 1 | 1 | 1 | | |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | | 1 | | 1 | | |
| Sensitive skin | 2 | 2 | 2 | 2 | | |
| Sensory loss | | 1 | | 1 | | |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Sluggishness | 1 | 1 | 1 | 1 | | |
| Tachycardia | 1 | 2 | | 1 | 1 | 1 |
| Thirst | | 1 | | 1 | | |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | | 1 | | 1 | | |
| Urinary incontinence | 1 | 1 | 1 | 1 | | |
| Urine flow decreased | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 4 | 1 | 4 | | |
| Vaccination site inflammation | 2 | 3 | 2 | 3 | | |
| Vaccination site pain | 7 | 10 | 7 | 10 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 126 | 230 | 106 | 201 | 20 | 29 |

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Gender

MALE

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 2 | 1 | 2 | | |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Bone pain | | 1 | | 1 | | |
| Cardiac failure | | 1 | | | | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 2 | 1 | 2 | | |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Death | | 1 | | | | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Discomfort | | 1 | | 1 | | |
| Erythema | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 2 | 1 | 2 | | |
| Feeling cold | | 1 | | 1 | | |
| Headache | 1 | 2 | 1 | 2 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 3 | 1 | 2 | | 1 |
| Myalgia | 1 | 2 | 1 | 2 | | |
| Myocardial infarction | | 1 | | | | 1 |
| Oropharyngeal pain | | 1 | | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | | 1 | | 1 | | |
| Pneumonia | | 1 | | | | 1 |
| Pyrexia | 2 | 6 | 1 | 4 | 1 | 2 |
| Respiration abnormal | | 1 | | | | 1 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Sepsis | | 1 | | | | 1 |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|---------------------------|--|--|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sudden death | | 1 | | | | 1 |
| Swelling | | 1 | | 1 | | |
| Vaccination site pain | 1 | 3 | 1 | 3 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| | 24 | 50 | 12 | 29 | 12 | 21 |

Gender

UNKNOWN

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Rhinorrhoea | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

INDIA

Gender

UNKNOWN

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | |
|-------------|---|
| Nonserious | |
| I | C |
| | 1 |
| 1 | 1 |

Suspected counterfeit product

1

1

1

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Country Where Event Occurred

IRELAND

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Ageusia | 3 | 3 | | | 3 | 3 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anxiety | 2 | 2 | | | 2 | 2 |
| Arthralgia | 15 | 15 | 2 | 2 | 13 | 13 |
| Asthenia | 26 | 27 | 3 | 4 | 23 | 23 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | 5 | 5 | | | 5 | 5 |
| Blindness | | 1 | | | | 1 |
| Blindness transient | 1 | 1 | | | 1 | 1 |
| Blood pressure diastolic increased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Blood pressure systolic increased | 1 | 1 | 1 | 1 | | |
| Body temperature abnormal | 1 | 1 | | | 1 | 1 |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Burning sensation | 6 | 6 | 1 | 1 | 5 | 5 |
| Cardiac failure congestive | 1 | 1 | | | 1 | 1 |
| Cheilitis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 6 | 6 | 1 | 1 | 5 | 5 |
| Chest pain | 7 | 7 | | | 7 | 7 |
| Chills | 17 | 17 | | | 17 | 17 |
| Choking sensation | 1 | 1 | 1 | 1 | | |
| Cold sweat | 1 | 2 | | | 1 | 2 |
| Confusional state | 2 | 2 | | | 2 | 2 |
| Contusion | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

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|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cough | 5 | 5 | | | 5 | 5 |
| COVID-19 | 3 | 3 | | | 3 | 3 |
| Cyanosis | | 1 | | 1 | | |
| Deafness | | 1 | | | | 1 |
| Death | | 1 | | | | 1 |
| Decreased appetite | 3 | 3 | | | 3 | 3 |
| Depressed level of consciousness | | 1 | | | | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 7 | 7 | 2 | 2 | 5 | 5 |
| Discomfort | 4 | 4 | 1 | 1 | 3 | 3 |
| Disease recurrence | 3 | 3 | | | 3 | 3 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 3 | 3 | 1 | 1 | 2 | 2 |
| Dizziness | 32 | 33 | 3 | 3 | 29 | 30 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Dry eye | 2 | 2 | | | 2 | 2 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 2 | 2 | | | 2 | 2 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 14 | 15 | 2 | 2 | 12 | 13 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Emotional distress | 1 | 1 | | | 1 | 1 |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Erythema | 4 | 4 | 2 | 2 | 2 | 2 |
| Erythema of eyelid | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Eye discharge | 1 | 1 | | | 1 | 1 |
| Eyelids pruritus | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # | Cumulative Total # |
|---------------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Eye pain | 1 | 1 |
| Eye pruritus | 1 | 1 |
| Eye swelling | 1 | 1 |
| Face injury | 1 | 1 |
| Facial pain | 1 | 1 |
| Facial paralysis | 5 | 5 |
| Faeces discoloured | 1 | 1 |
| Fatigue | 36 | 38 |
| Feeling abnormal | 6 | 6 |
| Feeling cold | 7 | 7 |
| Feeling drunk | 2 | 2 |
| Feeling hot | 11 | 11 |
| Feeling of body temperature change | 2 | 2 |
| Flank pain | 2 | 2 |
| Flatulence | 1 | 1 |
| Flushing | 4 | 4 |
| Gait disturbance | 2 | 2 |
| Gastric disorder | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Glossodynia | 1 | 1 |
| Haematemesis | 1 | 1 |
| Haematochezia | 1 | 1 |
| Haemoglobin decreased | 1 | 1 |
| Headache | 50 | 53 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 2 | 3 |
| Herpes zoster | 1 | 1 |
| Herpes zoster reactivation | 1 | 1 |
| Hyperaesthesia | 1 | 1 |
| Hyperhidrosis | 11 | 11 |
| Hypersensitivity | 3 | 3 |
| Hypertension | 9 | 9 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 5 | 5 |
| | | 1 | 1 |
| 3 | 5 | 33 | 33 |
| 1 | 1 | 5 | 5 |
| 2 | 2 | 5 | 5 |
| | | 2 | 2 |
| 1 | 1 | 10 | 10 |
| | | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 10 | 10 |
| | | 3 | 3 |
| | | 9 | 9 |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoaesthesia | 11 | 11 | 2 | 2 | 9 | 9 |
| Hypoaesthesia oral | 4 | 4 | | | 4 | 4 |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 3 | | | 3 | 3 |
| Illness | 1 | 1 | | | 1 | 1 |
| Impaired driving ability | 2 | 2 | | | 2 | 2 |
| Impaired work ability | 4 | 4 | | | 4 | 4 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect dose administered | | 3 | | 3 | | |
| Influenza like illness | 6 | 6 | 2 | 2 | 4 | 4 |
| Injected limb mobility decreased | | 1 | | | | 1 |
| Insomnia | 8 | 8 | 1 | 1 | 7 | 7 |
| IVth nerve paralysis | 1 | 2 | | | 1 | 2 |
| Joint stiffness | 2 | 2 | | | 2 | 2 |
| Lacrimation decreased | 1 | 1 | | | 1 | 1 |
| Lethargy | 7 | 7 | 1 | 1 | 6 | 6 |
| Limb discomfort | 4 | 4 | 1 | 1 | 3 | 3 |
| Lip discolouration | 1 | 1 | | | 1 | 1 |
| Lip swelling | 5 | 5 | | | 5 | 5 |
| Loss of consciousness | 2 | 2 | | | 2 | 2 |
| Loss of personal independence in daily activities | 2 | 2 | | | 2 | 2 |
| Lymphadenopathy | 5 | 6 | | 1 | 5 | 5 |
| Lymph node pain | 4 | 4 | | | 4 | 4 |
| Malaise | 21 | 22 | 3 | 3 | 18 | 19 |
| Mastitis | 1 | 1 | | | 1 | 1 |
| Maternal exposure during breast feeding | 1 | 1 | 1 | 1 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Melaena | 1 | 1 | | | 1 | 1 |
| Menstrual disorder | 1 | 1 | | | 1 | 1 |
| Metrorrhagia | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 2 | 9 | 9 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 4 | 4 |
| 1 | 1 | | |
| | 3 | | |
| 2 | 2 | 4 | 4 |
| | | | 1 |
| 1 | 1 | 7 | 7 |
| | | 1 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 6 | 6 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 2 | 2 |
| | | 2 | 2 |
| | 1 | 5 | 5 |
| | | 4 | 4 |
| 3 | 3 | 18 | 19 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Muscle spasms | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscle twitching | 3 | 3 | | | 3 | 3 |
| Muscular weakness | 3 | 3 | | | 3 | 3 |
| Musculoskeletal chest pain | 1 | 1 | | | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 13 | 13 | 1 | 1 | 12 | 12 |
| Myelitis transverse | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Nausea | 39 | 40 | 7 | 7 | 32 | 33 |
| Neck pain | 3 | 3 | | | 3 | 3 |
| Nerve injury | 1 | 1 | | | 1 | 1 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Night sweats | 2 | 2 | 1 | 1 | 1 | 1 |
| No adverse event | | 1 | | 1 | | |
| Off label use | 3 | 3 | 3 | 3 | | |
| Oropharyngeal pain | 4 | 4 | 1 | 1 | 3 | 3 |
| Oxygen saturation decreased | 3 | 3 | | | 3 | 3 |
| Pain | 16 | 17 | 2 | 2 | 14 | 15 |
| Pain in extremity | 17 | 17 | 3 | 3 | 14 | 14 |
| Pallor | 3 | 3 | 1 | 1 | 2 | 2 |
| Palpitations | 10 | 10 | | | 10 | 10 |
| Pancreatitis relapsing | 1 | 1 | | | 1 | 1 |
| Panic attack | 2 | 2 | | | 2 | 2 |
| Paraesthesia | 23 | 23 | 3 | 3 | 20 | 20 |
| Paraesthesia oral | 6 | 6 | | | 6 | 6 |
| Paranasal sinus discomfort | 1 | 1 | | | 1 | 1 |
| Periarthritis | | 1 | | | | 1 |
| Periorbital oedema | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 2 | 2 | | | 2 | 2 |

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Gender

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|---------------------------------|------------------------------------|--------------------------------------|
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | 2 | 2 |
| Platelet count decreased | 1 | 1 |
| Poor quality sleep | 1 | 1 |
| Presyncope | 1 | 1 |
| Product preparation issue | | 3 |
| Product use issue | 2 | 2 |
| Pruritus | 12 | 12 |
| Psychomotor hyperactivity | 1 | 1 |
| Pulse abnormal | 1 | 1 |
| Pyrexia | 24 | 26 |
| Quality of life decreased | 1 | 1 |
| Rash | 10 | 10 |
| Rash erythematous | 6 | 6 |
| Rash macular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Respiratory tract infection | 1 | 1 |
| Retching | 1 | 1 |
| Rhinitis | 1 | 1 |
| Road traffic accident | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 |
| Sensation of foreign body | 2 | 2 |
| Sensory loss | 1 | 1 |
| Skin tightness | 1 | 1 |
| Somnolence | 2 | 2 |
| Stridor | 1 | 1 |
| Sudden death | 1 | 1 |
| Suspected product quality issue | | 3 |
| Swelling | 4 | 4 |
| Swelling face | 3 | 3 |
| Swelling of eyelid | 2 | 2 |
| Swollen tongue | 4 | 4 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 3 | | |
| 2 | 2 | | |
| 2 | 2 | 10 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | 22 | 23 |
| | | 1 | 1 |
| 2 | 2 | 8 | 8 |
| 1 | 1 | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 3 | | |
| | | 4 | 4 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 4 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Syncope | 4 | 6 |
| Tachycardia | 15 | 15 |
| Tenderness | 1 | 1 |
| Tension headache | 1 | 1 |
| Thirst | 1 | 1 |
| Throat irritation | 1 | 1 |
| Throat tightness | 4 | 4 |
| Thrombosis | 1 | 1 |
| Tinnitus | 1 | 1 |
| Tongue disorder | 1 | 1 |
| Tremor | 5 | 5 |
| Trigeminal nerve disorder | 1 | 1 |
| Trigeminal neuralgia | 1 | 1 |
| Upper gastrointestinal haemorrhage | 1 | 1 |
| Urticaria | 7 | 7 |
| Urticarial vasculitis | 1 | 1 |
| Urticaria papular | 1 | 1 |
| Vaccination site bruising | 1 | 1 |
| Vaccination site discolouration | 1 | 1 |
| Vaccination site erythema | 2 | 2 |
| Vaccination site irritation | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 |
| Vaccination site mass | 1 | 1 |
| Vaccination site pain | 6 | 6 |
| Vaccination site pruritus | 3 | 3 |
| Vaccination site swelling | 1 | 1 |
| Vaccination site warmth | 1 | 1 |
| Vaginal haemorrhage | 1 | 1 |
| Vertigo | 1 | 1 |
| Vision blurred | 2 | 2 |
| Visual impairment | | 1 |
| Vitreous floaters | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 4 | 6 |
| | | 15 | 15 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 6 | 6 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 4 | 4 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 14 | 14 | | | 14 | 14 |
| Wheezing | 4 | 4 | | | 4 | 4 |
| | 835 | 872 | 99 | 117 | 736 | 755 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Acute cardiac event | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Agitation | 1 | 1 | | | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anosmia | 2 | 2 | 1 | 1 | 1 | 1 |
| Arthralgia | 4 | 4 | 1 | 1 | 3 | 3 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Blepharospasm | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 2 | | | 2 | 2 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | 1 | 1 | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Confusional state | 2 | 2 | | | 2 | 2 |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 2 | 2 | | | 2 | 2 |
| Death | 2 | 2 | | | 2 | 2 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | 1 | 1 | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Dyspnoea at rest | 1 | 1 | | | 1 | 1 |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Emotional distress | 1 | 1 | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Erythema | 1 | 1 |
| Exposure via breast milk | 1 | 1 |
| Eye movement disorder | 1 | 1 |
| Facial paralysis | 3 | 3 |
| Fatigue | 5 | 5 |
| Feeling abnormal | 2 | 2 |
| Feeling hot | 1 | 1 |
| Flushing | 1 | 1 |
| Headache | 7 | 7 |
| Hyperhidrosis | 2 | 2 |
| Hypertension | 2 | 2 |
| Hypoaesthesia | 2 | 2 |
| Hypoglycaemia | 1 | 1 |
| Hypotension | 1 | 1 |
| Hypotonia | 1 | 1 |
| Impaired work ability | 1 | 1 |
| Incorrect dose administered | | 2 |
| Inflammation | 1 | 1 |
| Joint swelling | 1 | 1 |
| Loss of consciousness | 2 | 2 |
| Lymphadenopathy | 2 | 2 |
| Malaise | 1 | 1 |
| Muscle tightness | 1 | 1 |
| Myalgia | 4 | 4 |
| Myokymia | 1 | 1 |
| Nasal congestion | 1 | 1 |
| Nausea | 2 | 2 |
| Neck pain | 1 | 1 |
| Nervousness | 1 | 1 |
| Neutropenia | 1 | 1 |
| No adverse event | | 2 |
| Oropharyngeal pain | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | 4 | 4 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 6 | 6 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| | | 1 | 1 |

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 * AE=Adverse Event
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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Oxygen saturation decreased | 2 | 2 |
| Pain | 3 | 3 |
| Pain in extremity | 1 | 1 |
| Pallor | 1 | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | 3 | 3 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pneumonia | 1 | 1 |
| Presyncope | 2 | 2 |
| Product preparation issue | | 2 |
| Pruritus | 1 | 1 |
| Pyrexia | 5 | 5 |
| Rales | 1 | 1 |
| Rash | 1 | 1 |
| Respiration abnormal | 1 | 1 |
| Respiratory rate increased | 1 | 1 |
| Sinusitis | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Somnolence | 1 | 1 |
| Stress | 1 | 1 |
| Sudden death | | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Suspected COVID-19 | 1 | 1 |
| Suspected product quality issue | | 2 |
| Syncope | 1 | 1 |
| Tachycardia | 1 | 1 |
| Tardive dyskinesia | 1 | 1 |
| Tongue movement disturbance | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 |
| Urticaria | 3 | 3 |
| Vaccination site pain | 3 | 3 |
| Vomiting | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 2 | | |
| | | 1 | 1 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 3 | 3 |
| | | 2 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 140 | 149 | 15 | 23 | 125 | 126 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| No adverse event | 1 | 2 | 1 | 2 | | |
| Product preparation issue | 1 | 1 | 1 | 1 | | |
| Suspected COVID-19 | 1 | 1 | | | 1 | 1 |
| | 8 | 9 | 3 | 4 | 5 | 5 |

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Country Where Event Occurred

ISRAEL

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal pain | 1 | 2 | | | 1 | 2 | | |
| Abdominal pain upper | | 1 | | | | 1 | | |
| Abortion spontaneous | 1 | 1 | | | | | 1 | 1 |
| Ageusia | 1 | 2 | | | 1 | 2 | | |
| Allergy to vaccine | | 3 | | | | 1 | | 2 |
| Anaphylactic reaction | 2 | 5 | | | | | 2 | 5 |
| Anaphylactic shock | | 1 | | | | | | 1 |
| Anger | | 1 | | | | 1 | | |
| Angina pectoris | 1 | 1 | | | | | 1 | 1 |
| Angioedema | 1 | 1 | | | | | 1 | 1 |
| Anosmia | 1 | 2 | | | 1 | 2 | | |
| Antibody test abnormal | | 1 | | | | 1 | | |
| Aphonia | | 1 | | | | | | 1 |
| Application site hypersensitivity | | 1 | | | | 1 | | |
| Arrhythmia | 2 | 4 | | | | | 2 | 4 |
| Arthralgia | 8 | 14 | | | 7 | 13 | 1 | 1 |
| Aspiration | 1 | 1 | | | | | 1 | 1 |
| Asthenia | 15 | 51 | | | 13 | 49 | 2 | 2 |
| Asthenopia | 1 | 1 | | | 1 | 1 | | |
| Asthma | | 1 | | | | 1 | | |
| Atrial f brillation | 1 | 1 | | | | | 1 | 1 |
| Back pain | 2 | 7 | | | 2 | 7 | | |
| Blood chloride increased | | 1 | | | | | | 1 |
| Blood glucose increased | | 2 | | | | | | 2 |
| Blood pressure decreased | | 1 | | | | 1 | | |
| Blood pressure increased | 2 | 7 | | | 2 | 5 | | 2 |
| Body temperature decreased | | 1 | | | | 1 | | |
| Bone pain | 1 | 2 | | | 1 | 2 | | |
| Brain injury | 1 | 1 | | | | | 1 | 1 |
| Breast inflammation | 1 | 1 | | | 1 | 1 | | |
| Cardiac arrest | 1 | 3 | | | | | 1 | 3 |
| Cardiac disorder | | 1 | | | | | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Cerebellar haemorrhage | | 1 |
| Cerebral ischaemia | | 1 |
| Cerebrovascular accident | | 1 |
| Chest discomfort | | 1 |
| Chest pain | 3 | 6 |
| Chills | 16 | 34 |
| Choking | | 1 |
| Cold sweat | | 1 |
| Condition aggravated | 1 | 1 |
| Contusion | | 1 |
| Coronavirus infection | | 1 |
| Cough | 1 | 3 |
| COVID-19 | 7 | 9 |
| Crying | | 1 |
| Death | 1 | 2 |
| Decreased appetite | 1 | 3 |
| Depressed level of consciousness | | 1 |
| Depressed mood | 1 | 2 |
| Depression | | 1 |
| Diarrhoea | 1 | 4 |
| Disease recurrence | 2 | 3 |
| Dizziness | 3 | 19 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 7 | 13 |
| Dry mouth | | 1 |
| Dysgeusia | 1 | 7 |
| Dysmenorrhoea | 1 | 1 |
| Dyspepsia | 1 | 5 |
| Dysphagia | | 4 |
| Dyspnoea | 7 | 17 |
| Dyspnoea exertional | 2 | 2 |
| Ear discomfort | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 3 | 5 | | 1 |
| | | 16 | 33 | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 3 | | |
| | 1 | | | 7 | 9 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | 1 | 3 | | |
| | | | | | 1 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | 2 | 3 | | |
| | | 2 | 16 | 1 | 3 |
| | | 1 | 1 | | |
| | 1 | | | 7 | 13 |
| | | | 1 | | |
| | | 1 | 7 | | |
| | | 1 | 1 | | |
| | | 1 | 5 | | |
| | | | 3 | | 1 |
| | | 3 | 8 | 4 | 9 |
| | | 2 | 2 | | |
| | | | 2 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Ear pain | | 3 |
| Endocarditis | 1 | 1 |
| Eosinophilic oesophagitis | | 1 |
| Erythema | | 6 |
| Exposure during pregnancy | | 1 |
| Exposure to SARS-CoV-2 | | |
| Exposure via breast milk | | 1 |
| Eye pain | 2 | 2 |
| Eye swelling | 1 | 2 |
| Facial asymmetry | | 1 |
| Facial pain | 1 | 1 |
| Facial paralysis | 3 | 9 |
| Fall | | 3 |
| Fatigue | 13 | 31 |
| Feeling abnormal | 2 | 8 |
| Feeling cold | 2 | 7 |
| Feeling hot | | 5 |
| Feeling of body temperature change | | 1 |
| Food craving | | 1 |
| Formication | | 2 |
| Gait disturbance | 1 | 1 |
| Gastric haemorrhage | 1 | 1 |
| Gastrointestinal necrosis | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Glomerular filtration rate decreased | | 1 |
| Hallucination | 1 | 1 |
| Hangover | | 1 |
| Headache | 18 | 51 |
| Head discomfort | 1 | 1 |
| Heart rate increased | 1 | 6 |
| Hemiplegia | 1 | 1 |
| Hepatitis | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 3 | | |
| | | | 1 | 1 | 1 |
| | | | 6 | | |
| | | | 1 | | |
| | 1 | | | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 3 | 9 |
| | | | 1 | | 2 |
| | | 13 | 31 | | |
| | | 2 | 7 | | 1 |
| | | 2 | 7 | | |
| | | | 5 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 17 | 49 | 1 | 2 |
| | | 1 | 1 | | |
| | | | 5 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Hepatitis acute | 1 | 1 |
| Herpes zoster | 3 | 4 |
| Hip fracture | | 1 |
| Hyperhidrosis | 1 | 4 |
| Hypersensitivity | 2 | 5 |
| Hypertension | | 2 |
| Hypoaesthesia | 2 | 16 |
| Hypoaesthesia oral | | 6 |
| Hypotension | | 1 |
| Illness | 1 | 1 |
| Impaired quality of life | | 1 |
| Inappropriate schedule of product administration | 1 | 4 |
| Influenza | 1 | 3 |
| Influenza like illness | 2 | 6 |
| Injection site erythema | | 1 |
| Injection site inflammation | | 1 |
| Injection site pain | 1 | 4 |
| Insomnia | 3 | 5 |
| International normalised ratio increased | | 1 |
| Joint noise | 1 | 1 |
| Joint swelling | | 1 |
| Leukocytosis | 1 | 2 |
| Limb discomfort | | 1 |
| Lip pruritus | | 1 |
| Lip swelling | | 2 |
| Loss of consciousness | | 1 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenopathy | 1 | 5 |
| Lymphopenia | | 1 |
| Malaise | 2 | 14 |
| Maternal exposure during pregnancy | 4 | 4 |
| Mean cell haemoglobin decreased | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 3 | 4 | | |
| | | | | | 1 |
| | | 1 | 4 | | |
| | | | | 2 | 5 |
| | | | 1 | | 1 |
| | | 1 | 15 | 1 | 1 |
| | | | 5 | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | 1 | 3 | | |
| | | 2 | 6 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | 3 | 5 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 5 | | |
| | | | | | 1 |
| | | 2 | 13 | | 1 |
| | | 4 | 4 | | |
| | | | 1 | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Mean platelet volume increased | | 1 |
| Mechanical urticaria | 1 | 1 |
| Menorrhagia | 1 | 1 |
| Menstrual disorder | 1 | 1 |
| Mental disorder | 1 | 1 |
| Migraine | 1 | 2 |
| Miliaria | | 1 |
| Mobility decreased | | 1 |
| Mood altered | 1 | 1 |
| Motor dysfunction | | 1 |
| Multiple sclerosis | | 1 |
| Multiple sclerosis relapse | | 2 |
| Muscle contractions involuntary | 2 | 4 |
| Muscle rigidity | 1 | 1 |
| Muscular weakness | 2 | 3 |
| Myalgia | 9 | 25 |
| Myasthenia gravis | 1 | 1 |
| Myocardial infarction | | 1 |
| Nasopharyngitis | 1 | 2 |
| Nausea | 8 | 25 |
| Neck pain | 1 | 3 |
| Neuralgia | | 1 |
| Neuralgic amyotrophy | | 1 |
| Neuritis | | 1 |
| Neutrophil count increased | | 1 |
| No adverse event | 1 | 1 |
| Odynophagia | | 1 |
| Off label use | 3 | 5 |
| Oral herpes | 1 | 2 |
| Oropharyngeal discomfort | | 1 |
| Oropharyngeal pain | 1 | 4 |
| Overdose | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 2 |
| | | 2 | 4 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | 1 | 1 |
| | | 8 | 24 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 2 | | |
| | | 8 | 24 | | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 3 | 5 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Oxygen saturation decreased | | 2 |
| Pain | 3 | 9 |
| Pain in extremity | 6 | 27 |
| Palmar erythema | | 1 |
| Palpitations | 1 | 6 |
| Paraesthesia | 4 | 21 |
| Paraesthesia oral | 2 | 10 |
| Paralysis | | 1 |
| Paraplegia | | 1 |
| Parosmia | 1 | 3 |
| Pelvic fracture | | 1 |
| Pelvic pain | | 1 |
| Pericarditis | | 1 |
| Peripheral swelling | | 1 |
| Personality change | | 1 |
| Pharyngeal swelling | 1 | 3 |
| Pneumonia | 1 | 1 |
| Poor quality product administered | | 1 |
| Presyncope | 1 | 2 |
| Product administered to patient of inappropriate age | 1 | 1 |
| Product packaging quantity issue | | 1 |
| Product preparation error | | 1 |
| Product preparation issue | | 1 |
| Product use issue | 1 | 3 |
| Pruritus | | 3 |
| Pulmonary oedema | 1 | 1 |
| Pulse abnormal | | 1 |
| Pyrexia | 20 | 44 |
| Rash | 1 | 10 |
| Rash macular | | 1 |
| Rash pruritic | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | 1 |
| | | 2 | 8 | 1 | 1 |
| | | 6 | 27 | | |
| | | | 1 | | |
| | | 1 | 6 | | |
| | | 2 | 18 | 2 | 3 |
| | | 1 | 8 | 1 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 3 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | | 2 | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 18 | 41 | 2 | 3 |
| | | 1 | 7 | | 3 |
| | | | 1 | | |
| | | | 1 | | |

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|-----------------------------------|------------------------------------|--------------------------------------|
| Reduced facial expression | | 1 |
| Respiratory arrest | 1 | 1 |
| Respiratory rate increased | | 1 |
| Rhinalgia | | 1 |
| Rhinorrhoea | | 1 |
| Rib fracture | | 1 |
| SARS-CoV-2 ant body test negative | 2 | 2 |
| SARS-CoV-2 test positive | | 3 |
| Seizure | 1 | 1 |
| Sensory disturbance | 1 | 3 |
| Sensory loss | | 1 |
| Skin burning sensation | | 2 |
| Skin disorder | | 1 |
| Sleep disorder | 1 | 1 |
| Somnolence | | 1 |
| Speech disorder | 2 | 3 |
| Stress | | 1 |
| Swelling | 2 | 2 |
| Swelling face | | 1 |
| Swollen tongue | | 4 |
| Syncope | | 3 |
| Tachycardia | 2 | 5 |
| Taste disorder | | 1 |
| Tenderness | | 1 |
| Thinking abnormal | 1 | 1 |
| Throat tightness | | 1 |
| Thrombosis | | 1 |
| Tic | | 1 |
| Tinnitus | | 1 |
| Tracheal oedema | 1 | 1 |
| Tremor | | 2 |
| Underdose | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | | | | 3 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | | 1 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | 1 | 1 |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | | | 4 |
| | | | | | 3 |
| | | 2 | 4 | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | 2 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Urinary tract infection | 1 | 1 | | | 1 | 1 | | |
| Urticaria | 1 | 4 | | | 1 | 2 | | 2 |
| Vaccination site bruising | | 1 | | | | 1 | | |
| Vaccination site cellulitis | 1 | 2 | | | | 1 | 1 | 1 |
| Vaccination site erythema | 3 | 6 | | | 3 | 6 | | |
| Vaccination site joint movement impairment | | 1 | | | | 1 | | |
| Vaccination site lymphadenopathy | 2 | 2 | | | 2 | 2 | | |
| Vaccination site movement impairment | | 2 | | | | 2 | | |
| Vaccination site pain | 7 | 44 | | | 7 | 44 | | |
| Vaccination site pruritus | | 1 | | | | 1 | | |
| Vaccination site reaction | | 1 | | | | 1 | | |
| Vaccination site swelling | 1 | 5 | | | 1 | 5 | | |
| Vaginal haemorrhage | 2 | 2 | | | 2 | 2 | | |
| Vision blurred | 1 | 2 | | | 1 | 2 | | |
| Vomiting | 1 | 6 | | | 1 | 6 | | |
| Wrong technique in product usage process | | 1 | | | | 1 | | |
| | 295 | 921 | | 3 | 223 | 742 | 72 | 179 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Agitation | 1 | 1 | 1 | 1 | | |
| Alcohol intolerance | 1 | 1 | 1 | 1 | | |
| Alopecia | | 1 | | 1 | | |
| Anaesthesia oral | | 1 | | 1 | | |
| Angina pectoris | 1 | 2 | | | 1 | 2 |
| Anxiety | 1 | 2 | 1 | 2 | | |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Arthralgia | 6 | 10 | 4 | 7 | 2 | 3 |
| Arthritis reactive | 1 | 1 | | | 1 | 1 |
| Asthenia | 10 | 25 | 9 | 22 | 1 | 3 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 3 | | | 1 | 3 |
| Autoimmune haemolytic anaemia | 1 | 1 | | | 1 | 1 |
| Back pain | 3 | 4 | 2 | 3 | 1 | 1 |
| Blood chloride increased | | 1 | | 1 | | |
| Blood glucose increased | | 1 | | 1 | | |
| Blood pressure increased | | 4 | | 1 | | 3 |
| Blood pressure systolic increased | | 1 | | 1 | | |
| Body temperature decreased | 2 | 2 | 2 | 2 | | |
| Bone pain | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | | 4 | | | | 4 |
| Cardiac disorder | | 1 | | | | 1 |
| Cardiac failure | 1 | 2 | | | 1 | 2 |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Cartilage injury | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | | 2 | | | | 2 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 3 | 6 | 3 | 6 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Choking | | 1 | | | | 1 |
| Circulatory collapse | | 1 | | | | 1 |
| Condition aggravated | | 1 | | 1 | | |
| Confusional state | 1 | 2 | | 1 | 1 | 1 |
| Coronavirus infection | 1 | 1 | 1 | 1 | | |
| Coronavirus test positive | | 1 | | | | 1 |
| Cough | 1 | 4 | 1 | 4 | | |
| COVID-19 | 7 | 10 | | | 7 | 10 |
| C-reactive protein increased | | 1 | | 1 | | |
| Death | | 4 | | | | 4 |
| Decreased appetite | | 2 | | 1 | | 1 |
| Depressed mood | 1 | 1 | | | 1 | 1 |
| Depression | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 5 | 2 | 4 | | 1 |
| Disease recurrence | | 1 | | | | 1 |
| Dizziness | 4 | 12 | 3 | 8 | 1 | 4 |
| Drug hypersensitivity | | 1 | | | | 1 |
| Drug ineffective | 7 | 15 | 1 | 1 | 6 | 14 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dyschromatopsia | 1 | 1 | 1 | 1 | | |
| Dysgeusia | | 1 | | 1 | | |
| Dyskinesia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dyspepsia | | 1 | | 1 | | |
| Dysphagia | | 1 | | 1 | | |
| Dyspnoea | 2 | 6 | 1 | 3 | 1 | 3 |
| Dyspnoea exertional | | 1 | | 1 | | |
| Dysstasia | 1 | 2 | 1 | 1 | | 1 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear pain | 2 | 2 | 2 | 2 | | |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Eye infection | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | | 1 |
| | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 4 | | |
| | | 7 | 10 |
| | 1 | | |
| | | | 4 |
| | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 4 | | 1 |
| | | | 1 |
| 3 | 8 | 1 | 4 |
| | | | 1 |
| 1 | 1 | 6 | 14 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 2 | 3 | 1 | 3 |
| | 1 | | |
| 1 | 1 | | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |

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Gender

MALE

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|--|------------------------------------|--------------------------------------|
| Eye irritation | | 2 |
| Eye pain | 1 | 1 |
| Facial paralysis | 5 | 10 |
| Fall | 1 | 1 |
| Fatigue | 8 | 14 |
| Feeling abnormal | 1 | 5 |
| Feeling cold | 2 | 4 |
| Food refusal | 1 | 1 |
| Formication | 1 | 1 |
| Gait disturbance | | 2 |
| Gastroenteritis viral | | 1 |
| Gingival pain | | 1 |
| Haemolytic anaemia | | 1 |
| Headache | 13 | 21 |
| Head discomfort | | 1 |
| Head injury | | 1 |
| Heart rate increased | 1 | 4 |
| Herpes zoster | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | | 1 |
| Hypertension | 1 | 3 |
| Hypoaesthesia | | 10 |
| Hypoaesthesia oral | | 2 |
| Hypoaesthesia teeth | | 1 |
| Hypotension | | 1 |
| Hypoventilation | | 1 |
| Illness | | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Inappropriate schedule of product administration | | 1 |
| Infection | | 1 |
| Inflammation | 1 | 1 |
| Inflammatory marker increased | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | 1 |
| 1 | 1 | | |
| | | 5 | 10 |
| | | 1 | 1 |
| 7 | 12 | 1 | 2 |
| 1 | 3 | | 2 |
| 2 | 4 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 2 |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| 12 | 18 | 1 | 3 |
| | | | 1 |
| | | | 1 |
| 1 | 4 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | 2 |
| | 8 | | 2 |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | 1 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Influenza like illness | | 4 | | 4 | | |
| Intentional dose omission | | 1 | | 1 | | |
| Ischaemic stroke | 1 | 1 | | | 1 | 1 |
| Jaundice | | 1 | | 1 | | |
| Joint swelling | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | | 2 | | 1 | | 1 |
| Limb discomfort | | 1 | | 1 | | |
| Lip disorder | | 1 | | 1 | | |
| Lip pruritus | | 1 | | 1 | | |
| Liquid product physical issue | | 1 | | 1 | | |
| Loss of consciousness | 3 | 5 | | | 3 | 5 |
| Loss of libido | 1 | 1 | 1 | 1 | | |
| Lung disorder | | 1 | | 1 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Lymphocyte count increased | | 1 | | 1 | | |
| Lymphocytosis | | 1 | | 1 | | |
| Malaise | 3 | 9 | 3 | 7 | | 2 |
| Mean cell haemoglobin concentration decreased | | 1 | | 1 | | |
| Mean cell haemoglobin decreased | | 1 | | 1 | | |
| Mean cell volume decreased | | 1 | | 1 | | |
| Mobility decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| Movement disorder | | 2 | | 1 | | 1 |
| Multiple sclerosis relapse | | 1 | | | | 1 |
| Muscle twitching | | 1 | | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 13 | 6 | 12 | | 1 |
| Myocardial infarction | | 1 | | | | 1 |
| Myocarditis | 3 | 3 | | | 3 | 3 |
| Nasopharyngitis | 2 | 3 | 2 | 3 | | |
| Nausea | 3 | 7 | 2 | 4 | 1 | 3 |
| Neck pain | 2 | 3 | 2 | 3 | | |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 4 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 3 | 5 |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 3 | 7 | | 2 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| | 1 | | 1 |
| | | | 1 |
| 1 | 1 | | |
| 6 | 12 | | 1 |
| | | | 1 |
| | | 3 | 3 |
| 2 | 3 | | |
| 2 | 4 | 1 | 3 |
| 2 | 3 | | |

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MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Odynophagia | | 1 | | 1 | | |
| Oedema | 1 | 1 | | | 1 | 1 |
| Oral discomfort | 1 | 1 | 1 | 1 | | |
| Oral herpes | 1 | 2 | 1 | 2 | | |
| Oral pain | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 4 | | 4 | | |
| Otitis media | | 1 | | 1 | | |
| Overdose | | 3 | | 3 | | |
| Pain | 5 | 11 | 4 | 10 | 1 | 1 |
| Pain in extremity | 7 | 12 | 7 | 12 | | |
| Pain in jaw | | 3 | | 3 | | |
| Palpitations | | 3 | | 3 | | |
| Pancreatitis | | 1 | | | | 1 |
| Paraesthesia | 1 | 5 | 1 | 5 | | |
| Paraesthesia oral | | 3 | | 3 | | |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Pericarditis | 2 | 3 | | | 2 | 3 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Pharyngeal paraesthesia | | 1 | | 1 | | |
| Pleural effusion | | 1 | | | | 1 |
| Pleuritic pain | | 1 | | | | 1 |
| Pneumonia | 2 | 2 | | | 2 | 2 |
| Poor quality product administered | | 3 | | 3 | | |
| Poor quality sleep | | 1 | | 1 | | |
| Product deposit | | 1 | | 1 | | |
| Product preparation error | | 3 | | 3 | | |
| Psychomotor hyperactivity | 1 | 1 | 1 | 1 | | |
| Pulpitis dental | | 1 | | 1 | | |
| Pyrexia | 6 | 12 | 4 | 9 | 2 | 3 |
| Red blood cell count increased | | 1 | | 1 | | |
| Respiratory arrest | | 1 | | | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | 4 | | |
| | 1 | | |
| | 3 | | |
| 4 | 10 | 1 | 1 |
| 7 | 12 | | |
| | 3 | | |
| | 3 | | |
| | | | 1 |
| 1 | 5 | | |
| | 3 | | |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| | | 2 | 2 |
| | 3 | | |
| | 1 | | |
| | 1 | | |
| | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| 4 | 9 | 2 | 3 |
| | 1 | | |
| | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory distress | | 1 | | | | 1 |
| Restlessness | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | | 2 | | 2 | | |
| SARS-CoV-2 test positive | | 3 | | | | 3 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sepsis | | 1 | | | | 1 |
| Sinus tachycardia | | 1 | | 1 | | |
| Sleep disorder due to general medical condition, insomnia type | | 1 | | 1 | | |
| Sneezing | | 2 | | 2 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Speech disorder | | 1 | | 1 | | |
| Sudden cardiac death | | 1 | | | | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Suffocation feeling | | 1 | | 1 | | |
| Suicidal ideation | 1 | 1 | | | 1 | 1 |
| Suspected COVID-19 | | 1 | | | | 1 |
| Swelling face | | 1 | | 1 | | |
| Syncope | | 3 | | | | 3 |
| Systemic inflammatory response syndrome | | 1 | | | | 1 |
| Tachycardia | | 1 | | 1 | | |
| Taste disorder | | 1 | | 1 | | |
| Therapeutic response unexpected | | 1 | | 1 | | |
| Thrombosis | | 2 | | | | 2 |
| Tongue discomfort | | 1 | | 1 | | |
| Toothache | | 2 | | 2 | | |
| Tooth injury | | 1 | | 1 | | |
| Torticollis | | 1 | | | | 1 |
| Tremor | | 2 | | 2 | | |
| Underdose | | 1 | | 1 | | |
| Urticaria | | 2 | | 2 | | |
| Uveitis | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 1 | 1 |
| | 2 | | |
| | | | 3 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | | 3 |
| | | | 1 |
| | 1 | | |
| | | | 2 |
| | 1 | | |
| | 2 | | |
| | 1 | | |
| | 2 | | |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination failure | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site hypersensitivity | | 1 | | 1 | | |
| Vaccination site pain | 4 | 17 | 4 | 17 | | |
| Vaccination site swelling | | 3 | | 3 | | |
| Vertigo | | 1 | | | | 1 |
| Vision blurred | 1 | 2 | 1 | 2 | | |
| Vomiting | | 4 | | 2 | | 2 |
| Weight decreased | | 2 | | 1 | | 1 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| Yawning | | 1 | | 1 | | |
| | 191 | 508 | 119 | 333 | 72 | 175 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Adverse event | | 1 | | 1 | | |
| Anosmia | | 1 | | 1 | | |
| Arthralgia | 1 | 2 | 1 | 1 | | 1 |
| Arthropathy | | 1 | | 1 | | |
| Asthenia | 1 | 10 | 1 | 10 | | |
| Back pain | | 1 | | 1 | | |
| Balance disorder | | 1 | | 1 | | |
| Chills | 2 | 6 | 2 | 6 | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | | 1 | | 1 | | |
| COVID-19 | 2 | 3 | 1 | 1 | 1 | 2 |
| Diarrhoea | | 1 | | 1 | | |
| Dizziness | 1 | 5 | 1 | 5 | | |
| Drug ineffective | 1 | 2 | | | 1 | 2 |
| Dysgeusia | | 1 | | 1 | | |
| Dyspnoea | | 1 | | | | 1 |
| Exposure via breast milk | 1 | 4 | 1 | 4 | | |
| Eye haemorrhage | | 1 | | | | 1 |
| Eye infection | | 1 | | 1 | | |
| Eye pain | | 2 | | | | 2 |
| Facial paralysis | | 1 | | | | 1 |
| Fatigue | | 8 | | 8 | | |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 7 | 1 | 6 | | 1 |
| Head discomfort | | 2 | | 2 | | |
| Herpes zoster | 5 | 5 | 5 | 5 | | |
| Hypertension | | 1 | | | | 1 |
| Hypoaesthesia | | 1 | | 1 | | |
| Inappropriate schedule of product administration | | 1 | | 1 | | |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Incomplete course of vaccination | | 1 | | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Initial insomnia | | 1 | | 1 | | |
| Liquid product physical issue | 1 | 14 | 1 | 14 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | | 1 | | | | 1 |
| Myalgia | 1 | 10 | 1 | 9 | | 1 |
| Nausea | | 3 | | 3 | | |
| Neuralgic amyotrophy | | 1 | | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oral herpes | | 1 | | | | 1 |
| Oropharyngeal pain | | 1 | | 1 | | |
| Pain in extremity | 1 | 5 | 1 | 5 | | |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | | 1 | | | | 1 |
| Photopsia | | 1 | | 1 | | |
| Poor quality product administered | 1 | 26 | 1 | 26 | | |
| Product complaint | | 1 | | 1 | | |
| Product packaging quantity issue | | 11 | | 11 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 9 | 1 | 8 | | 1 |
| Rash | | 1 | | 1 | | |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 1 | 1 | 1 | 1 | | |
| Seizure | 7 | 7 | | | 7 | 7 |
| Syncope | | 1 | | | | 1 |
| Therapeutic response unexpected | | 1 | | 1 | | |
| Tremor | 1 | 1 | 1 | 1 | | |
| Urticaria | | 1 | | | | 1 |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site pain | 1 | 10 | 1 | 10 | | |
| Vaccination site swelling | | 1 | | 1 | | |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 14 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 9 | | 1 |
| | 3 | | |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| | 1 | | |
| 1 | 5 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| 1 | 26 | | |
| | 1 | | |
| | 11 | | |
| 1 | 1 | | |
| 1 | 8 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 7 | 7 |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 10 | | |
| | 1 | | |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vision blurred | | 1 | | 1 | | |
| Vomiting | 1 | 2 | 1 | 2 | | |
| Wheezing | | 1 | | | | 1 |
| | 40 | 197 | 28 | 167 | 12 | 30 |

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Country Where Event Occurred

ITALY

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Gender

FEMALE

| Preferred Term | Interval Total # | Cumulative Total # |
|---|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Abdominal discomfort | | 1 |
| Abdominal distension | 4 | 4 |
| Abdominal pain | 42 | 53 |
| Abdominal pain lower | 1 | 1 |
| Abdominal pain upper | 22 | 28 |
| Abortion | 1 | 1 |
| Acquired macroglossia | 1 | 1 |
| Acute coronary syndrome | | 3 |
| Acute respiratory failure | 2 | 2 |
| Administration site movement impairment | 1 | 1 |
| Administration site reaction | | 1 |
| Ageusia | 8 | 9 |
| Agitation | 7 | 9 |
| Alanine aminotransferase increased | 2 | 2 |
| Allergic cough | 1 | 1 |
| Allergy to vaccine | 5 | 6 |
| Altered state of consciousness | 1 | 1 |
| Amnesia | 1 | 1 |
| Amylase increased | 1 | 1 |
| Anaemia | 2 | 2 |
| Anaesthesia | 5 | 7 |
| Anaesthesia oral | 3 | 3 |
| Anal sphincter atony | 1 | 1 |
| Anaphylactic reaction | 12 | 20 |
| Anaphylactic shock | 5 | 10 |
| Anaphylactoid reaction | 1 | 1 |
| Angina pectoris | 3 | 3 |
| Angioedema | 23 | 24 |
| Angiomyolipoma | 1 | 1 |
| Anosmia | 5 | 6 |
| Anterograde amnesia | 1 | 1 |
| Anuria | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | 3 | 3 |
| | | 23 | 33 | 19 | 20 |
| | | 1 | 1 | | |
| | | 7 | 13 | 15 | 15 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 4 | 5 | 4 | 4 |
| | | 3 | 5 | 4 | 4 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | | | 5 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 2 | 4 | 3 | 3 |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 12 | 20 |
| | | | | 5 | 10 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 23 | 24 |
| | | | | 1 | 1 |
| | | 2 | 3 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Anxiety | 5 | 7 |
| Apathy | 1 | 1 |
| Aphasia | 4 | 4 |
| Aphonia | 3 | 3 |
| Aphthous ulcer | 3 | 3 |
| Application site coldness | 1 | 1 |
| Arrhythmia | 4 | 4 |
| Arteriosclerosis | | 1 |
| Arthralgia | 186 | 217 |
| Arthropod sting | 1 | 1 |
| Asphyxia | | 1 |
| Asthenia | 189 | 215 |
| Asthenopia | 2 | 2 |
| Asthma | 5 | 5 |
| Asthmatic crisis | 5 | 5 |
| Atrial fibrillation | 2 | 2 |
| Atrioventricular block complete | | 1 |
| Aura | | 1 |
| Autoimmune thyroiditis | 1 | 1 |
| Axillary pain | 10 | 16 |
| Azotaemia | 1 | 1 |
| Back pain | 20 | 25 |
| Balance disorder | 4 | 5 |
| Band sensation | 2 | 3 |
| Basedow's disease | 1 | 1 |
| Blepharospasm | 1 | 1 |
| Blindness | 2 | 2 |
| Blister | 2 | 2 |
| Blood alkaline phosphatase increased | 1 | 1 |
| Blood glucose increased | 1 | 1 |
| Blood potassium decreased | 1 | 1 |
| Blood pressure decreased | 8 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 4 | 4 |
| | | | | 1 | 1 |
| | | 2 | 2 | 2 | 2 |
| | | 3 | 3 | | |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 4 | 4 |
| | | | | | 1 |
| 2 | 2 | 79 | 109 | 107 | 108 |
| | | | | 1 | 1 |
| | | | | | 1 |
| 3 | 3 | 81 | 106 | 108 | 109 |
| | | 2 | 2 | | |
| | | | | 5 | 5 |
| | | | | 5 | 5 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 8 | 7 | 8 |
| | | | | 1 | 1 |
| 2 | 2 | 6 | 9 | 14 | 16 |
| | | | 1 | 4 | 4 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 5 | 5 | 3 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Blood pressure diastolic increased | | 1 |
| Blood pressure fluctuation | 2 | 2 |
| Blood pressure increased | 19 | 24 |
| Blood pressure systolic increased | 1 | 1 |
| Body temperature decreased | | 1 |
| Body temperature increased | 3 | 6 |
| Bone pain | 33 | 37 |
| Bradycardia | 4 | 6 |
| Breast abscess | 1 | 1 |
| Breast discomfort | | 1 |
| Breast pain | 2 | 3 |
| Breast swelling | | 1 |
| Breath sounds | 1 | 1 |
| Breath sounds abnormal | 1 | 1 |
| Bronchospasm | 13 | 14 |
| Bronchostenosis | 1 | 1 |
| Burning sensation | 6 | 7 |
| Butterfly rash | 1 | 1 |
| Cardiac arrest | 2 | 2 |
| Cardiac failure | | 1 |
| Catarrh | 1 | 1 |
| Central cord syndrome | 1 | 1 |
| Cerebellar haemorrhage | | 1 |
| Cerebral disorder | 1 | 1 |
| Cerebral venous sinus thrombosis | 1 | 1 |
| Cerebrovascular accident | | 1 |
| Cervical radiculopathy | 1 | 1 |
| Chest discomfort | 18 | 21 |
| Chest expansion decreased | 1 | 1 |
| Chest pain | 18 | 21 |
| Chills | 200 | 230 |
| Choking | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 5 | 18 | 19 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 2 | 5 | 1 | 1 |
| | | 18 | 22 | 15 | 15 |
| | | | | 4 | 6 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | | | 13 | 14 |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 5 | 8 | 13 | 13 |
| | | 1 | 1 | | |
| 1 | 1 | 1 | 4 | 17 | 17 |
| 2 | 3 | 94 | 122 | 106 | 108 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Chromaturia | 1 | 1 |
| Chronic respiratory failure | 1 | 1 |
| Circulatory collapse | 1 | 2 |
| Circumoral swelling | 1 | 1 |
| Clonus | 4 | 4 |
| Coagulopathy | 1 | 1 |
| Cold sweat | 5 | 5 |
| Coma | 2 | 2 |
| Coma scale abnormal | | 1 |
| Condition aggravated | 1 | 2 |
| Confusional state | 19 | 24 |
| Conjunctival haemorrhage | 3 | 3 |
| Conjunctival hyperaemia | 1 | 1 |
| Conjunctival irritation | 1 | 1 |
| Conjunctivitis | 5 | 5 |
| Constipation | | 1 |
| Coordination abnormal | 1 | 1 |
| Corneal bleeding | | 1 |
| Cough | 51 | 57 |
| COVID-19 | 32 | 37 |
| Cranial nerve paralysis | 1 | 1 |
| C-reactive protein increased | 1 | 1 |
| Crying | | 1 |
| Cyanosis | 4 | 4 |
| Cystitis | 1 | 1 |
| Cystitis haemorrhagic | 4 | 4 |
| Deafness | 2 | 2 |
| Deafness neurosensory | 2 | 2 |
| Death | 1 | 1 |
| Decreased appetite | 11 | 13 |
| Deep vein thrombosis | 1 | 2 |
| Dehydration | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 4 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 9 | 13 | 10 | 11 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| 1 | 1 | 11 | 16 | 40 | 41 |
| | | 3 | 5 | 29 | 32 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 6 | 8 | 5 | 5 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |

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Gender

FEMALE

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|------------------------------------|------------------------------------|--------------------------------------|
| Delirium | 1 | 1 |
| Demyelinating polyneuropathy | 1 | 1 |
| Depressed level of consciousness | 19 | 22 |
| Dermatitis | | 1 |
| Dermatitis allergic | 2 | 2 |
| Dermatitis atopic | 1 | 1 |
| Dermatitis bullous | 5 | 5 |
| Dermatitis exfoliative generalised | 1 | 2 |
| Diaphragmatic spasm | 1 | 1 |
| Diarrhoea | 72 | 89 |
| Diastolic hypotension | 1 | 1 |
| Diplopia | 2 | 2 |
| Discomfort | 3 | 4 |
| Disease recurrence | 3 | 4 |
| Disorientation | 4 | 5 |
| Disturbance in attention | 5 | 5 |
| Dizziness | 90 | 107 |
| Drug hypersensitivity | 3 | 3 |
| Drug ineffective | 29 | 32 |
| Dry eye | 1 | 1 |
| Dry mouth | 14 | 23 |
| Dry skin | 4 | 4 |
| Dry throat | 1 | 1 |
| Dysaesthesia | 3 | 5 |
| Dysaesthesia pharynx | 1 | 1 |
| Dysentery | 88 | 88 |
| Dysgeusia | 12 | 22 |
| Dysgraphia | 1 | 1 |
| Dyskinesia | 1 | 1 |
| Dysmetria | 1 | 1 |
| Dyspepsia | 6 | 7 |
| Dysphagia | 26 | 35 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 18 | 21 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 5 | 5 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 29 | 46 | 43 | 43 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 3 | 4 | | |
| | | | 1 | 3 | 3 |
| | | | 1 | 4 | 4 |
| | | 1 | 1 | 4 | 4 |
| | | 38 | 54 | 52 | 53 |
| | | | | 3 | 3 |
| | | 1 | 1 | 28 | 31 |
| | | 1 | 1 | | |
| 1 | 1 | 2 | 11 | 12 | 12 |
| | | | | 4 | 4 |
| | | 1 | 1 | | |
| | | 2 | 4 | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | | | 88 | 88 |
| | | 4 | 14 | 8 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 6 | 1 | 1 |
| 2 | 2 | 10 | 15 | 16 | 20 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Dysphonia | 16 | 17 |
| Dyspnoea | 97 | 110 |
| Dyspnoea at rest | 1 | 1 |
| Dyspnoea exertional | 3 | 3 |
| Dysuria | 2 | 2 |
| Ear discomfort | 2 | 2 |
| Ear infection | 2 | 2 |
| Ear pain | 11 | 12 |
| Ear pruritus | 2 | 3 |
| Ear swelling | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Enanthema | 1 | 1 |
| Encephalopathy | 1 | 1 |
| Eosinophil count decreased | 1 | 1 |
| Eosinophil count increased | 1 | 1 |
| Epilepsy | 2 | 2 |
| Episcleritis | 1 | 1 |
| Epistaxis | 6 | 6 |
| Erythema | 59 | 81 |
| Erythema multiforme | 1 | 1 |
| Erythema of eyelid | 1 | 1 |
| Exposure during pregnancy | | 1 |
| Exposure to SARS-CoV-2 | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 |
| Extrasystoles | 3 | 3 |
| Eye colour change | 1 | 1 |
| Eye haematoma | 1 | 1 |
| Eye irritation | 7 | 9 |
| Eyelid myoclonus | 1 | 1 |
| Eyelid oedema | 6 | 7 |
| Eyelid ptosis | 2 | 2 |
| Eye oedema | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 5 | 6 | 11 | 11 |
| 2 | 3 | 11 | 18 | 86 | 92 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 5 | 6 | 6 | 6 |
| | | 2 | 3 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 4 | 4 | 2 | 2 |
| | | 10 | 28 | 49 | 53 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 3 | 5 | 4 | 4 |
| | | | | 1 | 1 |
| 1 | 1 | | | 6 | 7 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Eye pain | 8 | 10 |
| Eye pruritus | 1 | 4 |
| Eye swelling | 3 | 3 |
| Face oedema | 9 | 11 |
| Facial bones fracture | 1 | 1 |
| Facial nerve disorder | 3 | 3 |
| Facial neuralgia | 1 | 1 |
| Facial pain | 4 | 5 |
| Facial paralysis | 17 | 19 |
| Facial paresis | 7 | 7 |
| Facial spasm | | 1 |
| Faeces soft | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 132 | 150 |
| Febrile convulsion | 1 | 1 |
| Feeling abnormal | 4 | 6 |
| Feeling cold | 18 | 21 |
| Feeling hot | 31 | 45 |
| Feeling of body temperature change | 2 | 3 |
| Flatulence | | 2 |
| Fluid retention | 1 | 1 |
| Flushing | 19 | 27 |
| Foreign body in throat | 1 | 1 |
| Gait disturbance | 5 | 5 |
| Gait inability | 1 | 1 |
| Gamma-glutamyltransferase increased | 1 | 1 |
| Gastritis | | 1 |
| Gastroenteritis | 1 | 1 |
| Gastrointestinal disorder | 3 | 4 |
| Gastrointestinal hypermotility | 1 | 1 |
| Gastrointestinal pain | 1 | 1 |
| Gastrointestinal sounds abnormal | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 6 | 4 | 4 |
| | | | 2 | 1 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 2 | 8 | 9 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | 1 | 4 | 4 |
| | | | | 17 | 19 |
| | | 2 | 2 | 5 | 5 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | 1 | 53 | 70 | 79 | 80 |
| | | 2 | 3 | 2 | 3 |
| | 1 | 4 | 7 | 14 | 14 |
| 1 | 1 | 8 | 19 | 23 | 26 |
| | | | 1 | 2 | 2 |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 5 | 13 | 14 | 14 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 4 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| General physical health deterioration | | 1 |
| Gingival swelling | | 1 |
| Glossodynia | 2 | 2 |
| Goitre | 1 | 1 |
| Haematochezia | 2 | 2 |
| Haematoma | | 1 |
| Haematuria | 2 | 2 |
| Haemorrhage subcutaneous | 1 | 1 |
| Hallucination | 1 | 1 |
| Hallucination, auditory | 1 | 1 |
| Hallucination, olfactory | 1 | 1 |
| Hallucinations, mixed | 1 | 1 |
| Hallucination, visual | 1 | 1 |
| Haptoglobin increased | 1 | 1 |
| Headache | 369 | 461 |
| Head discomfort | 2 | 2 |
| Heart rate abnormal | 1 | 1 |
| Heart rate decreased | 1 | 2 |
| Heart rate increased | 7 | 7 |
| Hemianaesthesia | 5 | 5 |
| Hemianopia heteronymous | 1 | 1 |
| Hemidysaesthesia | 3 | 3 |
| Hemihyperaesthesia | 1 | 1 |
| Hemiparaesthesia | 20 | 20 |
| Hemiparesis | 7 | 8 |
| Hemiplegia | 2 | 2 |
| Hepatitis acute | 1 | 1 |
| Herpes ophthalmic | 1 | 1 |
| Herpes simplex | 1 | 1 |
| Herpes virus infection | 1 | 1 |
| Herpes zoster | 3 | 4 |
| Hot flush | 12 | 18 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 4 | 5 | 163 | 253 | 206 | 208 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 7 | 7 |
| | | | | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 20 | 20 |
| | | | | 7 | 8 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | 1 | 2 |
| | | 2 | 8 | 10 | 10 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyperaesthesia | 1 | 2 |
| Hyperglycaemia | 1 | 1 |
| Hyperhidrosis | 22 | 30 |
| Hyperkinesia | 1 | 1 |
| Hyperpyrexia | 110 | 110 |
| Hypersensitivity | 18 | 20 |
| Hypersomnia | 1 | 1 |
| Hypertension | 30 | 35 |
| Hypertensive crisis | 35 | 39 |
| Hyperthermia | 8 | 10 |
| Hypertransaminasaemia | 2 | 2 |
| Hypertrophy of tongue papillae | 1 | 1 |
| Hyperventilation | 4 | 5 |
| Hypoaesthesia | 23 | 28 |
| Hypoaesthesia oral | 6 | 13 |
| Hypoglycaemia | | 1 |
| Hyporeflexia | 1 | 1 |
| Hypotension | 34 | 42 |
| Hypotensive crisis | 3 | 3 |
| Hypothermia | 10 | 10 |
| Hypotonia | 3 | 3 |
| Hypoxia | 3 | 3 |
| Idiosyncratic drug reaction | 1 | 1 |
| Illness | 1 | 2 |
| Immobile | 1 | 1 |
| Immunisation anxiety related reaction | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 2 |
| Incorrect dose administered | | 2 |
| Incorrect route of product administration | 5 | 7 |
| Inflammation | 1 | 2 |
| Inflammatory pain | 1 | 1 |
| Influenza | 5 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 7 | 14 | 15 | 16 |
| | | 1 | 1 | | |
| | | | | 110 | 110 |
| 1 | 1 | 2 | 3 | 16 | 17 |
| | | 1 | 1 | | |
| | | 4 | 6 | 26 | 29 |
| | | | | 35 | 39 |
| | | 3 | 4 | 5 | 6 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | 1 | 4 | 4 |
| 1 | 1 | 9 | 14 | 14 | 14 |
| | | 4 | 11 | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| 1 | 1 | 8 | 14 | 26 | 28 |
| | | | | 3 | 3 |
| | | | | 10 | 10 |
| | | 1 | 1 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | | 2 | | |
| | | 5 | 7 | | |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 4 | 4 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Influenza like illness | 11 | 15 |
| Initial insomnia | 2 | 2 |
| Injection site hypersensitivity | 1 | 1 |
| Injection site pain | 6 | 7 |
| Injection site pruritus | 1 | 1 |
| Injection site rash | 1 | 1 |
| Injection site urticaria | 2 | 2 |
| Insomnia | 13 | 15 |
| Inspiratory capacity abnormal | | 1 |
| Interstitial lung disease | 2 | 2 |
| Intestinal pseudo-obstruction | 1 | 1 |
| Intranasal hypoaesthesia | | 1 |
| Intranasal paraesthesia | | 1 |
| Irritability | 1 | 2 |
| Ischaemic stroke | 1 | 1 |
| Joint lock | 1 | 1 |
| Joint range of motion decreased | 2 | 3 |
| Joint stiffness | 1 | 1 |
| Joint warmth | 1 | 1 |
| Labyrinthitis | 2 | 2 |
| Lacrimation increased | 2 | 4 |
| Laryngeal dyspnoea | 2 | 2 |
| Laryngeal obstruction | 2 | 2 |
| Laryngeal oedema | 27 | 34 |
| Laryngeal pain | | 1 |
| Laryngeal stenosis | 2 | 2 |
| Laryngospasm | 5 | 6 |
| Limb discomfort | 6 | 9 |
| Lipodystrophy acquired | 1 | 1 |
| Lip oedema | 18 | 21 |
| Lip pain | 2 | 2 |
| Lip pruritus | 6 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 6 | 10 | 5 | 5 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 4 | 6 | 9 | 9 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 3 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 27 | 34 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | 4 | 5 |
| | | 3 | 6 | 3 | 3 |
| | | | | 1 | 1 |
| | | 2 | 4 | 16 | 17 |
| | | 2 | 2 | | |
| | | 2 | 3 | 4 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Lip swelling | 6 | 8 |
| Localised oedema | 3 | 4 |
| Loss of consciousness | 31 | 31 |
| Loss of personal independence in daily activities | 2 | 2 |
| Lymphadenitis | 9 | 10 |
| Lymphadenopathy | 106 | 129 |
| Lymphangitis | 3 | 4 |
| Lymph node pain | 11 | 15 |
| Lymphocyte count increased | 1 | 1 |
| Lymphocytosis | 1 | 1 |
| Lymphoedema | 3 | 4 |
| Macroglossia | 1 | 1 |
| Malaise | 60 | 78 |
| Mastitis | 2 | 3 |
| Maternal exposure during pregnancy | 5 | 5 |
| Mechanical urticaria | 2 | 3 |
| Menstrual disorder | 1 | 1 |
| Mental disorder | 1 | 1 |
| Mental impairment | 2 | 2 |
| Metrorrhagia | 2 | 2 |
| Middle insomnia | 2 | 2 |
| Migraine | 19 | 22 |
| Miosis | 1 | 1 |
| Mobility decreased | 1 | 1 |
| Monocyte count decreased | 1 | 1 |
| Monoparesis | | 1 |
| Monoplegia | 3 | 3 |
| Mood altered | 2 | 2 |
| Mouth swelling | 1 | 1 |
| Mouth ulceration | 1 | 1 |
| Movement disorder | 7 | 7 |
| Mucosal hyperaemia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 5 | 6 |
| | | 2 | 3 | 1 | 1 |
| | | | | 31 | 31 |
| | | 2 | 2 | | |
| | | 2 | 3 | 7 | 7 |
| | | 31 | 52 | 75 | 77 |
| | | | | 3 | 4 |
| | | 5 | 9 | 6 | 6 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | 22 | 37 | 38 | 41 |
| | | | | 2 | 3 |
| | | 4 | 4 | 1 | 1 |
| 2 | 2 | | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 2 | 2 | | |
| | | 7 | 10 | 12 | 12 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 7 | 7 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Mucous stools | 1 | 1 |
| Multiple organ dysfunction syndrome | 2 | 2 |
| Muscle contractions involuntary | 1 | 2 |
| Muscle contracture | 4 | 4 |
| Muscle oedema | 1 | 1 |
| Muscle rigidity | 3 | 4 |
| Muscle spasms | 11 | 11 |
| Muscle tightness | 2 | 2 |
| Muscular weakness | 15 | 16 |
| Musculoskeletal chest pain | 2 | 2 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal disorder | 2 | 2 |
| Musculoskeletal pain | 45 | 49 |
| Musculoskeletal stiffness | 10 | 11 |
| Myalgia | 209 | 240 |
| Myalgia intercostal | 1 | 1 |
| Myasthenia gravis crisis | 1 | 1 |
| Myocardial infarction | | 1 |
| Myocardial ischaemia | | 1 |
| Myoclonus | 1 | 1 |
| Narcolepsy | 1 | 1 |
| Nasal congestion | 3 | 5 |
| Nasal obstruction | 1 | 1 |
| Nasal oedema | 1 | 1 |
| Nasopharyngitis | 3 | 5 |
| Nausea | 194 | 232 |
| Neck pain | 15 | 18 |
| Neuralgia | 6 | 8 |
| Neuritis | | 1 |
| Neurological symptom | 1 | 1 |
| Neuropathy peripheral | 5 | 5 |
| Neurotoxicity | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | | 1 |
| | | 2 | 2 | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 3 |
| | | 4 | 4 | 7 | 7 |
| | | 2 | 2 | | |
| | | 6 | 7 | 9 | 9 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 19 | 23 | 26 | 26 |
| 1 | 1 | 3 | 4 | 7 | 7 |
| 2 | 2 | 92 | 121 | 117 | 119 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 3 | 1 | 2 |
| 2 | 2 | 71 | 106 | 123 | 126 |
| | | 5 | 8 | 10 | 10 |
| | | 2 | 4 | 4 | 4 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Neutrophil count increased | 1 | 1 |
| Nightmare | 1 | 1 |
| Night sweats | 1 | 2 |
| Nuchal rigidity | 4 | 6 |
| Nystagmus | 1 | 1 |
| Obstructive airways disorder | 2 | 2 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | 3 | 5 |
| Oculogyric crisis | 1 | 1 |
| Odynophagia | 1 | 1 |
| Oedema | 3 | 3 |
| Oedema mouth | 2 | 2 |
| Oedema mucosal | 2 | 2 |
| Oedema peripheral | 3 | 4 |
| Oesophageal pain | 1 | 1 |
| Oesophageal spasm | 1 | 1 |
| Off label use | 14 | 14 |
| Optic neuritis | 4 | 4 |
| Optic neuropathy | 1 | 1 |
| Oral candidiasis | 1 | 1 |
| Oral discomfort | 5 | 6 |
| Oral dysaesthesia | | 1 |
| Oral herpes | 6 | 8 |
| Oral mucosal erythema | 1 | 1 |
| Oral pain | 1 | 1 |
| Oral pruritus | 4 | 4 |
| Orbital oedema | 1 | 1 |
| Oropharyngeal discomfort | 5 | 5 |
| Oropharyngeal oedema | 2 | 2 |
| Oropharyngeal pain | 18 | 21 |
| Orthopnoea | 1 | 1 |
| Orthostatic hypotension | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | 3 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 4 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 13 | 13 | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 3 | 2 | 3 |
| | | | 1 | | |
| | | 1 | 3 | 5 | 5 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 4 |
| | | | | 2 | 2 |
| | | 5 | 8 | 13 | 13 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Overdose | 24 | 26 |
| Oxygen saturation decreased | 20 | 21 |
| Pain | 59 | 70 |
| Pain in extremity | 88 | 112 |
| Pain in jaw | 4 | 4 |
| Palatal oedema | 3 | 4 |
| Palatal swelling | 1 | 2 |
| Pallor | 4 | 4 |
| Palpitations | 8 | 11 |
| Panic attack | 2 | 2 |
| Panic reaction | 1 | 1 |
| Panniculitis | 1 | 1 |
| Papilloedema | 1 | 1 |
| Papule | 1 | 1 |
| Paraesthesia | 112 | 139 |
| Paraesthesia oral | 55 | 72 |
| Paralysis | 2 | 2 |
| Paresis | 1 | 1 |
| Parosmia | 2 | 2 |
| Partial seizures | 1 | 1 |
| Pemphigoid | 1 | 1 |
| Pericardial effusion | 1 | 1 |
| Pericarditis | 1 | 1 |
| Periorbital oedema | 1 | 1 |
| Periorbital swelling | 1 | 2 |
| Peripheral coldness | 4 | 7 |
| Peripheral sensorimotor neuropathy | 1 | 1 |
| Peripheral sensory neuropathy | 1 | 1 |
| Peripheral swelling | 12 | 14 |
| Peripheral venous disease | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal erythema | 2 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 24 | 26 | | |
| | | 3 | 3 | 17 | 18 |
| | | 27 | 36 | 32 | 34 |
| | | 34 | 57 | 54 | 55 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | 2 | 3 |
| | | 1 | 2 | | |
| | | | | 4 | 4 |
| | | 2 | 5 | 6 | 6 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 31 | 55 | 81 | 84 |
| 2 | 2 | 12 | 25 | 43 | 47 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| 1 | 1 | 2 | 5 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 4 | 6 | 8 | 8 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Pharyngeal hypoaesthesia | 1 | 1 |
| Pharyngeal oedema | 4 | 4 |
| Pharyngeal paraesthesia | 6 | 9 |
| Pharyngeal swelling | 7 | 8 |
| Pharyngitis | 2 | 3 |
| Photophobia | 3 | 4 |
| Photopsia | 2 | 2 |
| Photosensitivity reaction | 1 | 1 |
| Pityriasis | 1 | 1 |
| Plicated tongue | 1 | 1 |
| Pneumonia bacterial | 1 | 1 |
| Polyuria | 1 | 1 |
| Presyncope | 29 | 35 |
| Product administered at inappropriate site | 4 | 4 |
| Product administered to patient of inappropriate age | | 1 |
| Productive cough | 2 | 2 |
| Product preparation issue | 3 | 3 |
| Product use issue | 11 | 11 |
| Pruritus | 59 | 81 |
| Psoriasis | 1 | 1 |
| Pulmonary embolism | | 1 |
| Pulmonary pain | 1 | 1 |
| Pulse abnormal | 1 | 1 |
| Pyrexia | 435 | 514 |
| Q fever | 4 | 4 |
| Quality of life decreased | 2 | 2 |
| Radiculopathy | 1 | 1 |
| Rales | 1 | 1 |
| Rash | 64 | 86 |
| Rash erythematous | 5 | 7 |
| Rash macular | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | 2 | 6 | 7 |
| | | 3 | 3 | 4 | 5 |
| | | | 1 | 2 | 2 |
| | | 2 | 3 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 6 | 12 | 23 | 23 |
| | | 4 | 4 | | |
| | | | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 3 | 3 | | |
| | | 9 | 9 | 2 | 2 |
| 1 | 1 | 14 | 33 | 45 | 48 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 5 | 6 | 166 | 241 | 269 | 273 |
| | | | | 4 | 4 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 2 | 2 | 13 | 33 | 51 | 53 |
| | | | 2 | 5 | 5 |
| | | 1 | 1 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Rash morbilliform | 1 | 1 |
| Rash pruritic | 10 | 11 |
| Rash vesicular | 2 | 2 |
| Reaction to excipient | 1 | 1 |
| Reduced facial expression | | 1 |
| Regurgitation | 1 | 1 |
| Renal failure | | 2 |
| Renal pain | 1 | 2 |
| Respiratory arrest | 1 | 2 |
| Respiratory depression | 1 | 1 |
| Respiratory disorder | 2 | 3 |
| Respiratory distress | 4 | 5 |
| Respiratory failure | 1 | 1 |
| Respiratory fatigue | 4 | 4 |
| Respiratory rate increased | 1 | 1 |
| Respiratory tract oedema | 1 | 1 |
| Restless legs syndrome | 1 | 1 |
| Restlessness | 2 | 2 |
| Retching | 4 | 6 |
| Retinal degeneration | 1 | 1 |
| Retinal detachment | 1 | 1 |
| Retinal disorder | 1 | 1 |
| Retinal vascular thrombosis | 1 | 1 |
| Retrograde amnesia | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 |
| Rhinalgia | 1 | 1 |
| Rhinitis | 2 | 2 |
| Rhinorrhoea | 4 | 8 |
| Root canal infection | 1 | 1 |
| Rosacea | 1 | 1 |
| Salivary hypersecretion | 2 | 2 |
| SARS-CoV-2 ant body test negative | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 2 | 3 | 8 | 8 |
| | | 2 | 2 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | 1 | 2 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 4 | 8 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| SARS-CoV-2 ant body test positive | 3 | 5 |
| SARS-CoV-2 test positive | 3 | 4 |
| Scab | 1 | 1 |
| Sciatica | | 1 |
| Scleral discolouration | 1 | 1 |
| Seasonal allergy | 1 | 1 |
| Sedation | 1 | 1 |
| Seizure | 5 | 5 |
| Sensation of foreign body | 7 | 9 |
| Sense of oppression | 2 | 2 |
| Sensory loss | 3 | 3 |
| Sepsis | 1 | 1 |
| Septic shock | 1 | 1 |
| Sinus bradycardia | 1 | 1 |
| Sinus headache | 1 | 1 |
| Sinus tachycardia | 4 | 5 |
| Sjogren's syndrome | 1 | 1 |
| Skin burning sensation | 1 | 1 |
| Skin discolouration | 1 | 1 |
| Skin lesion | 1 | 1 |
| Skin reaction | 3 | 4 |
| Skin swelling | 1 | 1 |
| Skin warm | 4 | 4 |
| Sneezing | | 1 |
| Soft tissue infection | 1 | 1 |
| Somnolence | 29 | 37 |
| Speech disorder | 1 | 2 |
| Spinal pain | 3 | 7 |
| Stertor | 1 | 1 |
| Stoma site pain | 1 | 1 |
| Stomatitis | 1 | 1 |
| Stupor | 3 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | 2 | 2 |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 5 | 5 |
| | | 1 | 3 | 6 | 6 |
| | | | | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 13 | 21 | 16 | 16 |
| | | | 1 | 1 | 1 |
| | | 2 | 6 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 3 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Sudden death | 3 | 3 |
| Suffocation feeling | 1 | 1 |
| Swelling | 8 | 11 |
| Swelling face | 8 | 11 |
| Swelling of eyelid | 2 | 2 |
| Swollen tongue | 5 | 7 |
| Syncope | 54 | 55 |
| Systolic hypertension | | 1 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 84 | 102 |
| Tachycardia paroxysmal | 1 | 2 |
| Tachypnoea | 5 | 6 |
| Taste disorder | 4 | 4 |
| Temporomandibular joint syndrome | 1 | 1 |
| Tenderness | 1 | 2 |
| Tension | 1 | 1 |
| Tension headache | 1 | 1 |
| Terminal insomnia | 1 | 1 |
| Throat irritation | 19 | 22 |
| Throat tightness | 24 | 37 |
| Thrombocytopenia | 1 | 1 |
| Thrombophlebitis superficial | 1 | 1 |
| Thyroid disorder | 1 | 1 |
| Thyroid pain | 1 | 1 |
| Tinnitus | 6 | 6 |
| Tongue discolouration | 1 | 1 |
| Tongue discomfort | 1 | 2 |
| Tongue disorder | 1 | 2 |
| Tongue dry | | 1 |
| Tongue erythema | 1 | 1 |
| Tongue oedema | 12 | 14 |
| Tongue pruritus | 3 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 3 | 5 | 5 | 6 |
| 1 | 1 | 1 | 3 | 7 | 8 |
| | | 2 | 2 | | |
| | | | 2 | 5 | 5 |
| 1 | 1 | | | 54 | 55 |
| | | | | | 1 |
| | | 1 | 1 | | |
| 3 | 3 | 16 | 29 | 68 | 73 |
| | | | | 1 | 2 |
| | | 2 | 3 | 3 | 3 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 6 | 16 | 16 |
| 2 | 2 | 2 | 10 | 22 | 27 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 3 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 3 | 4 | 9 | 10 |
| | | | 1 | 3 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Tonic clonic movements | 1 | 1 |
| Tonic convulsion | 1 | 1 |
| Tonsillitis | 1 | 1 |
| Toothache | 1 | 1 |
| Tooth infection | 1 | 1 |
| Torticollis | 1 | 1 |
| Toxic skin eruption | 1 | 1 |
| Tracheal pain | 1 | 1 |
| Tracheitis | 1 | 1 |
| Transaminases increased | 2 | 2 |
| Tremor | 33 | 41 |
| Trigeminal nerve disorder | 4 | 4 |
| Trigeminal neuralgia | 1 | 1 |
| Type I hypersensitivity | 4 | 4 |
| Underdose | 3 | 5 |
| Upper airway obstruction | 1 | 1 |
| Upper respiratory tract inflammation | 1 | 1 |
| Urinary incontinence | 1 | 1 |
| Urinary retention | 1 | 1 |
| Urine output decreased | 1 | 1 |
| Urticaria | 58 | 86 |
| Use of accessory respiratory muscles | 1 | 1 |
| Uveitis | 2 | 2 |
| Vaccination complication | 15 | 17 |
| Vaccination failure | 1 | 1 |
| Vaccination site bruising | 2 | 2 |
| Vaccination site cellulitis | 1 | 1 |
| Vaccination site discolouration | | 1 |
| Vaccination site discomfort | | 1 |
| Vaccination site erythema | 29 | 41 |
| Vaccination site hypersensitivity | 1 | 1 |
| Vaccination site hypoaesthesia | 3 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 1 | 1 | 6 | 14 | 27 | 27 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | 3 | 5 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 9 | 34 | 49 | 52 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 1 | 1 | 4 | 6 | 11 | 11 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 12 | 23 | 17 | 18 |
| | | | | 1 | 1 |
| | | 2 | 2 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Vaccination site induration | 3 | 4 |
| Vaccination site inflammation | | 1 |
| Vaccination site ischaemia | 1 | 1 |
| Vaccination site joint swelling | | 1 |
| Vaccination site joint warmth | | 1 |
| Vaccination site lymphadenopathy | 3 | 5 |
| Vaccination site mass | 1 | 1 |
| Vaccination site movement impairment | 3 | 5 |
| Vaccination site oedema | 14 | 18 |
| Vaccination site pain | 184 | 279 |
| Vaccination site paraesthesia | 7 | 11 |
| Vaccination site pruritus | 7 | 10 |
| Vaccination site rash | 1 | 2 |
| Vaccination site reaction | 4 | 4 |
| Vaccination site swelling | 32 | 42 |
| Vaccination site urticaria | 3 | 9 |
| Vaccination site vesicles | 1 | 1 |
| Vaccination site warmth | 11 | 16 |
| Vaginal haemorrhage | 1 | 1 |
| Vascular rupture | 1 | 1 |
| Vasculitis | 1 | 1 |
| Vasoconstriction | 3 | 4 |
| Vasodilatation | 1 | 1 |
| Vasomotor rhinitis | | 1 |
| Ventricular extrasystoles | 1 | 1 |
| Vertigo | 54 | 71 |
| Vertigo positional | 1 | 1 |
| Vision blurred | 10 | 13 |
| Visual acuity reduced | 1 | 1 |
| Visual impairment | 6 | 7 |
| Vitreous detachment | 1 | 1 |
| Vitreous floaters | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 3 | 1 | 2 |
| | | 1 | 1 | | |
| | | 3 | 5 | | |
| | | 4 | 8 | 10 | 10 |
| 2 | 2 | 93 | 185 | 91 | 94 |
| | | 2 | 6 | 5 | 5 |
| | | 3 | 5 | 4 | 5 |
| | | 1 | 2 | | |
| | | 1 | 1 | 3 | 3 |
| | | 13 | 22 | 19 | 20 |
| | | 1 | 6 | 2 | 3 |
| | | | | 1 | 1 |
| | | 4 | 8 | 7 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 19 | 36 | 35 | 35 |
| | | | | 1 | 1 |
| | | 3 | 6 | 7 | 7 |
| | | | | 1 | 1 |
| | | 2 | 3 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vocal cord dysfunction | 1 | 1 | | | | | 1 | 1 |
| Vomiting | 76 | 89 | | | 16 | 27 | 60 | 62 |
| Vomiting projectile | 2 | 2 | | | | | 2 | 2 |
| Vulvovaginal burning sensation | 1 | 1 | | | 1 | 1 | | |
| Weight decreased | | 1 | | | | | | 1 |
| Wheezing | 5 | 5 | | | 2 | 2 | 3 | 3 |
| White blood cell count increased | 2 | 2 | | | | | 2 | 2 |
| Wrong technique in product usage process | | 1 | | | | 1 | | |
| Xanthopsia | 1 | 1 | | | | | 1 | 1 |
| | 5,960 | 7,241 | 61 | 67 | 1888 | 2973 | 4072 | 4268 |

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Gender

MALE

| Preferred Term | Interval Total # | Cumulative Total # |
|------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Abdominal discomfort | 1 | 1 |
| Abdominal distension | 1 | 1 |
| Abdominal pain | 8 | 11 |
| Abdominal pain upper | 4 | 6 |
| Accommodation disorder | 1 | 1 |
| Acute myocardial infarction | | 2 |
| Acute respiratory failure | 1 | 2 |
| Ageusia | 1 | 1 |
| Agitation | 2 | 3 |
| Allergic respiratory symptom | | 1 |
| Allodynia | | 1 |
| Anaesthesia oral | 1 | 1 |
| Anal incontinence | | 1 |
| Anaphylactic reaction | 1 | 5 |
| Anaphylactic shock | 1 | 2 |
| Anaphylactoid reaction | 1 | 1 |
| Angioedema | 6 | 7 |
| Anterograde amnesia | 1 | 1 |
| Anuria | 1 | 1 |
| Anxiety | | 1 |
| Aphonia | 1 | 1 |
| Apnoea | 1 | 1 |
| Arrhythmia | 4 | 4 |
| Arthralgia | 48 | 60 |
| Asthenia | 48 | 66 |
| Asthenopia | 1 | 1 |
| Asthmatic crisis | 1 | 1 |
| Asymptomatic COVID-19 | 1 | 1 |
| Atrial fibrillation | 2 | 2 |
| Atrial tachycardia | 1 | 1 |
| Axillary pain | 7 | 7 |
| Back pain | 7 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 5 | 6 | 6 |
| | | 2 | 4 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | 1 | 2 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 5 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 6 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | 23 | 34 | 25 | 26 |
| | | 22 | 38 | 26 | 28 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 5 | 5 | 2 | 2 |
| 1 | 1 | 3 | 4 | 4 | 4 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Balance disorder | 1 | 2 |
| Barotrauma | 1 | 1 |
| Blindness | 1 | 1 |
| Blood glucose increased | | 1 |
| Blood pressure decreased | 1 | 2 |
| Blood pressure increased | 5 | 7 |
| Blood pressure systolic increased | 1 | 1 |
| Body temperature decreased | | 1 |
| Body temperature increased | 1 | 3 |
| Bone pain | 3 | 4 |
| Bradycardia | 3 | 3 |
| Brain neoplasm | 1 | 1 |
| Burning sensation | 1 | 1 |
| Cardiac arrest | 1 | 1 |
| Cardiac failure | 1 | 1 |
| Cervicobrachial syndrome | 1 | 1 |
| Chest discomfort | 4 | 6 |
| Chest pain | 7 | 8 |
| Chills | 36 | 51 |
| Circumstance or information capable of leading to medication error | | 1 |
| Clonus | 1 | 1 |
| Cold burn | 1 | 1 |
| Cold sweat | 3 | 3 |
| Condition aggravated | 1 | 1 |
| Confusional state | 5 | 6 |
| Conjunctival hyperaemia | 1 | 1 |
| Conjunctival irritation | 1 | 1 |
| Conjunctivitis | 1 | 1 |
| Contusion | 1 | 1 |
| Coronary artery disease | 1 | 1 |
| Cough | 5 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | 3 | 4 | 2 | 3 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 2 |
| | | 2 | 3 | 1 | 1 |
| 1 | 1 | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 4 | 1 | 2 |
| | | 1 | 2 | 6 | 6 |
| | | 16 | 31 | 20 | 20 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 5 | 5 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 3 | 5 | 5 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| COVID-19 | 23 | 28 |
| Cranial nerve disorder | | 1 |
| C-reactive protein increased | 1 | 1 |
| Death | | 2 |
| Decreased appetite | 2 | 2 |
| Deep vein thrombosis | 1 | 1 |
| Dehydration | 1 | 1 |
| Depressed level of consciousness | 9 | 9 |
| Dermatitis allergic | 1 | 2 |
| Dermatitis exfoliative | 1 | 1 |
| Diarrhoea | 15 | 25 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplegia | 1 | 1 |
| Diplopia | 5 | 5 |
| Disease recurrence | 1 | 1 |
| Disorientation | 2 | 2 |
| Dizziness | 11 | 15 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 21 | 26 |
| Dry mouth | 2 | 5 |
| Dry throat | | 1 |
| Dysaesthesia | | 2 |
| Dysentery | 10 | 10 |
| Dysgeusia | 3 | 8 |
| Dyspepsia | 1 | 1 |
| Dysphagia | 3 | 4 |
| Dysphonia | | 1 |
| Dyspnoea | 16 | 19 |
| Dysstasia | 1 | 1 |
| Ear discomfort | 1 | 1 |
| Ear pain | 1 | 1 |
| Encephalitis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | 21 | 25 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 9 | 9 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 4 | 14 | 11 | 11 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 7 | 11 | 4 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | 20 | 25 |
| | | 2 | 3 | | 2 |
| | | | 1 | | |
| | | | 2 | | |
| | | | | 10 | 10 |
| | | 2 | 5 | 1 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | 1 | | |
| | | 1 | 2 | 15 | 17 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------------|--|--|
| Enterocolitis | 1 | 1 |
| Epilepsy | 4 | 4 |
| Epistaxis | 1 | 1 |
| Erythema | 10 | 19 |
| Euphoric mood | 1 | 1 |
| Exposure via breast milk | | 1 |
| Extrasystoles | 3 | 3 |
| Extremity contracture | | 1 |
| Eye disorder | 1 | 1 |
| Eye irritation | 2 | 2 |
| Eyelid retraction | 1 | 1 |
| Eye pain | 1 | 1 |
| Eye pruritus | 1 | 1 |
| Facial paralysis | 12 | 13 |
| Facial paresis | 2 | 2 |
| Fall | 1 | 2 |
| Fatigue | 19 | 28 |
| Feeding disorder | 1 | 1 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | 2 | 4 |
| Feeling drunk | 1 | 1 |
| Feeling hot | 6 | 8 |
| Feeling of body temperature change | 2 | 2 |
| Fibrin D dimer increased | 1 | 1 |
| Flushing | | 2 |
| Gait disturbance | 3 | 3 |
| Gastrointestinal disorder | 1 | 2 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Gingival swelling | 1 | 1 |
| Haematuria | 1 | 1 |
| Hallucination | 1 | 1 |
| Headache | 74 | 114 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 2 | 9 | 8 | 10 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 12 | 13 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | 6 | 15 | 13 | 13 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 2 |
| | | 1 | 1 | | |
| | | 3 | 5 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 2 | 2 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 33 | 72 | 41 | 42 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Head discomfort | 1 | 2 |
| Head injury | 1 | 1 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 2 | 2 |
| Hemiparaesthesia | 2 | 2 |
| Hemiplegia | 1 | 1 |
| Herpes virus infection | 1 | 1 |
| Herpes zoster | 2 | 3 |
| Herpes zoster infection neurological | 1 | 1 |
| Herpes zoster oticus | 1 | 1 |
| Hot flush | 2 | 4 |
| Hyperaemia | 2 | 2 |
| Hyperhidrosis | 18 | 24 |
| Hyperpyrexia | 33 | 35 |
| Hyperreflexia | 1 | 1 |
| Hypersensitivity | 5 | 5 |
| Hypertension | 10 | 11 |
| Hypertensive crisis | 9 | 12 |
| Hyperthermia | 1 | 1 |
| Hyperventilation | 2 | 2 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 5 | 12 |
| Hypoaesthesia oral | 1 | 1 |
| Hypoglossal nerve disorder | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hyposmia | 1 | 1 |
| Hypotension | 8 | 10 |
| Hypotonia | 1 | 1 |
| Illness | 1 | 1 |
| Incorrect route of product administration | 1 | 2 |
| Inflammation | 1 | 1 |
| Influenza | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 2 | 2 |
| | | | | 2 | 2 |
| | | 5 | 10 | 13 | 14 |
| | | | | 33 | 35 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 4 |
| | | 1 | 1 | 9 | 10 |
| | | | | 9 | 12 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 7 | 4 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 3 | 7 | 7 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Influenza like illness | 2 | 4 |
| Injection site pain | | 2 |
| Insomnia | 3 | 5 |
| International normalised ratio increased | 1 | 1 |
| Intervertebral discitis | 1 | 1 |
| Joint range of motion decreased | 2 | 2 |
| Joint swelling | 1 | 1 |
| Lack of vaccination site rotation | | |
| Laryngeal obstruction | 1 | 1 |
| Laryngeal oedema | 4 | 5 |
| Limb discomfort | 1 | 4 |
| Lip oedema | | 3 |
| Lip pruritus | | 1 |
| Listeriosis | 1 | 1 |
| Localised oedema | 1 | 2 |
| Loss of consciousness | 10 | 11 |
| Loss of personal independence in daily activities | 1 | 1 |
| Lymphadenitis | 2 | 3 |
| Lymphadenopathy | 27 | 35 |
| Lymph node pain | 3 | 4 |
| Lymphocyte count decreased | 1 | 1 |
| Lymphoedema | 1 | 1 |
| Lymphopenia | 1 | 1 |
| Macroglossia | 1 | 1 |
| Macular rupture | 1 | 1 |
| Malaise | 15 | 20 |
| Mean cell volume increased | 1 | 1 |
| Mechanical urticaria | 1 | 1 |
| Memory impairment | 1 | 1 |
| Meningeal disorder | 1 | 1 |
| Metamorphopsia | 1 | 1 |
| Middle insomnia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | 2 | 2 |
| | | | 2 | | |
| | | 2 | 4 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | | | |
| | | | | 1 | 1 |
| | | | | 4 | 5 |
| | | 1 | 4 | | |
| | | | 2 | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 10 | 11 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 9 | 16 | 18 | 19 |
| | | | 1 | 3 | 3 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 6 | 11 | 9 | 9 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Migraine | 7 | 13 |
| Mobility decreased | 2 | 2 |
| Monocyte count increased | 1 | 1 |
| Monoplegia | 1 | 1 |
| Mouth ulceration | 1 | 1 |
| Mucosal dryness | | 1 |
| Muscle contractions involuntary | 1 | 1 |
| Muscle spasms | | 2 |
| Muscle swelling | 1 | 1 |
| Muscular weakness | 1 | 3 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal pain | 8 | 12 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 59 | 79 |
| Myocardial necrosis marker increased | 1 | 1 |
| Myocarditis | 2 | 2 |
| Myositis | | |
| Nausea | 26 | 40 |
| Neck pain | 3 | 4 |
| Neuralgia | 3 | 3 |
| Neuralgic amyotrophy | | |
| Neuritis | 1 | 1 |
| Neurogenic bladder | 1 | 1 |
| Neuropathy peripheral | 1 | 1 |
| Night sweats | 2 | 2 |
| No adverse event | 1 | 1 |
| Obstructive airways disorder | 1 | 2 |
| Ocular hyperaemia | 1 | 1 |
| Odynophagia | 1 | 1 |
| Oedema mouth | | 3 |
| Oedema peripheral | 1 | 1 |
| Off label use | 2 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 9 | 4 | 4 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 6 | 6 | 6 |
| | | | 1 | | |
| 1 | 1 | 30 | 50 | 29 | 29 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| 1 | 1 | | | | |
| | | 10 | 24 | 16 | 16 |
| | | 1 | 2 | 2 | 2 |
| | | | | 3 | 3 |
| 1 | 1 | | | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | | 1 |
| | | 1 | 1 | | |
| | | 2 | 5 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Ophthalmic herpes simplex | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal pain | 4 | 5 |
| Overdose | 5 | 6 |
| Oxygen saturation decreased | 6 | 7 |
| Pain | 11 | 13 |
| Pain in extremity | 14 | 27 |
| Palatal oedema | 1 | 2 |
| Pallor | 3 | 5 |
| Palpitations | 2 | 2 |
| Paraesthesia | 18 | 21 |
| Paraesthesia oral | 2 | 7 |
| Paralysis | 1 | 1 |
| Paraparesis | 1 | 1 |
| Paresis | 1 | 1 |
| Paresis cranial nerve | | 1 |
| Parosmia | | 1 |
| Parotid gland enlargement | | 1 |
| Pericarditis | 3 | 3 |
| Periorbital discomfort | 1 | 1 |
| Periorbital oedema | | 1 |
| Periorbital swelling | | 1 |
| Peripheral coldness | | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal erythema | 1 | 1 |
| Pharyngitis | 1 | 3 |
| Photophobia | 1 | 1 |
| Photopsia | 1 | 1 |
| Pityriasis rosea | | 1 |
| Pleurisy | 1 | 1 |
| Pneumonia | 2 | 2 |
| Pneumonitis | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | 2 | 2 |
| | | 5 | 6 | | |
| | | | 1 | 6 | 6 |
| | | 7 | 9 | 4 | 4 |
| | | 10 | 22 | 4 | 5 |
| | | | 1 | 1 | 1 |
| | | 1 | 3 | 2 | 2 |
| | | 2 | 2 | | |
| | | 4 | 7 | 14 | 14 |
| | | 1 | 5 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 3 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Polyuria | | 1 |
| Presyncope | 13 | 17 |
| Product administered at inappropriate site | 2 | 2 |
| Product label confusion | | 1 |
| Product preparation issue | 3 | 3 |
| Product use issue | 1 | 3 |
| Pruritus | 7 | 13 |
| Pulmonary embolism | 1 | 1 |
| Purpura | 1 | 1 |
| Pyrexia | 125 | 162 |
| Q fever | 2 | 2 |
| Quadriparesis | 1 | 1 |
| Rash | 7 | 11 |
| Rash erythematous | 1 | 2 |
| Rash pruritic | 1 | 1 |
| Red blood cell count decreased | 1 | 1 |
| Red cell distribution width increased | 1 | 1 |
| Renal failure | 1 | 1 |
| Respiratory fatigue | 2 | 2 |
| Respiratory tract infection | 1 | 1 |
| Restlessness | 1 | 2 |
| Retching | 1 | 1 |
| Retinal detachment | 1 | 1 |
| Retrograde amnesia | 1 | 1 |
| Rheumatic disorder | 1 | 1 |
| Rhinitis | 1 | 1 |
| Rhinitis allergic | 1 | 1 |
| Rhonchi | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 3 |
| Sciatica | 1 | 1 |
| Sedation | 1 | 1 |
| Seizure like phenomena | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 4 | 12 | 13 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | 3 | 3 | | |
| | | 1 | 3 | | |
| | | | 5 | 7 | 8 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 47 | 83 | 78 | 79 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 2 | 5 | 5 | 6 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Sensory disturbance | 2 | 2 |
| Sensory loss | 1 | 1 |
| Sepsis | 1 | 1 |
| Severe acute respiratory syndrome | 1 | 1 |
| Sinus rhythm | 1 | 1 |
| Sinus tachycardia | | 2 |
| Skin reaction | 2 | 3 |
| Somnolence | 6 | 14 |
| Sopor | 1 | 1 |
| Speech disorder | 1 | 1 |
| Spinal pain | 1 | 1 |
| Stupor | 1 | 1 |
| Sudden death | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling | 2 | 3 |
| Swelling face | 1 | 1 |
| Swelling of eyelid | | 1 |
| Swollen tongue | 2 | 3 |
| Syncope | 20 | 21 |
| Tachycardia | 13 | 22 |
| Tachycardia paroxysmal | | 1 |
| Taste disorder | 1 | 1 |
| Terminal insomnia | 1 | 1 |
| Thermal burns of eye | 1 | 1 |
| Throat irritation | 1 | 2 |
| Throat tightness | 3 | 4 |
| Thrombocytopenia | 1 | 1 |
| Thyroid hormones increased | 1 | 1 |
| Tinnitus | 3 | 3 |
| Tongue dry | | 2 |
| Tongue oedema | | 1 |
| Tonic clonic movements | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 1 | 2 | 1 | 1 |
| | | 3 | 11 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 3 |
| | | | | 20 | 21 |
| | | 3 | 11 | 10 | 11 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Tonsillar erythema | | 1 |
| Tonsillar hypertrophy | | 1 |
| Torticollis | | 1 |
| Tremor | 9 | 13 |
| Troponin T increased | 1 | 1 |
| Underdose | 2 | 4 |
| Urinary tract infection | 1 | 1 |
| Urticaria | 11 | 14 |
| Vaccination failure | 1 | 1 |
| Vaccination site discomfort | | 2 |
| Vaccination site erythema | 2 | 4 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site induration | 1 | 1 |
| Vaccination site inflammation | 2 | 2 |
| Vaccination site joint movement impairment | 1 | 1 |
| Vaccination site movement impairment | | 1 |
| Vaccination site oedema | 2 | 3 |
| Vaccination site pain | 41 | 118 |
| Vaccination site paraesthesia | 1 | 2 |
| Vaccination site pruritus | 1 | 2 |
| Vaccination site reaction | 3 | 3 |
| Vaccination site swelling | 4 | 7 |
| Vaccination site vesicles | 1 | 1 |
| Vaccination site warmth | | 1 |
| Venous thrombosis limb | 1 | 1 |
| Ventricular extrasystoles | 2 | 2 |
| Ventricular tachycardia | 1 | 1 |
| Vertigo | 12 | 18 |
| Vision blurred | 1 | 3 |
| Vlth nerve paralysis | 1 | 1 |
| Vlth nerve paresis | 1 | 1 |
| Vitreous disorder | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 3 | 6 | 6 | 7 |
| | | | | 1 | 1 |
| | | 2 | 4 | | |
| | | 1 | 1 | | |
| | | 2 | 4 | 9 | 10 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | 1 | 3 | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | 2 | 2 |
| 1 | 1 | 32 | 109 | 9 | 9 |
| | | 1 | 2 | | |
| | | 1 | 2 | | |
| | | 2 | 2 | 1 | 1 |
| | | 4 | 7 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| 1 | 1 | 6 | 11 | 6 | 7 |
| | | | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # | Cumulative Total # |
|----------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Vitreous floaters | 1 | 1 |
| Volvulus | 1 | 1 |
| Vomiting | 10 | 12 |
| Wandering pacemaker | 1 | 1 |
| White blood cell count decreased | 1 | 1 |
| Wound | 1 | 1 |
| | 1,329 | 1,878 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 7 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 9 | 9 | 446 | 919 | 883 | 959 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | | 3 | | | | 3 |
| Anaphylactic shock | | 1 | | | | 1 |
| Arthralgia | 4 | 5 | 3 | 4 | 1 | 1 |
| Asthenia | 5 | 7 | 1 | 3 | 4 | 4 |
| Asthenopia | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Bone pain | 2 | 2 | 2 | 2 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Carotid artery dissection | 1 | 1 | | | 1 | 1 |
| Catarrh | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chills | 5 | 5 | 4 | 4 | 1 | 1 |
| Confusional state | | 1 | | 1 | | |
| COVID-19 | 5 | 6 | | | 5 | 6 |
| Cranial nerve disorder | 1 | 1 | 1 | 1 | | |
| Deafness bilateral | | 1 | | | | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Dermatitis bullous | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 2 | | 1 | 1 | 1 |
| Dizziness | | 1 | | 1 | | |
| Drug ineffective | 5 | 6 | | | 5 | 6 |
| Dry mouth | | 1 | | 1 | | |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Dysuria | | 1 | | | | 1 |
| Ear pruritus | 1 | 1 | 1 | 1 | | |
| Epiglottic oedema | 1 | 1 | | | 1 | 1 |
| Erythema | 4 | 5 | 2 | 3 | 2 | 2 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | | 1 | | 1 | | |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Flushing | 1 | 1 | | | 1 | 1 |
| Gait inability | 2 | 2 | 2 | 2 | | |
| Headache | 9 | 11 | 5 | 7 | 4 | 4 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | | 1 | | 1 | | |
| Hyperpyrexia | 3 | 3 | | | 3 | 3 |
| Hypersensitivity | | 1 | | | | 1 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 1 | 1 | 1 | 1 | | |
| Hypoacusis | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | | 1 | | 1 | | |
| Hypotension | | 1 | | | | 1 |
| Incorrect dose administered | | 1 | | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Influenza like illness | | 1 | | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Laryngeal oedema | 2 | 3 | | | 2 | 3 |
| Lip oedema | | 3 | | 3 | | |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 4 | 8 | 3 | 7 | 1 | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 3 | 3 | 2 | 2 | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Mechanical urticaria | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 2 | | 1 | 1 | 1 |
| Musculoskeletal pain | | 1 | | 1 | | |
| Myalgia | 6 | 6 | 2 | 2 | 4 | 4 |
| Nausea | 5 | 5 | 3 | 3 | 2 | 2 |
| Nuchal rigidity | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oral pain | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 2 | 2 | 2 | 2 | | |
| Palatal oedema | 1 | 1 | | | 1 | 1 |
| Pallor | | 1 | | 1 | | |
| Palpitations | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 1 | 4 | 1 | 4 | | |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Peripheral coldness | | 1 | | 1 | | |
| Petechiae | 1 | 1 | 1 | 1 | | |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | | 1 | | 1 | | |
| Presyncope | 1 | 1 | 1 | 1 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product administration error | | 1 | | 1 | | |
| Product preparation issue | | 1 | | 1 | | |
| Pruritus | 3 | 3 | 1 | 1 | 2 | 2 |
| Pyrexia | 6 | 9 | 2 | 4 | 4 | 5 |
| Rash | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Skin tightness | 1 | 1 | | | 1 | 1 |
| Somnolence | | 1 | | 1 | | |
| Sopor | 1 | 1 | 1 | 1 | | |
| Sudden death | | 1 | | | | 1 |
| Swelling face | 2 | 2 | 1 | 1 | 1 | 1 |
| Tachycardia | 1 | 2 | | 1 | 1 | 1 |
| Tongue oedema | | 1 | | 1 | | |
| Underdose | | 1 | | 1 | | |
| Urticaria | 2 | 6 | 1 | 5 | 1 | 1 |
| Vaccination site oedema | | 2 | | 2 | | |
| Vaccination site pain | 4 | 7 | 3 | 6 | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site paraesthesia | | 1 | | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vertigo | | 1 | | | | 1 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 130 | 198 | 58 | 111 | 72 | 87 |

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Country Where Event Occurred

JAPAN

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abortion | 1 | 1 | | | 1 | 1 |
| Affect lability | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Brain oedema | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Haemorrhage | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Hospitalisation | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Mouth haemorrhage | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Oral discomfort | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| | 35 | 35 | 16 | 16 | 19 | 19 |

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Country Where Event Occurred
JORDAN

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Muscle spasms | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Taste disorder | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred
KUWAIT

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Fatigue | | 1 | | 1 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Neck pain | | 1 | | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Swelling | | 1 | | 1 | | |
| Tenderness | 1 | 2 | 1 | 2 | | |
| Vaccination site pain | | 1 | | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| | 5 | 14 | 3 | 12 | 2 | 2 |

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Country Where Event Occurred

LATVIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 4 | 4 | 4 | 4 | | |
| Abdominal pain upper | 2 | 2 | | | 2 | 2 |
| Anxiety | | 1 | | | | 1 |
| Arthralgia | 20 | 24 | 17 | 20 | 3 | 4 |
| Asthenia | 8 | 11 | 7 | 9 | 1 | 2 |
| Asthma | | 1 | | 1 | | |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Bacille Calmette-Guerin scar reactivation | 1 | 1 | 1 | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 3 | | 1 | 1 | 2 |
| Body temperature increased | 25 | 30 | 25 | 29 | | 1 |
| Bone pain | 2 | 2 | 2 | 2 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bradyphrenia | 1 | 1 | 1 | 1 | | |
| Burning sensation | 2 | 3 | | | 2 | 3 |
| Chest pain | 1 | 2 | 1 | 2 | | |
| Chills | 23 | 24 | 23 | 24 | | |
| Cold sweat | | 1 | | | | 1 |
| Condition aggravated | | 1 | | 1 | | |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Coordination abnormal | 1 | 1 | 1 | 1 | | |
| Cough | 4 | 5 | 4 | 5 | | |
| COVID-19 | | 2 | | 2 | | |
| C-reactive protein increased | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 4 | 4 | 4 | 4 | | |
| Depressed mood | 1 | 1 | 1 | 1 | | |
| Depression | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 4 | 5 | 4 | 5 | | |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 3 | 3 | 3 | 3 | | |
| Dizziness | 13 | 13 | 10 | 10 | 3 | 3 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Dry mouth | 1 | 2 |
| Dysgeusia | 2 | 3 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 2 | 3 |
| Ear discomfort | 1 | 1 |
| Ear pain | 1 | 1 |
| Epistaxis | 1 | 1 |
| Erythema | 1 | 2 |
| Exposure during pregnancy | 1 | 1 |
| Extrasystoles | 1 | 1 |
| Eye pain | 5 | 6 |
| Facial paralysis | 1 | 1 |
| Facial paresis | 1 | 1 |
| Fatigue | 25 | 28 |
| Feeling hot | | 1 |
| Gait disturbance | 1 | 1 |
| Headache | 35 | 39 |
| Hot flush | 2 | 2 |
| Hyperaesthesia | 3 | 3 |
| Hyperhidrosis | 4 | 4 |
| Hypertensive crisis | 2 | 2 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 1 | 1 |
| Illness | | 2 |
| Insomnia | 2 | 2 |
| Joint stiffness | 1 | 1 |
| Lymphadenitis | 1 | 2 |
| Lymphadenopathy | 6 | 6 |
| Lymph node pain | 5 | 6 |
| Malaise | 2 | 3 |
| Mental impairment | 1 | 1 |
| Migraine | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | 1 |
| 1 | 1 | 1 | 2 |
| 1 | 1 | | |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 5 | 6 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 22 | 25 | 3 | 3 |
| | 1 | | |
| 1 | 1 | | |
| 31 | 33 | 4 | 6 |
| 1 | 1 | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 3 | 3 | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 2 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 5 | 5 | 1 | 1 |
| 3 | 3 | 2 | 3 |
| 2 | 3 | | |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 2 | 2 | 2 | 2 | | |
| Musculoskeletal discomfort | 1 | 2 | 1 | 2 | | |
| Musculoskeletal stiffness | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 23 | 25 | 20 | 22 | 3 | 3 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nasal oedema | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Nausea | 14 | 14 | 13 | 13 | 1 | 1 |
| Neck pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Neuralgia | | 1 | | | | 1 |
| Night sweats | | 1 | | 1 | | |
| Oropharyngeal pain | 3 | 3 | 3 | 3 | | |
| Pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain in extremity | 3 | 5 | 3 | 4 | | 1 |
| Palatal swelling | | 1 | | 1 | | |
| Palpitations | 3 | 3 | | | 3 | 3 |
| Paraesthesia | 3 | 4 | 1 | 1 | 2 | 3 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | | 2 | | 1 | | 1 |
| Peripheral sensory neuropathy | 1 | 1 | | | 1 | 1 |
| Pharyngeal oedema | 1 | 1 | 1 | 1 | | |
| Photophobia | 2 | 2 | 1 | 1 | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 2 | | | 1 | 2 |
| Pyrexia | 39 | 43 | 36 | 39 | 3 | 4 |
| Rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | 1 | 2 | | | 1 | 2 |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Skin tightness | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sleep disorder due to general medical condition, insomnia type | 1 | 1 | 1 | 1 | | |
| Somnolence | 7 | 7 | 5 | 5 | 2 | 2 |
| Syncope | 1 | 2 | | | 1 | 2 |
| Tachycardia | 3 | 3 | | | 3 | 3 |
| Thirst | 2 | 2 | 1 | 1 | 1 | 1 |
| Throat irritation | 3 | 4 | 3 | 4 | | |
| Upper respiratory tract congestion | 1 | 1 | 1 | 1 | | |
| Vaccination site discolouration | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 6 | 7 | 4 | 5 | 2 | 2 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 2 | 2 | | | 2 | 2 |
| Vaccination site oedema | 5 | 6 | 4 | 4 | 1 | 2 |
| Vaccination site pain | 37 | 43 | 34 | 40 | 3 | 3 |
| Vaccination site pruritus | 2 | 4 | 1 | 3 | 1 | 1 |
| Vaccination site rash | 2 | 2 | | | 2 | 2 |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vaccination site warmth | 2 | 2 | 1 | 1 | 1 | 1 |
| Vertigo | 3 | 3 | 3 | 3 | | |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Vomiting | 5 | 6 | 4 | 5 | 1 | 1 |
| | 444 | 518 | 349 | 401 | 95 | 117 |

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Gender

MALE

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|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal sensation in eye | 1 | 1 | 1 | 1 | | |
| Arthralgia | 8 | 9 | 8 | 9 | | |
| Asthenia | 4 | 5 | 2 | 3 | 2 | 2 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blepharitis | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | | 1 | | 1 | | |
| Body temperature increased | 8 | 9 | 8 | 9 | | |
| Chills | 7 | 7 | 7 | 7 | | |
| COVID-19 | | 1 | | | | 1 |
| Disturbance in attention | 3 | 3 | | | 3 | 3 |
| Dizziness | | 1 | | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Eye pain | 3 | 3 | 3 | 3 | | |
| Fatigue | 11 | 11 | 7 | 7 | 4 | 4 |
| Headache | 6 | 7 | 5 | 6 | 1 | 1 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 2 | 2 | 2 | 2 | | |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Increased appetite | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 2 | 2 | | | 2 | 2 |
| Myalgia | 9 | 11 | 8 | 10 | 1 | 1 |
| Nausea | | 1 | | 1 | | |
| Oropharyngeal pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Pain in extremity | | 1 | | 1 | | |
| Pyrexia | 6 | 6 | 4 | 4 | 2 | 2 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tunnel vision | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 7 | 7 | 6 | 6 | 1 | 1 |
| | 90 | 102 | 71 | 81 | 19 | 21 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| COVID-19 | | 1 | | 1 |
| Drug ineffective | | 1 | | 1 |
| | | 2 | | 2 |

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Country Where Event Occurred

LEBANON

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

LITHUANIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Accidental overdose | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 2 | 3 | | 1 | 2 | 2 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 4 | 5 | | 1 | 4 | 4 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 3 | | 2 | 1 | 1 |
| Dizziness | 1 | 2 | | 1 | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Feeling drunk | | 1 | | 1 | | |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Headache | 5 | 7 | 2 | 4 | 3 | 3 |
| Heart rate increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | | 1 | | 1 | | |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 5 | 6 | 4 | 5 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | 1 | 1 | | |
| Local reaction | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 3 | 3 | 2 | 2 | 1 | 1 |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 3 | 1 | 3 | | |
| Myositis | 1 | 1 | 1 | 1 | | |
| Nausea | 2 | 3 | | 1 | 2 | 2 |
| Neck pain | | 1 | | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 4 | 2 | 4 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 2 | | 1 | 1 | 1 |
| Polymyositis | 1 | 1 | | | 1 | 1 |
| Product preparation issue | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 5 | 2 | 5 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Skin mass | 1 | 1 | | | 1 | 1 |
| Stress | 1 | 1 | 1 | 1 | | |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | | 1 | | 1 | | |
| Taste disorder | 1 | 1 | | | 1 | 1 |
| Tendon pain | 1 | 1 | 1 | 1 | | |
| Tremor | 3 | 3 | 1 | 1 | 2 | 2 |
| Underdose | | 1 | | 1 | | |
| Vaccination site erythema | 2 | 3 | 1 | 2 | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 4 | 6 | 3 | 5 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site warmth | 2 | 2 | 1 | 1 | 1 | 1 |
| Vomiting | 3 | 3 | 1 | 1 | 2 | 2 |
| | 93 | 119 | 43 | 69 | 50 | 50 |

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | | 2 | | 2 | | |
| Back pain | | 1 | | 1 | | |
| Chills | | 1 | | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Dizziness | | 1 | | 1 | | |
| Headache | | 2 | | 2 | | |
| Myalgia | | 3 | | 3 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Overdose | | 1 | | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | | 3 | | 3 | | |
| Sensitive skin | | 1 | | 1 | | |
| Tremor | | 1 | | 1 | | |
| Vaccination complication | | 1 | | 1 | | |
| Vaccination site pain | | 1 | | 1 | | |
| | 3 | 21 | 2 | 20 | 1 | 1 |

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Country Where Event Occurred

LUXEMBOURG

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Chillblains | 1 | 1 | 1 | 1 | | |
| Chills | 3 | 3 | | | 3 | 3 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | | | 2 | 2 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dry skin | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Dyspnoea exertional | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 5 | 5 | | | 5 | 5 |
| Feeding disorder | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Headache | 4 | 4 | | | 4 | 4 |
| Herpes zoster | | 1 | | 1 | | |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 4 | 4 | | | 4 | 4 |
| Nausea | 1 | 1 | | | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Oral herpes | | 1 | | 1 | | |
| Pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | | | 1 | 1 |
| Pyrexia | 2 | 2 | | | 2 | 2 |

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Gender

FEMALE

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rash | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | | | 1 | 1 |
| Skin haemorrhage | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Tongue ulceration | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 55 | 57 | 3 | 5 | 52 | 52 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Acute kidney injury | 1 | 1 | 1 | 1 |
| Altered state of consciousness | 1 | 1 | 1 | 1 |
| Fatigue | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 |
| Hypernatraemia | 1 | 1 | 1 | 1 |
| Hyperthermia | 1 | 1 | 1 | 1 |
| Hypotension | 1 | 1 | 1 | 1 |
| Insomnia | 1 | 1 | 1 | 1 |
| Loss of consciousness | 1 | 1 | 1 | 1 |
| Lung disorder | 1 | 1 | 1 | 1 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| Pallor | 1 | 1 | 1 | 1 |
| Presyncope | 1 | 1 | 1 | 1 |
| Pulse abnormal | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| Sepsis | 1 | 1 | 1 | 1 |
| Vaccination complication | 1 | 1 | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 |
| | 20 | 20 | 20 | 20 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Influenza | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 1 | 1 | 2 | 2 |

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Country Where Event Occurred

MALTA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | 2 | 2 | | |
| Administration site movement impairment | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 3 | 4 | | | 3 | 4 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Asthma | 1 | 2 | | | 1 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Cough | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Defaecation urgency | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 3 | 1 | 2 | 1 | 1 |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Erythema | 1 | 2 | | 1 | 1 | 1 |
| Facial paralysis | 2 | 3 | | | 2 | 3 |
| Fatigue | 5 | 7 | 4 | 6 | 1 | 1 |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gait inability | 1 | 1 | 1 | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Hot flush | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | | 1 | | | | 1 |
| Hypertension | | 1 | | | | 1 |
| Hypoaesthesia | 1 | 2 | 1 | 2 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Lethargy | 1 | 3 | 1 | 3 | | |
| Limb discomfort | 3 | 3 | 2 | 2 | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 2 | 2 | | |

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Gender

FEMALE

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|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 3 | 4 | 2 | 3 | 1 | 1 |
| Nausea | 2 | 3 | 1 | 2 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Off label use | | 1 | | 1 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Pain | 4 | 5 | 4 | 5 | | |
| Pain in extremity | 5 | 5 | 4 | 4 | 1 | 1 |
| Palpitations | 1 | 2 | | 1 | 1 | 1 |
| Paraesthesia | 3 | 5 | 3 | 5 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product use issue | | 1 | | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 4 | 4 | 3 | 3 | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash erythematous | 2 | 3 | | 1 | 2 | 2 |
| Rash pruritic | | 1 | | | | 1 |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 2 | 1 | 2 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 2 | | | 1 | 2 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 3 | 3 | 3 | 3 | | |
| Vaccination site urticaria | 1 | 2 | | 1 | 1 | 1 |
| Vomiting | 2 | 3 | 1 | 2 | 1 | 1 |
| Wheezing | 1 | 2 | | | 1 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 89 | 120 | 53 | 75 | 36 | 45 |

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 1 | | | | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Drug ineffective | | 1 | | | | 1 |
| Fatigue | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Injection site pain | | 1 | | 1 | | |
| Lethargy | 1 | 2 | 1 | 2 | | |
| Malaise | 1 | 2 | 1 | 2 | | |
| Myalgia | | 1 | | 1 | | |
| Nausea | | 1 | | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Pyrexia | 3 | 4 | 2 | 3 | 1 | 1 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 3 | 4 | 3 | 4 | | |
| | 20 | 30 | 13 | 21 | 7 | 9 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fear of injection | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

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Country Where Event Occurred

MEXICO

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 48 | 49 | 43 | 44 | 5 | 5 |
| Abdominal pain upper | 1 | 3 | | 2 | 1 | 1 |
| Abnormal faeces | 1 | 1 | | | 1 | 1 |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Akathisia | | 1 | | 1 | | |
| Allergy to vaccine | 4 | 4 | 3 | 3 | 1 | 1 |
| Allodynia | 2 | 2 | 2 | 2 | | |
| Anaphylactic reaction | 5 | 6 | | | 5 | 6 |
| Anaphylactic shock | 15 | 16 | | | 15 | 16 |
| Angina pectoris | | 1 | | | | 1 |
| Angioedema | | 2 | | | | 2 |
| Anosmia | 6 | 6 | 4 | 4 | 2 | 2 |
| Anxiety | 11 | 11 | 9 | 9 | 2 | 2 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arthralgia | 159 | 166 | 144 | 150 | 15 | 16 |
| Asthenia | 208 | 209 | 186 | 186 | 22 | 23 |
| Asthma | | 1 | | 1 | | |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Auricular swelling | 1 | 1 | 1 | 1 | | |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Axonal neuropathy | | 1 | | | | 1 |
| Back pain | 8 | 8 | 8 | 8 | | |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blindness | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure diastolic increased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 14 | 14 | 9 | 9 | 5 | 5 |
| Body temperature decreased | 1 | 1 | 1 | 1 | | |
| Body temperature fluctuation | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 33 | 33 | 30 | 30 | 3 | 3 |
| Bradycardia | 3 | 3 | | | 3 | 3 |

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Gender

FEMALE

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|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Brain oedema | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Bronchial disorder | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 23 | 23 | 9 | 9 | 14 | 14 |
| Burning sensation | | 2 | | | | 2 |
| Cellulitis | 8 | 8 | | | 8 | 8 |
| Chest discomfort | 7 | 7 | 6 | 6 | 1 | 1 |
| Chest pain | 31 | 32 | 27 | 28 | 4 | 4 |
| Chills | 160 | 165 | 141 | 146 | 19 | 19 |
| Colitis | 1 | 1 | 1 | 1 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Conjunctival hyperaemia | 1 | 1 | 1 | 1 | | |
| Conjunctivitis | 3 | 3 | 3 | 3 | | |
| Cough | 103 | 103 | 89 | 89 | 14 | 14 |
| COVID-19 | 6 | 8 | 1 | 2 | 5 | 6 |
| COVID-19 pneumonia | | 1 | | | | 1 |
| Crying | 8 | 8 | 7 | 7 | 1 | 1 |
| Cyanosis | 1 | 2 | 1 | 2 | | |
| Deafness | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Decreased activity | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 26 | 26 | 23 | 23 | 3 | 3 |
| Demyelination | 1 | 3 | | | 1 | 3 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Dermatosis | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 45 | 46 | 37 | 38 | 8 | 8 |
| Diplegia | 1 | 1 | | | 1 | 1 |
| Discharge | 1 | 1 | 1 | 1 | | |
| Discomfort | 8 | 10 | 6 | 8 | 2 | 2 |
| Disease recurrence | 1 | 1 | 1 | 1 | | |
| Disorientation | 3 | 3 | 2 | 2 | 1 | 1 |
| Disseminated Bacillus Calmette-Guerin infection | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

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|--------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | 193 | 197 | 164 | 168 | 29 | 29 |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 4 | 6 | | | 4 | 6 |
| Dry mouth | 5 | 5 | 3 | 3 | 2 | 2 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dysarthria | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 8 | 8 | 5 | 5 | 3 | 3 |
| Dysphagia | 6 | 6 | 5 | 5 | 1 | 1 |
| Dysphonia | 2 | 2 | 2 | 2 | | |
| Dyspnoea | 248 | 250 | 179 | 181 | 69 | 69 |
| Dyspnoea exertional | 4 | 4 | 4 | 4 | | |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Ear disorder | 1 | 1 | 1 | 1 | | |
| Ear infection | 2 | 2 | 2 | 2 | | |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Encephalitis post immunisation | | 1 | | | | 1 |
| Epigastric discomfort | | 1 | | 1 | | |
| Epistaxis | 2 | 2 | 2 | 2 | | |
| Erythema | 48 | 48 | 43 | 43 | 5 | 5 |
| Expired product administered | 1 | 1 | 1 | 1 | | |
| External ear inflammation | 1 | 1 | 1 | 1 | | |
| Eye disorder | 1 | 1 | 1 | 1 | | |
| Eye inflammation | | 1 | | 1 | | |
| Eye injury | 8 | 8 | 6 | 6 | 2 | 2 |
| Eye irritation | 3 | 3 | 3 | 3 | | |
| Eyelid oedema | 3 | 3 | 3 | 3 | | |
| Eyelid rash | 1 | 1 | 1 | 1 | | |
| Eye pain | 7 | 7 | 7 | 7 | | |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Eye swelling | | 2 | | 1 | | 1 |
| Face oedema | 2 | 3 | 2 | 3 | | |
| Facial paralysis | 3 | 3 | | | 3 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Fatigue | 170 | 172 |
| Febrile convulsion | 3 | 3 |
| Feeling abnormal | 2 | 2 |
| Feeling cold | 1 | 2 |
| Feeling hot | 5 | 6 |
| Feeling of despair | 1 | 1 |
| Flushing | 2 | 2 |
| Foreign body sensation in eyes | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Gastrointestinal motility disorder | | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| General physical condition abnormal | 1 | 1 |
| General physical health deterioration | 4 | 4 |
| Guillain-Barre syndrome | 2 | 2 |
| Haematochezia | 2 | 2 |
| Haemoptysis | 1 | 1 |
| Haemorrhage | 3 | 3 |
| Headache | 292 | 304 |
| Head discomfort | 2 | 2 |
| Heart rate decreased | 1 | 1 |
| Heart rate increased | 5 | 5 |
| Hemiparaesthesia | 1 | 1 |
| Hemiparesis | 2 | 2 |
| Hemiplegia | 2 | 2 |
| Hepatic pain | 1 | 1 |
| Hot flush | 1 | 1 |
| Hunger | 1 | 1 |
| Hyperaesthesia | 2 | 2 |
| Hyperhidrosis | 9 | 9 |
| Hyperpyrexia | 1 | 1 |
| Hypersensitivity | 18 | 19 |
| Hypersomnia | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 152 | 154 | 18 | 18 |
| 1 | 1 | 2 | 2 |
| | | 2 | 2 |
| 1 | 2 | | |
| 2 | 3 | 3 | 3 |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | | |
| | | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 3 | 3 |
| 256 | 266 | 36 | 38 |
| 2 | 2 | | |
| 1 | 1 | | |
| 4 | 4 | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 6 | 6 | 3 | 3 |
| | | 1 | 1 |
| 14 | 15 | 4 | 4 |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypertension | 29 | 29 | 18 | 18 | 11 | 11 |
| Hypertensive crisis | 15 | 15 | | | 15 | 15 |
| Hyperthermia | 2 | 2 | 2 | 2 | | |
| Hypoaesthesia | 11 | 13 | 5 | 6 | 6 | 7 |
| Hypoaesthesia oral | 6 | 6 | 5 | 5 | 1 | 1 |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Hypotension | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypothermia | 3 | 3 | | | 3 | 3 |
| Hypoventilation | 1 | 1 | | | 1 | 1 |
| Hypovolaemic shock | 2 | 2 | | | 2 | 2 |
| Inappropriate schedule of product administration | 1 | 2 | 1 | 2 | | |
| Induration | 33 | 33 | 31 | 31 | 2 | 2 |
| Inflammation | 40 | 41 | 35 | 35 | 5 | 6 |
| Influenza | 2 | 2 | 2 | 2 | | |
| Injection site pain | 1 | 1 | 1 | 1 | | |
| Intussusception | 2 | 2 | | | 2 | 2 |
| Irritability | 16 | 16 | 14 | 14 | 2 | 2 |
| Irritability postvaccinal | 1 | 1 | 1 | 1 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Lacrimation increased | 3 | 3 | 3 | 3 | | |
| Laryngeal oedema | 2 | 2 | | | 2 | 2 |
| Laryngospasm | 2 | 2 | | | 2 | 2 |
| Lethargy | 1 | 1 | | | 1 | 1 |
| Limb discomfort | 1 | 1 | | | 1 | 1 |
| Lip oedema | 2 | 3 | 2 | 3 | | |
| Localised oedema | 1 | 1 | 1 | 1 | | |
| Local reaction | 17 | 17 | 16 | 16 | 1 | 1 |
| Loss of consciousness | 4 | 5 | | | 4 | 5 |
| Loss of personal independence in daily activities | | 1 | | | | 1 |
| Lymphadenopathy | 26 | 26 | 23 | 23 | 3 | 3 |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 18 | 18 | 11 | 11 |
| | | 15 | 15 |
| 2 | 2 | | |
| 5 | 6 | 6 | 7 |
| 5 | 5 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 2 | | |
| 31 | 31 | 2 | 2 |
| 35 | 35 | 5 | 6 |
| 2 | 2 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 14 | 14 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 3 | | |
| 1 | 1 | | |
| 16 | 16 | 1 | 1 |
| | | 4 | 5 |
| | | | 1 |
| 23 | 23 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-------------------------------------|--|--|
| Malaise | 21 | 21 |
| Mass | 1 | 1 |
| Maternal exposure during pregnancy | 5 | 6 |
| Mechanical urticaria | | 1 |
| Metamorphopsia | 1 | 1 |
| Metrorrhagia | 1 | 1 |
| Mobility decreased | 1 | 2 |
| Mononeuropathy | 1 | 2 |
| Mouth haemorrhage | 1 | 1 |
| Muscle contractions involuntary | 2 | 3 |
| Muscle contracture | | 1 |
| Muscle rigidity | 1 | 1 |
| Muscle spasms | 1 | 3 |
| Muscle spasticity | | 1 |
| Muscular weakness | 7 | 8 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 182 | 188 |
| Myelitis | 1 | 1 |
| Myelitis transverse | | 1 |
| Nasal congestion | 5 | 6 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 140 | 143 |
| Neck pain | 2 | 2 |
| Nerve degeneration | | 1 |
| Nervousness | 2 | 2 |
| Neuritis | | 2 |
| Neuropathy peripheral | 1 | 1 |
| Nodule | 40 | 40 |
| Obstructive airways disorder | 1 | 1 |
| Occupational exposure to SARS-CoV-2 | 1 | 1 |
| Odynophagia | 19 | 19 |
| Oedema | 68 | 68 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 18 | 18 | 3 | 3 |
| 1 | 1 | | |
| 5 | 6 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | 1 |
| | | | 1 |
| 4 | 5 | 3 | 3 |
| 1 | 1 | | |
| 164 | 169 | 18 | 19 |
| | | 1 | 1 |
| | | | 1 |
| 5 | 6 | | |
| 1 | 1 | | |
| 125 | 126 | 15 | 17 |
| 2 | 2 | | |
| | | | 1 |
| 2 | 2 | | |
| | | | 2 |
| | | 1 | 1 |
| 36 | 36 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 15 | 15 | 4 | 4 |
| 56 | 56 | 12 | 12 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oedema peripheral | 3 | 3 | 3 | 3 | | |
| Off label use | 4 | 6 | 4 | 6 | | |
| Oral dysaesthesia | 1 | 1 | 1 | 1 | | |
| Oropharyngeal discomfort | 4 | 4 | 2 | 2 | 2 | 2 |
| Oropharyngeal pain | 116 | 117 | 107 | 108 | 9 | 9 |
| Otitis externa | 1 | 1 | 1 | 1 | | |
| Otitis media acute | 1 | 1 | 1 | 1 | | |
| Oxygen saturation abnormal | 4 | 4 | 2 | 2 | 2 | 2 |
| Oxygen saturation decreased | 20 | 20 | 11 | 11 | 9 | 9 |
| Pain | 197 | 199 | 177 | 179 | 20 | 20 |
| Pain in extremity | 14 | 15 | 12 | 13 | 2 | 2 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Pallor | 2 | 2 | 2 | 2 | | |
| Palpitations | 3 | 3 | 3 | 3 | | |
| Papule | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 36 | 39 | 27 | 28 | 9 | 11 |
| Paraesthesia oral | 6 | 6 | 5 | 5 | 1 | 1 |
| Paralysis | 4 | 5 | | | 4 | 5 |
| Peripheral coldness | 2 | 2 | 2 | 2 | | |
| Peripheral motor neuropathy | | 1 | | | | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Peroneal nerve injury | | 1 | | | | 1 |
| Petechiae | 2 | 2 | | | 2 | 2 |
| Pharyngeal disorder | 1 | 1 | 1 | 1 | | |
| Pharyngeal hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Pharyngeal inflammation | 2 | 2 | | | 2 | 2 |
| Pharyngeal oedema | 2 | 2 | | | 2 | 2 |
| Pharyngeal paraesthesia | 1 | 1 | | | 1 | 1 |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Photopsia | 1 | 1 | 1 | 1 | | |
| Pneumonia | 7 | 7 | | | 7 | 7 |
| Presyncope | 1 | 1 | 1 | 1 | | |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 3 | | |
| 4 | 6 | | |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| 107 | 108 | 9 | 9 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| 11 | 11 | 9 | 9 |
| 177 | 179 | 20 | 20 |
| 12 | 13 | 2 | 2 |
| 1 | 1 | | |
| 2 | 2 | | |
| 3 | 3 | | |
| 1 | 1 | | |
| 27 | 28 | 9 | 11 |
| 5 | 5 | 1 | 1 |
| | | 4 | 5 |
| 2 | 2 | | |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 7 | 7 |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Product use issue | 4 | 6 | 4 | 6 | | |
| Prurigo | 1 | 1 | 1 | 1 | | |
| Pruritus | 50 | 53 | 42 | 44 | 8 | 9 |
| Purpura | 2 | 2 | 1 | 1 | 1 | 1 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 118 | 123 | 107 | 112 | 11 | 11 |
| Radiculopathy | | 2 | | | | 2 |
| Rales | 1 | 1 | 1 | 1 | | |
| Rash | 49 | 54 | 37 | 40 | 12 | 14 |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Rash maculo-papular | 2 | 2 | 2 | 2 | | |
| Raynaud's phenomenon | 1 | 1 | 1 | 1 | | |
| Respiratory disorder | 1 | 1 | 1 | 1 | | |
| Respiratory distress | 244 | 246 | | | 244 | 246 |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 81 | 81 | 71 | 71 | 10 | 10 |
| Sacroiliitis | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 2 | 2 | 2 | 2 | | |
| Sciatica | | 1 | | | | 1 |
| Sciatic nerve neuropathy | | 1 | | | | 1 |
| Secretion discharge | 1 | 1 | 1 | 1 | | |
| Seizure | 12 | 13 | | | 12 | 13 |
| Sensation of foreign body | 3 | 3 | 2 | 2 | 1 | 1 |
| Sensitisation | 1 | 1 | 1 | 1 | | |
| Sensitive skin | 119 | 119 | 106 | 106 | 13 | 13 |
| Sensory disturbance | 1 | 1 | 1 | 1 | | |
| Sensory loss | | 1 | | | | 1 |
| Shock | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Skin disorder | 1 | 1 | 1 | 1 | | |
| Skin haemorrhage | 1 | 1 | 1 | 1 | | |

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 4 | 6 | | |
| 1 | 1 | | |
| 42 | 44 | 8 | 9 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 107 | 112 | 11 | 11 |
| | | | 2 |
| 1 | 1 | | |
| 37 | 40 | 12 | 14 |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 244 | 246 |
| 1 | 1 | | |
| 71 | 71 | 10 | 10 |
| | | | 1 |
| 2 | 2 | | |
| | | | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 12 | 13 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| 106 | 106 | 13 | 13 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Skin lesion | 1 | 1 |
| Skin swelling | 1 | 1 |
| Sleep inertia | 1 | 1 |
| Slow response to stimuli | | 1 |
| Sneezing | | 1 |
| Somnolence | 4 | 5 |
| Speech disorder | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Suspected COVID-19 | 3 | 3 |
| Sweating fever | 1 | 1 |
| Swelling | 2 | 2 |
| Swelling face | 1 | 1 |
| Syncope | 21 | 21 |
| Systemic lupus erythematosus | 1 | 1 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 156 | 156 |
| Tachypnoea | 3 | 3 |
| Tenderness | 3 | 3 |
| Tension headache | 1 | 1 |
| Thirst | 1 | 1 |
| Throat irritation | 6 | 8 |
| Throat tightness | 1 | 1 |
| Thrombocytopenic purpura | 1 | 1 |
| Tinnitus | 3 | 3 |
| Tongue oedema | 3 | 3 |
| Toothache | 1 | 1 |
| Transaminases increased | 1 | 1 |
| Tremor | 5 | 5 |
| Tympanic membrane disorder | 1 | 1 |
| Upper airway obstruction | 1 | 1 |
| Urinary tract infection | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| 4 | 5 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 21 | 21 |
| | | 1 | 1 |
| 1 | 1 | | |
| 130 | 130 | 26 | 26 |
| 1 | 1 | 2 | 2 |
| 3 | 3 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 4 | 6 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 5 | 5 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urticaria | 3 | 3 | 3 | 3 | | |
| Vaccination site cellulitis | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 4 | 4 | 3 | 3 | 1 | 1 |
| Vaccination site hyperaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site hypersensitivity | 17 | 17 | 17 | 17 | | |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 12 | 12 | 9 | 9 | 3 | 3 |
| Vaccination site inflammation | 5 | 5 | 5 | 5 | | |
| Vaccination site joint pain | | 1 | | 1 | | |
| Vaccination site movement impairment | 2 | 2 | 2 | 2 | | |
| Vaccination site nodule | 6 | 6 | 5 | 5 | 1 | 1 |
| Vaccination site oedema | 7 | 7 | 6 | 6 | 1 | 1 |
| Vaccination site pain | 74 | 80 | 71 | 77 | 3 | 3 |
| Vaccination site paraesthesia | 3 | 3 | 3 | 3 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site reaction | 8 | 8 | 7 | 7 | 1 | 1 |
| Vaccination site warmth | 7 | 8 | 7 | 8 | | |
| Vertigo | 7 | 7 | 5 | 5 | 2 | 2 |
| Vision blurred | 10 | 10 | 9 | 9 | 1 | 1 |
| Vomiting | 49 | 49 | 43 | 43 | 6 | 6 |
| | 4,404 | 4,552 | 3425 | 3522 | 979 | 1030 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 11 | 11 | 10 | 10 | 1 | 1 |
| Affect lability | 1 | 1 | 1 | 1 | | |
| Ageusia | 2 | 3 | 2 | 3 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anaphylactic shock | 4 | 4 | | | 4 | 4 |
| Anosmia | 3 | 4 | 3 | 4 | | |
| Anxiety | 4 | 4 | 1 | 1 | 3 | 3 |
| Arthralgia | 42 | 46 | 36 | 40 | 6 | 6 |
| Asthenia | 48 | 50 | 41 | 43 | 7 | 7 |
| Atypical pneumonia | 1 | 1 | | | 1 | 1 |
| Aura | 1 | 1 | | | 1 | 1 |
| Axillary mass | 1 | 1 | 1 | 1 | | |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Back pain | 2 | 2 | 2 | 2 | | |
| Blood glucose decreased | | 1 | | | | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 9 | 9 | 6 | 6 | 3 | 3 |
| Bowel movement irregularity | 1 | 1 | 1 | 1 | | |
| Bronchospasm | 4 | 4 | 3 | 3 | 1 | 1 |
| Cellulitis | 2 | 2 | | | 2 | 2 |
| Chest pain | 5 | 5 | 5 | 5 | | |
| Chills | 41 | 42 | 33 | 34 | 8 | 8 |
| Choluria | 1 | 1 | | | 1 | 1 |
| Coagulation time prolonged | | 1 | | | | 1 |
| Cough | 19 | 20 | 15 | 16 | 4 | 4 |
| COVID-19 | 8 | 9 | 2 | 2 | 6 | 7 |
| COVID-19 pneumonia | 1 | 2 | | | 1 | 2 |
| Crying | 2 | 2 | 2 | 2 | | |
| Cyanosis | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 6 | 6 | 3 | 3 | 3 | 3 |
| Decreased immune responsiveness | 1 | 1 | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # | Cumulative Total # |
|---------------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Deficiency of bile secretion | 1 | 1 |
| Dehydration | 1 | 2 |
| Diarrhoea | 21 | 23 |
| Discomfort | 5 | 6 |
| Disease recurrence | 1 | 1 |
| Disorientation | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 46 | 46 |
| Drug ineffective | 6 | 9 |
| Dry mouth | 2 | 2 |
| Dysgeusia | 1 | 1 |
| Dyspnoea | 48 | 48 |
| Dysstasia | 1 | 1 |
| Ear discomfort | 2 | 2 |
| Ear pain | 2 | 2 |
| Electrolyte imbalance | 1 | 1 |
| Erythema | 6 | 6 |
| Eye injury | 2 | 2 |
| Eye irritation | 1 | 1 |
| Eye movement disorder | 1 | 1 |
| Eye pain | 1 | 1 |
| Facial paralysis | 1 | 1 |
| Fatigue | 40 | 43 |
| Febrile convulsion | 2 | 2 |
| Feeling cold | 1 | 1 |
| Gastrointestinal disorder | | 1 |
| Generalised tonic-clonic seizure | 2 | 2 |
| General physical health deterioration | 2 | 2 |
| Haematochezia | 1 | 1 |
| Headache | 73 | 77 |
| Hot flush | 1 | 1 |
| Hyperbilirubinaemia | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 2 |
| 19 | 20 | 2 | 3 |
| 5 | 6 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 37 | 37 | 9 | 9 |
| | | 6 | 9 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 32 | 32 | 16 | 16 |
| | | 1 | 1 |
| 2 | 2 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 5 | 5 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 34 | 37 | 6 | 6 |
| 2 | 2 | | |
| 1 | 1 | | |
| | | | 1 |
| | | 2 | 2 |
| 2 | 2 | | |
| | | 1 | 1 |
| 63 | 67 | 10 | 10 |
| 1 | 1 | | |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyperhidrosis | 4 | 4 |
| Hypernatraemia | | 1 |
| Hypersensitivity | 4 | 4 |
| Hypertension | 6 | 6 |
| Hypertensive crisis | 2 | 2 |
| Hyperthermia | 1 | 1 |
| Hypoaesthesia | 4 | 5 |
| Hyposmia | 1 | 1 |
| Hypotension | 2 | 2 |
| Inappropriate schedule of product administration | 1 | 1 |
| Induration | 9 | 9 |
| Inflammation | 5 | 5 |
| Irritability | 4 | 4 |
| Irritability postvaccinal | 1 | 1 |
| Jaundice | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Lateropulsion | 1 | 1 |
| Local reaction | 10 | 10 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 5 | 6 |
| Lymphopenia | | 1 |
| Malaise | 7 | 7 |
| Masticatory pain | | 1 |
| Mobility decreased | 2 | 2 |
| Muscle spasms | | 1 |
| Muscular weakness | 2 | 2 |
| Myalgia | 51 | 57 |
| Nasal congestion | 1 | 1 |
| Nasopharyngitis | 2 | 2 |
| Nausea | 37 | 41 |
| Nodule | 10 | 10 |
| Ocular discomfort | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 4 | | |
| | | | 1 |
| 2 | 2 | 2 | 2 |
| 2 | 2 | 4 | 4 |
| | | 2 | 2 |
| 1 | 1 | | |
| 3 | 4 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 7 | 7 | 2 | 2 |
| 3 | 3 | 2 | 2 |
| 3 | 3 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 8 | 8 | 2 | 2 |
| | | 1 | 1 |
| 4 | 5 | 1 | 1 |
| | | | 1 |
| 5 | 5 | 2 | 2 |
| | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 44 | 50 | 7 | 7 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 29 | 32 | 8 | 9 |
| 8 | 8 | 2 | 2 |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Ocular hyperaemia | 1 | 1 |
| Odynophagia | 5 | 5 |
| Oedema | 10 | 10 |
| Oropharyngeal discomfort | 2 | 2 |
| Oropharyngeal pain | 15 | 15 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 48 | 49 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 3 | 3 |
| Pain in jaw | 1 | 1 |
| Pain of skin | 1 | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | 5 | 7 |
| Paralysis | 4 | 4 |
| Parotid gland enlargement | | 1 |
| Parotitis | | 1 |
| Pharyngitis | 1 | 1 |
| Pneumonia | 1 | 1 |
| Pruritus | 9 | 9 |
| Pyrexia | 44 | 51 |
| Rash | 10 | 10 |
| Rash erythematous | 1 | 1 |
| Respiratory distress | 47 | 47 |
| Respiratory failure | 1 | 1 |
| Rhinorrhoea | 19 | 19 |
| Salivary hypersecretion | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| SARS-CoV-2 test positive | 2 | 3 |
| Seizure | 4 | 4 |
| Sensitisation | 1 | 1 |
| Sensitive skin | 20 | 20 |
| Shock | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 4 | 4 | 1 | 1 |
| 6 | 6 | 4 | 4 |
| 1 | 1 | 1 | 1 |
| 12 | 12 | 3 | 3 |
| 1 | 1 | | |
| 41 | 42 | 7 | 7 |
| 1 | 1 | | |
| 3 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 6 | 1 | 1 |
| | | 4 | 4 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 7 | 7 | 2 | 2 |
| 36 | 42 | 8 | 9 |
| 5 | 5 | 5 | 5 |
| | | 1 | 1 |
| | | 47 | 47 |
| | | 1 | 1 |
| 17 | 17 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 2 |
| | | 4 | 4 |
| 1 | 1 | | |
| 17 | 17 | 3 | 3 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Somnolence | 3 | 3 | 3 | 3 | | |
| Stevens-Johnson syndrome | 1 | 1 | | | 1 | 1 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Syncope | 6 | 6 | | | 6 | 6 |
| Tachycardia | 28 | 29 | 21 | 22 | 7 | 7 |
| Tachypnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Tenderness | 1 | 1 | 1 | 1 | | |
| Thirst | 1 | 1 | 1 | 1 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Transaminases increased | 1 | 1 | | | 1 | 1 |
| Traumatic lung injury | 2 | 2 | 2 | 2 | | |
| Tremor | 2 | 2 | 2 | 2 | | |
| Vaccination site discomfort | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site hypersensitivity | 1 | 2 | 1 | 2 | | |
| Vaccination site induration | 2 | 2 | 2 | 2 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site nodule | 2 | 2 | 2 | 2 | | |
| Vaccination site pain | 18 | 22 | 16 | 20 | 2 | 2 |
| Vaccination site reaction | 2 | 3 | 2 | 3 | | |
| Vertigo | 2 | 3 | 1 | 2 | 1 | 1 |
| Vision blurred | 2 | 2 | 1 | 1 | 1 | 1 |
| Vomiting | 15 | 16 | 11 | 11 | 4 | 5 |
| Wheezing | 2 | 2 | 1 | 1 | 1 | 1 |
| White blood cell count increased | | 1 | | | | 1 |
| | 1,037 | 1,105 | 750 | 801 | 287 | 304 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Abdominal pain | | 3 | | 3 | | | |
| Allergy to vaccine | | 3 | | 3 | | | |
| Anaphylactoid reaction | 1 | 1 | | | 1 | | 1 |
| Arthralgia | | 24 | | 24 | | | |
| Asthenia | 1 | 21 | 1 | 20 | | | 1 |
| Back pain | | 1 | | 1 | | | |
| Blood pressure increased | | 1 | | | | | 1 |
| Body temperature increased | | 4 | | 4 | | | |
| Chest discomfort | | 1 | | 1 | | | |
| Chest pain | 1 | 1 | | | 1 | | 1 |
| Chills | | 9 | | 9 | | | |
| Cough | | 8 | | 8 | | | |
| COVID-19 | | 3 | | | | | 3 |
| COVID-19 pneumonia | | 1 | | | | | 1 |
| Decreased appetite | | 2 | | 2 | | | |
| Diarrhoea | | 3 | | 3 | | | |
| Discomfort | | 4 | | 4 | | | |
| Dizziness | | 14 | | 13 | | | 1 |
| Drug ineffective | | 5 | | | | | 5 |
| Dysgeusia | | 2 | | 2 | | | |
| Dyspnoea | 1 | 7 | | 3 | 1 | | 4 |
| Ear pain | | 1 | | 1 | | | |
| Epilepsy | | 1 | | | | | 1 |
| Erythema | | 2 | | 2 | | | |
| Eye pain | | 1 | | 1 | | | |
| Fatigue | | 1 | | 1 | | | |
| Feeling hot | | 1 | | 1 | | | |
| Headache | | 39 | | 38 | | | 1 |
| Hot flush | | 1 | | 1 | | | |
| Hyperhidrosis | | 1 | | 1 | | | |
| Hypersensitivity | | 2 | | 2 | | | |
| Hypertension | | 2 | | 1 | | | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Hypertensive crisis | | 2 |
| Hypoaesthesia | 1 | 1 |
| Incomplete course of vaccination | 1 | 1 |
| Inflammation | | 1 |
| Laryngospasm | | 1 |
| Local reaction | | 2 |
| Lymphadenopathy | | 2 |
| Mobility decreased | | 2 |
| Myalgia | | 21 |
| Nausea | | 10 |
| Neck pain | | 1 |
| Nervousness | 1 | 1 |
| Nodule | | 1 |
| Oedema | | 7 |
| Oropharyngeal pain | | 2 |
| Oxygen saturation decreased | | 1 |
| Pain | 1 | 12 |
| Pain in extremity | | 2 |
| Palpitations | | 1 |
| Paraesthesia | | 4 |
| Paraesthesia oral | | 2 |
| Pelvic pain | | 1 |
| Pneumonia | | 3 |
| Pruritus | | 2 |
| Pyrexia | | 19 |
| Rash | | 9 |
| Rash maculo-papular | | 1 |
| Rhinorrhoea | | 6 |
| Seizure | | 5 |
| Sensory loss | | 1 |
| Suspected COVID-19 | | 1 |
| Swelling | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 2 | | |
| | 2 | | |
| | 21 | | |
| | 10 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 7 | | |
| | 2 | | |
| | 1 | | 1 |
| 1 | 11 | | 1 |
| | 2 | | |
| | 1 | | |
| | 3 | | 1 |
| | 1 | | 1 |
| | 1 | | |
| | 2 | | |
| | 19 | | |
| | 8 | | 1 |
| | 1 | | |
| | 6 | | |
| | | | 5 |
| | 1 | | |
| | | | 1 |
| | 1 | | |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Syncope | | 2 | | | | 2 |
| Tachycardia | 1 | 11 | | 9 | 1 | 2 |
| Vaccination site erythema | | 2 | | 2 | | |
| Vaccination site hyperaesthesia | | 1 | | 1 | | |
| Vaccination site induration | | 2 | | 2 | | |
| Vaccination site inflammation | | 1 | | 1 | | |
| Vaccination site nodule | | 3 | | 3 | | |
| Vaccination site oedema | | 1 | | 1 | | |
| Vaccination site pain | | 31 | | 30 | | 1 |
| Vaccination site rash | | 1 | | 1 | | |
| Vomiting | | 3 | | 3 | | |
| | 9 | 354 | 5 | 312 | 4 | 42 |

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Country Where Event Occurred

NETHERLANDS

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 2 | 1 | 2 | | |
| Allergy to vaccine | | 1 | | | | 1 |
| Anaphylactic reaction | 8 | 10 | | | 8 | 10 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 4 | 5 | | | 4 | 5 |
| Anxiety | | 1 | | | | 1 |
| Apallic syndrome | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 13 | 13 | 13 | 13 | | |
| Atrial f brillation | 2 | 2 | | | 2 | 2 |
| Axillary pain | | 1 | | 1 | | |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Basilar artery thrombosis | 1 | 1 | | | 1 | 1 |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | 2 | 2 | | |
| Body temperature increased | 5 | 5 | 3 | 3 | 2 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Bundle branch block right | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 3 | 3 | | | 3 | 3 |
| Cerebral infarction | 2 | 2 | | | 2 | 2 |
| Cerebral ischaemia | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 4 | 4 | | | 4 | 4 |
| Chest discomfort | 1 | 2 | 1 | 1 | | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 28 | 30 | 25 | 26 | 3 | 4 |
| Choking | 1 | 1 | | | 1 | 1 |
| Choking sensation | 1 | 2 | | | 1 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Cold sweat | 2 | 2 |
| Condition aggravated | 1 | 1 |
| Confusional state | 1 | 1 |
| Cough | 4 | 5 |
| COVID-19 | 2 | 2 |
| Cystitis | 1 | 1 |
| Death | 4 | 4 |
| Decreased appetite | 1 | 1 |
| Dehydration | 1 | 1 |
| Depressed level of consciousness | 2 | 2 |
| Derealisation | 1 | 1 |
| Diarrhoea | 1 | 2 |
| Diplopia | 1 | 1 |
| Disorganised speech | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 10 | 12 |
| Drug ineffective | 1 | 1 |
| Dysarthria | 1 | 1 |
| Dysphagia | 4 | 5 |
| Dyspnoea | 15 | 15 |
| Dyspnoea exertional | 1 | 1 |
| Ear pain | 1 | 1 |
| Electrocardiogram ST segment abnormal | 1 | 1 |
| Epilepsy | 6 | 6 |
| Erythema | 1 | 3 |
| Exposure to SARS-CoV-2 | 1 | 1 |
| Extensive swelling of vaccinated limb | 2 | 2 |
| Facial paralysis | 2 | 2 |
| Faeces discoloured | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 26 | 27 |
| Feeding disorder | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 3 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 7 | 8 | 3 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 3 | 4 |
| 4 | 4 | 11 | 11 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 6 | 6 |
| | 1 | 1 | 2 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 20 | 21 | 6 | 6 |
| 1 | 1 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Feeling abnormal | 1 | 1 |
| Feeling cold | 1 | 1 |
| Feeling drunk | 1 | 1 |
| Fluid retention | 1 | 1 |
| Flushing | 1 | 1 |
| Gaze palsy | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Hallucination | 1 | 1 |
| Headache | 37 | 41 |
| Head discomfort | | 1 |
| Heart rate decreased | 1 | 1 |
| Hemianaesthesia | 1 | 1 |
| Hemiparesis | 1 | 1 |
| Hemiplegia | 1 | 1 |
| Hepatic failure | 1 | 1 |
| Herpes ophthalmic | 1 | 1 |
| Hot flush | 1 | 1 |
| Hyperacusis | 1 | 1 |
| Hyperhidrosis | 2 | 2 |
| Hyperpyrexia | 11 | 11 |
| Hypersensitivity | 5 | 5 |
| Hypertension | 2 | 2 |
| Hypertensive crisis | 1 | 1 |
| Hyperventilation | 1 | 2 |
| Hyponatraemia | 1 | 1 |
| Hypotension | 3 | 3 |
| Incorrect route of product administration | | 1 |
| Influenza like illness | | 1 |
| Injection site erythema | 2 | 2 |
| Injection site inflammation | 1 | 1 |
| Injection site pain | 2 | 2 |
| Injection site pruritus | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 34 | 38 | 3 | 3 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 11 | 11 |
| | | 5 | 5 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | | |
| | | | |
| 2 | 2 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Injection site swelling | 2 | 2 | 2 | 2 | | |
| Injection site warmth | 2 | 2 | 2 | 2 | | |
| Ischaemic cerebral infarction | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 3 | 3 | | | 3 | 3 |
| Lymphadenopathy | 7 | 7 | 7 | 7 | | |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 48 | 50 | 34 | 35 | 14 | 15 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Mood altered | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle twitching | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 2 | 2 | 2 | 2 | | |
| Musculoskeletal disorder | 1 | 1 | 1 | 1 | | |
| Myalgia | 30 | 33 | 28 | 31 | 2 | 2 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 1 | 1 | | | 1 | 1 |
| Nausea | 33 | 35 | 26 | 28 | 7 | 7 |
| Nystagmus | 1 | 1 | 1 | 1 | | |
| Occupational exposure to product | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Oral pruritus | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 2 | 1 | 2 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 4 | 4 | 4 | 4 | | |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pallor | 3 | 3 | | | 3 | 3 |
| Palpitations | 2 | 3 | 1 | 1 | 1 | 2 |
| Paraesthesia | | 1 | | | | 1 |
| Paraesthesia oral | 2 | 3 | 1 | 2 | 1 | 1 |
| Peripheral coldness | 2 | 3 | 1 | 2 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Pharyngeal oedema | | 1 |
| Pharyngeal paraesthesia | 1 | 1 |
| Pharyngeal swelling | 5 | 6 |
| Pneumonia aspiration | 1 | 1 |
| Polyuria | 1 | 1 |
| Postmenopausal haemorrhage | 1 | 1 |
| Presyncope | 2 | 2 |
| Pruritus | 2 | 3 |
| Psychotic symptom | 1 | 1 |
| Pulmonary oedema | 1 | 1 |
| Pupillary disorder | 1 | 1 |
| Pyrexia | 15 | 15 |
| Rash | 1 | 2 |
| Rash maculo-papular | | 1 |
| Respiration abnormal | 1 | 1 |
| Retching | 1 | 1 |
| Rhinitis | 1 | 1 |
| Seizure | 2 | 2 |
| Sialoadenitis | 2 | 2 |
| Sinus tachycardia | 1 | 1 |
| Sneezing | | 1 |
| Somnolence | 1 | 1 |
| Speech disorder | 1 | 1 |
| Status epilepticus | 1 | 1 |
| Sudden cardiac death | 1 | 1 |
| Sudden death | 2 | 2 |
| Sudden hearing loss | 4 | 4 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling face | 3 | 4 |
| Swelling of eyelid | 1 | 1 |
| Swollen tongue | 3 | 3 |
| Syncope | 13 | 13 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 6 | 6 | 9 | 9 |
| | | 1 | 2 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 2 | 2 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 4 | 4 |
| | | 1 | 1 |
| 1 | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | 12 | 12 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Throat tightness | 2 | 2 | | | 2 | 2 |
| Thrombosis | 2 | 2 | | | 2 | 2 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tongue disorder | 2 | 2 | | | 2 | 2 |
| Tongue oedema | | 1 | | | | 1 |
| Torticollis | 1 | 1 | 1 | 1 | | |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 3 | 3 | 3 | | |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urticaria | 7 | 9 | 4 | 5 | 3 | 4 |
| Vaccination site bruising | 2 | 2 | 2 | 2 | | |
| Vaccination site erythema | 6 | 7 | 6 | 7 | | |
| Vaccination site haematoma | 3 | 3 | 3 | 3 | | |
| Vaccination site inflammation | 11 | 12 | 11 | 12 | | |
| Vaccination site pain | 23 | 25 | 21 | 23 | 2 | 2 |
| Vaccination site pruritus | 1 | 2 | 1 | 2 | | |
| Vaccination site swelling | 8 | 9 | 8 | 9 | | |
| Vaccination site warmth | 10 | 11 | 10 | 11 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 4 | 5 | 3 | 4 | 1 | 1 |
| Weight decreased | 1 | 1 | | | 1 | 1 |
| | 600 | 657 | 362 | 397 | 238 | 260 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accommodation disorder | 1 | 1 | 1 | 1 | | |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 2 | 2 | 2 | | |
| Cardiac disorder | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 2 | 2 | | | 2 | 2 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cerebral haemorrhage | 2 | 2 | | | 2 | 2 |
| Chills | 3 | 3 | 1 | 1 | 2 | 2 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Confusional state | 2 | 2 | 1 | 1 | 1 | 1 |
| Conjunctival oedema | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Deafness neurosensory | 1 | 1 | | | 1 | 1 |
| Death | 3 | 3 | | | 3 | 3 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Epilepsy | 4 | 4 | | | 4 | 4 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 7 | 7 | 3 | 3 | 4 | 4 |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Gastrointestinal haemorrhage | 2 | 2 | | | 2 | 2 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 4 | 4 | 3 | 3 | 1 | 1 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |

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MALE

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|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hyperpyrexia | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hyperventilation | 1 | 1 | 1 | 1 | | |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Hypovolaemic shock | 1 | 1 | | | 1 | 1 |
| Ischaemic cerebral infarction | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Malaise | 11 | 11 | 4 | 4 | 7 | 7 |
| Migraine | 1 | 1 | | | 1 | 1 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Myalgia | 3 | 3 | 2 | 2 | 1 | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Nausea | 6 | 6 | 4 | 4 | 2 | 2 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 6 | 6 | | | 6 | 6 |
| Pain | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pituitary apoplexy | 1 | 1 | | | 1 | 1 |
| Pneumonia | 2 | 2 | | | 2 | 2 |
| Postictal state | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 6 | 6 | 1 | 1 | 5 | 5 |
| Rash | 2 | 2 | 2 | 2 | | |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Respiratory disorder | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Status epilepticus | 1 | 1 | | | 1 | 1 |
| Sudden death | 2 | 2 | | | 2 | 2 |
| Swelling face | 1 | 1 | | | 1 | 1 |

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Gender

MALE

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|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vestibular neuritis | 1 | 1 | | | 1 | 1 |
| Vision blurred | 2 | 2 | 2 | 2 | | |
| | 131 | 131 | 43 | 43 | 88 | 88 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Exposure via breast milk | | 1 | | 1 | | |
| Product label confusion | | 1 | | 1 | | |
| Product preparation error | | 1 | | 1 | | |
| | 2 | 6 | | 4 | 2 | 2 |

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Country Where Event Occurred
NORTHERN MARIANA ISLANDS

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | | 1 | | 1 |
| Chest discomfort | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Disorientation | | 1 | | 1 |
| Dizziness | | 1 | | 1 |
| Fatigue | | 1 | | 1 |
| Headache | | 1 | | 1 |
| Inappropriate schedule of product administration | 2 | 2 | 2 | 2 |
| Pain in extremity | | 1 | | 1 |
| Poor quality sleep | | 1 | | 1 |
| | 2 | 11 | 2 | 11 |

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Country Where Event Occurred
NORWAY

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Abdominal pain upper | 2 | 2 | 1 | 1 | 1 | 1 |
| Acute coronary syndrome | | 1 | | | | 1 |
| Acute kidney injury | | 1 | | | | 1 |
| Acute myocardial infarction | 2 | 3 | | | 2 | 3 |
| Altered state of consciousness | 5 | 5 | | | 5 | 5 |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 2 | | 1 | 1 | 1 |
| Apathy | | 1 | | | | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Apnoea | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Asthenia | 2 | 2 | 1 | 1 | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bedridden | 4 | 4 | | | 4 | 4 |
| Blepharospasm | | 1 | | 1 | | |
| Blood pressure decreased | 3 | 4 | 1 | 1 | 2 | 3 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature decreased | | 1 | | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| Bradycardia | 2 | 2 | | | 2 | 2 |
| Breast enlargement | 1 | 1 | 1 | 1 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Burning sensation | | 1 | | | | 1 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | | 1 | | | | 1 |
| Cardiovascular disorder | | 1 | | | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # | Cumulative Total # |
|----------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Cerebral haemorrhage | 1 | 2 |
| Cerebral infarction | 1 | 1 |
| Cerebrovascular accident | 5 | 6 |
| Cerebrovascular disorder | 1 | 1 |
| Chest discomfort | | 1 |
| Chest pain | 3 | 3 |
| Chills | 11 | 12 |
| Chronic kidney disease | 1 | 1 |
| Circulatory collapse | 1 | 1 |
| Cognitive disorder | 1 | 1 |
| Cold sweat | 3 | 6 |
| Communication disorder | 1 | 1 |
| Concomitant disease aggravated | | 1 |
| Concussion | 1 | 1 |
| Condition aggravated | | 1 |
| Confusional state | 9 | 11 |
| Coordination abnormal | | 1 |
| Coronary artery occlusion | 1 | 1 |
| Cough | 5 | 6 |
| C-reactive protein increased | 12 | 12 |
| Death | 12 | 17 |
| Decreased activity | 1 | 1 |
| Decreased appetite | 7 | 8 |
| Delirium | 1 | 1 |
| Depressed level of consciousness | 2 | 3 |
| Diarrhoea | 9 | 10 |
| Discomfort | 2 | 2 |
| Disease recurrence | 1 | 2 |
| Dizziness | 8 | 10 |
| Droling | 1 | 1 |
| Dry mouth | 1 | 1 |
| Dry skin | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 5 | 6 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | 2 | 2 |
| 8 | 9 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 4 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| 4 | 4 | 5 | 7 |
| | | | 1 |
| | | 1 | 1 |
| 4 | 4 | 1 | 2 |
| 2 | 2 | 10 | 10 |
| | | 12 | 17 |
| 1 | 1 | | |
| 2 | 2 | 5 | 6 |
| | | 1 | 1 |
| | | 2 | 3 |
| 8 | 8 | 1 | 2 |
| 2 | 2 | | |
| | | 1 | 2 |
| 5 | 6 | 3 | 4 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |

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FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Dysarthria | 2 | 2 |
| Dysgeusia | 2 | 2 |
| Dysphagia | 3 | 3 |
| Dysphonia | 2 | 2 |
| Dyspnoea | 19 | 23 |
| Ear discomfort | 2 | 2 |
| Ear pain | 1 | 1 |
| Ear swelling | 1 | 1 |
| Erythema | 1 | 1 |
| Eye haemorrhage | 2 | 2 |
| Eye pain | 1 | 1 |
| Facial paralysis | 1 | 1 |
| Facial paresis | 2 | 2 |
| Faeces discoloured | 1 | 1 |
| Fall | 6 | 6 |
| Fatigue | 37 | 41 |
| Feeling abnormal | 4 | 4 |
| Feeling cold | 1 | 1 |
| Feeling drunk | 1 | 1 |
| Feeling hot | 2 | 4 |
| Feeling of body temperature change | 1 | 1 |
| Femoral neck fracture | 1 | 1 |
| Flushing | | 1 |
| Food refusal | 1 | 1 |
| Fracture | 1 | 1 |
| Frostbite | 1 | 1 |
| Gastroenteritis | 1 | 1 |
| General physical health deterioration | 20 | 25 |
| Haematemesis | 1 | 1 |
| Haemoglobin decreased | 1 | 1 |
| Hallucination | 1 | 1 |
| Headache | 31 | 33 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| 2 | 2 | | |
| | | 3 | 3 |
| 2 | 2 | | |
| 7 | 7 | 12 | 16 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 5 | 5 |
| 30 | 32 | 7 | 9 |
| 3 | 3 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 3 | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 19 | 24 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 27 | 29 | 4 | 4 |

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|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Heart rate increased | 4 | 5 | 1 | 1 | 3 | 4 |
| Heart rate irregular | 1 | 2 | | 1 | 1 | 1 |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 3 | 4 | 2 | 2 | 1 | 2 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hyperventilation | | 2 | | 1 | | 1 |
| Hypoaesthesia | 2 | 2 | 2 | 2 | | |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 | | |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Hypotension | 4 | 5 | | | 4 | 5 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Increased bronchial secretion | 2 | 2 | 1 | 1 | 1 | 1 |
| Infection | 3 | 4 | | | 3 | 4 |
| Influenza | 2 | 2 | 2 | 2 | | |
| Influenza like illness | 1 | 2 | 1 | 1 | | 1 |
| Intracardiac thrombus | | 1 | | | | 1 |
| Intranasal hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Intranasal paraesthesia | 1 | 1 | 1 | 1 | | |
| Ischaemic stroke | 1 | 1 | | | 1 | 1 |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Local reaction | | 1 | | | | 1 |
| Loss of consciousness | 2 | 3 | | | 2 | 3 |
| Lower respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 10 | 13 | 9 | 10 | 1 | 3 |

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|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Malignant hypertension | | 1 | | | | 1 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Metastases to peritoneum | 1 | 1 | | | 1 | 1 |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Motor dysfunction | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 3 | 3 | 1 | 1 | 2 | 2 |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal stiffness | 4 | 4 | 4 | 4 | | |
| Myalgia | 12 | 12 | 10 | 10 | 2 | 2 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Nausea | 22 | 24 | 17 | 18 | 5 | 6 |
| Neck pain | 2 | 2 | 2 | 2 | | |
| Nitrite urine present | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 2 | 2 | 1 | 1 | 1 | 1 |
| Oedema peripheral | 2 | 2 | 1 | 1 | 1 | 1 |
| Oropharyngeal pain | 7 | 7 | 5 | 5 | 2 | 2 |
| Oxygen saturation decreased | 4 | 6 | | | 4 | 6 |
| Pain | 6 | 6 | 4 | 4 | 2 | 2 |
| Pain in extremity | 3 | 4 | 2 | 3 | 1 | 1 |
| Pallor | 1 | 3 | | | 1 | 3 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Paranasal sinus discomfort | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pharyngeal swelling | 1 | 1 | 1 | 1 | | |
| Photophobia | 2 | 2 | 2 | 2 | | |
| Pneumonia | 4 | 5 | | | 4 | 5 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Presyncope | 3 | 3 | | | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 4 | 4 | | |
| 10 | 10 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 17 | 18 | 5 | 6 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 5 | 5 | 2 | 2 |
| | | 4 | 6 |
| 4 | 4 | 2 | 2 |
| 2 | 3 | 1 | 1 |
| | | 1 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 4 | 5 |
| | | 1 | 1 |
| | | 3 | 3 |

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|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Productive cough | 3 | 3 | | | 3 | 3 |
| Pruritus | 4 | 4 | 2 | 2 | 2 | 2 |
| Psychomotor hyperactivity | 1 | 1 | 1 | 1 | | |
| Pupil fixed | | 2 | | | | 2 |
| Pyrexia | 30 | 36 | 15 | 17 | 15 | 19 |
| Rales | 1 | 2 | 1 | 1 | | 1 |
| Rash | 3 | 3 | 2 | 2 | 1 | 1 |
| Rash pruritic | 2 | 2 | 1 | 1 | 1 | 1 |
| Respiratory a kalosis | | 1 | | | | 1 |
| Respiratory arrest | 1 | 2 | | | 1 | 2 |
| Respiratory failure | 2 | 2 | | | 2 | 2 |
| Respiratory rate decreased | 1 | 1 | 1 | 1 | | |
| Respiratory rate increased | 1 | 4 | 1 | 1 | | 3 |
| Restlessness | 3 | 4 | | 1 | 3 | 3 |
| Retching | | 1 | | 1 | | |
| Rhinorrhoea | 3 | 3 | 3 | 3 | | |
| Secretion discharge | 1 | 1 | | | 1 | 1 |
| Skin laceration | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Somnolence | 5 | 7 | 4 | 4 | 1 | 3 |
| Speech disorder | 3 | 3 | 2 | 2 | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Sudden death | 3 | 5 | | | 3 | 5 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Syncope | 5 | 7 | | | 5 | 7 |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Tachypnoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Tendon pain | 1 | 1 | 1 | 1 | | |
| Terminal state | 1 | 1 | | | 1 | 1 |
| Thirst | 1 | 1 | 1 | 1 | | |
| Throat clearing | 1 | 1 | 1 | 1 | | |

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|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Throat irritation | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | 1 | 2 | | | 1 | 2 |
| Urinary incontinence | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | | 1 | | 1 | | |
| Urticaria | 2 | 2 | | | 2 | 2 |
| Vaccination site erythema | 4 | 5 | 4 | 4 | | 1 |
| Vaccination site hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 13 | 14 | 12 | 12 | 1 | 2 |
| Vaccination site paraesthesia | 2 | 2 | 2 | 2 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 2 | | 1 | | 1 |
| Vaccination site warmth | 2 | 2 | 2 | 2 | | |
| Vomiting | 10 | 14 | 3 | 3 | 7 | 11 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | | | 1 | 1 |
| | 570 | 681 | 298 | 323 | 272 | 358 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | 2 | 2 | | |
| Abdominal pain upper | 2 | 2 | 1 | 1 | 1 | 1 |
| Abdominal wall haemorrhage | 1 | 1 | | | 1 | 1 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anal incontinence | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Apnoea | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 4 | 3 | 4 | | |
| Aspiration | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bacterial sepsis | 1 | 1 | | | 1 | 1 |
| Bacterial test positive | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | | 1 | | | | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 2 | 2 | | | 2 | 2 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 2 | 3 | | | 2 | 3 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | 2 | 2 | | |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 2 | 2 | 1 | 1 | 1 | 1 |
| Confusional state | 2 | 3 | 1 | 1 | 1 | 2 |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Constipation | 1 | 1 | 1 | 1 | | |
| Cough | 4 | 4 | 2 | 2 | 2 | 2 |
| C-reactive protein increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Death | 4 | 7 | | | 4 | 7 |
| Decreased appetite | 2 | 3 | 2 | 2 | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dehydration | 1 | 1 | | | 1 | 1 |
| Delirium | | 1 | | | | 1 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 2 | | | 1 | 2 |
| Diarrhoea | 6 | 7 | 4 | 4 | 2 | 3 |
| Diverticulitis | 1 | 1 | | | 1 | 1 |
| Dizziness | 3 | 3 | 3 | 3 | | |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysphagia | 2 | 3 | | | 2 | 3 |
| Dyspnoea | 7 | 7 | 1 | 1 | 6 | 6 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Faeces discoloured | 1 | 1 | 1 | 1 | | |
| Fall | 1 | 1 | 1 | 1 | | |
| Fatigue | 7 | 9 | 6 | 7 | 1 | 2 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Flushing | 1 | 1 | 1 | 1 | | |
| Gastritis | 1 | 1 | 1 | 1 | | |
| Gastrointestinal haemorrhage | | 1 | | | | 1 |
| General physical health deterioration | 8 | 11 | 2 | 2 | 6 | 9 |
| General symptom | 1 | 1 | | | 1 | 1 |
| Hallucination | 1 | 2 | | | 1 | 2 |
| Headache | 2 | 2 | 2 | 2 | | |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 2 | 3 | 1 | 1 | 1 | 2 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hyperkalaemia | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hyperventilation | 2 | 2 | 2 | 2 | | |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 4 | 4 | 2 | 3 |
| | | 1 | 1 |
| 3 | 3 | | |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | 6 | 6 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 6 | 7 | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 2 | 2 | 6 | 9 |
| | | 1 | 1 |
| | | 1 | 2 |
| 2 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |

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Gender

MALE

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|---|------------------------------------|--------------------------------------|
| Hypophagia | | 1 |
| Hypotension | 2 | 3 |
| Hypoxia | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Infection | 3 | 3 |
| Infective exacerbation of chronic obstructive airways disease | 1 | 1 |
| Influenza like illness | 3 | 3 |
| Injection site muscle weakness | | 1 |
| International normalised ratio increased | 1 | 1 |
| Leukocytosis | 1 | 1 |
| Listless | 1 | 1 |
| Livedo reticularis | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Malaise | 2 | 2 |
| Malignant hypertension | 1 | 1 |
| Malnutrition | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Myalgia | 1 | 1 |
| Nasal congestion | 3 | 3 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 6 | 7 |
| Neck pain | 1 | 1 |
| Obstructive airways disorder | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Ophthalmic herpes zoster | 1 | 1 |
| Oxygen saturation decreased | 3 | 4 |
| Pain | 1 | 1 |
| Pain in extremity | 2 | 2 |
| Pallor | 2 | 2 |
| Paralysis | 1 | 1 |
| Peripheral coldness | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| | | 1 | 1 |
| 5 | 5 | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |

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Gender

MALE

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|----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pneumonia | 6 | 8 | | | 6 | 8 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 1 | | | 1 | 1 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 12 | 12 | 6 | 6 | 6 | 6 |
| Rales | 1 | 1 | 1 | 1 | | |
| Rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory failure | 2 | 2 | | | 2 | 2 |
| Respiratory rate increased | 1 | 1 | 1 | 1 | | |
| Restlessness | 2 | 2 | 1 | 1 | 1 | 1 |
| Rhinorrhoea | 2 | 2 | 2 | 2 | | |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | 1 | 1 | 1 | 1 |
| Sputum increased | 1 | 1 | 1 | 1 | | |
| Syncope | 4 | 4 | | | 4 | 4 |
| Tachycardia | 3 | 3 | 1 | 1 | 2 | 2 |
| Terminal state | 1 | 1 | | | 1 | 1 |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 3 | 3 | | | 3 | 3 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 2 | 2 | 2 | 2 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 5 | 3 | 5 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vomiting | 7 | 8 | 4 | 5 | 3 | 3 |
| | 221 | 251 | 100 | 106 | 121 | 145 |

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Gender

UNKNOWN

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|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Adverse reaction | 1 | 1 | 1 | 1 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Incorrect dose administered | | 1 | | 1 | | |
| Intercepted product preparation error | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Poor quality product administered | | 6 | | 6 | | |
| Product preparation error | | 2 | | 2 | | |
| Product temperature excursion issue | | 6 | | 6 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 7 | 23 | 6 | 22 | 1 | 1 |

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Country Where Event Occurred

OMAN

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| Product supply issue | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea | | 1 | | 1 |
| Fatigue | | 1 | | 1 |
| Gastritis | | 1 | | 1 |
| Headache | | 1 | | 1 |
| Pain | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| | | 6 | | 6 |

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Country Where Event Occurred

PANAMA

Gender

MALE

Preferred Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | |
|-------------|---|
| Nonserious | |
| I | C |
| 1 | 1 |
| 1 | 1 |

Flatulence

1

1

1

1

1

1

1

1

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Country Where Event Occurred

POLAND

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 4 | 1 | 4 | | |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Abdominal pain upper | 1 | 2 | 1 | 1 | | 1 |
| Adnexa uteri pain | 1 | 1 | 1 | 1 | | |
| Ageusia | 4 | 6 | 4 | 6 | | |
| Anaphylactic reaction | 5 | 5 | | | 5 | 5 |
| Anaphylactic shock | 4 | 4 | | | 4 | 4 |
| Angioedema | 3 | 3 | | | 3 | 3 |
| Anosmia | 5 | 8 | 5 | 8 | | |
| Anxiety | 1 | 2 | 1 | 2 | | |
| Aphthous ulcer | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 2 | 3 | | | 2 | 3 |
| Arthralgia | 11 | 24 | 9 | 21 | 2 | 3 |
| Arthritis | | 1 | | 1 | | |
| Arthropathy | 1 | 1 | 1 | 1 | | |
| Asthenia | 29 | 48 | 21 | 39 | 8 | 9 |
| Asthma | 3 | 3 | | | 3 | 3 |
| Axillary pain | 2 | 4 | 2 | 4 | | |
| Back pain | 4 | 4 | 4 | 4 | | |
| Blood glucose increased | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 7 | 8 | 1 | 2 | 6 | 6 |
| Blood pressure increased | 4 | 6 | 1 | 1 | 3 | 5 |
| Blood urine present | | 1 | | 1 | | |
| Body temperature increased | 2 | 4 | 2 | 4 | | |
| Bone pain | 3 | 7 | 3 | 6 | | 1 |
| Brachial plexus injury | 1 | 1 | | | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 2 | | 1 | 1 | 1 |
| Bronchial oedema | 1 | 1 | | | 1 | 1 |
| Burning sensation | | 1 | | 1 | | |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Cerebral haematoma | 1 | 1 | | | 1 | 1 |

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|---------------------------|------------------------------------|--------------------------------------|
| Chest discomfort | 2 | 4 |
| Chest pain | 1 | 1 |
| Chills | 19 | 29 |
| Chorea | 1 | 1 |
| Coagulopathy | 1 | 1 |
| Confusional state | 2 | 2 |
| Conjunctival hyperaemia | | 1 |
| Contusion | 3 | 3 |
| Cough | 3 | 4 |
| COVID-19 | 17 | 25 |
| Cyanosis | 1 | 1 |
| Cystitis | | 1 |
| Death | 1 | 1 |
| Decreased activity | | 1 |
| Decreased appetite | 2 | 4 |
| Decreased nasolabial fold | 1 | 1 |
| Delirium | 1 | 1 |
| Diarrhoea | 3 | 6 |
| Discomfort | 1 | 1 |
| Disease recurrence | 1 | 1 |
| Disturbance in attention | 3 | 3 |
| Dizziness | 10 | 14 |
| Drug ineffective | 14 | 21 |
| Dry mouth | | 1 |
| Dysgeusia | 1 | 2 |
| Dysphonia | 1 | 1 |
| Dyspnoea | 7 | 9 |
| Dysstasia | | 1 |
| Ear swelling | 1 | 1 |
| Ecchymosis | 1 | 1 |
| Electrolyte imbalance | 1 | 1 |
| Epistaxis | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 4 | | |
| 1 | 1 | | |
| 16 | 24 | 3 | 5 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| | | 3 | 3 |
| 2 | 3 | 1 | 1 |
| 3 | 4 | 14 | 21 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 2 | 4 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 5 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 3 | 3 | | |
| 6 | 10 | 4 | 4 |
| | | 14 | 21 |
| | 1 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 3 | 5 | 4 | 4 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 2 | | |

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | 1 | 2 | 1 | 1 | | 1 |
| Erythema multiforme | 1 | 1 | | | 1 | 1 |
| Exercise tolerance decreased | 1 | 1 | 1 | 1 | | |
| Exposure during pregnancy | 1 | 2 | 1 | 2 | | |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Eye pain | 2 | 3 | | 1 | 2 | 2 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 6 | 11 | 5 | 10 | 1 | 1 |
| Feeling abnormal | 4 | 8 | 4 | 8 | | |
| Feeling cold | 3 | 5 | 3 | 4 | | 1 |
| Feeling hot | 4 | 5 | 4 | 5 | | |
| Flushing | 2 | 2 | 2 | 2 | | |
| Gait disturbance | | 1 | | 1 | | |
| Haematoma | | 1 | | 1 | | |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Haemorrhagic stroke | 1 | 1 | | | 1 | 1 |
| Headache | 31 | 51 | 25 | 44 | 6 | 7 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 2 | 5 | 2 | 3 | | 2 |
| Helplessness | | 1 | | | | 1 |
| Herpes virus infection | | 2 | | 2 | | |
| Hot flush | | 2 | | 1 | | 1 |
| Hydronephrosis | 1 | 1 | | | 1 | 1 |
| Hyperacusis | 1 | 1 | 1 | 1 | | |
| Hyperaesthesia | 2 | 3 | 1 | 1 | 1 | 2 |
| Hyperaesthesia teeth | | 1 | | 1 | | |
| Hyperhidrosis | 7 | 8 | 6 | 7 | 1 | 1 |
| Hypersensitivity | 2 | 3 | | 1 | 2 | 2 |
| Hypertension | | 1 | | 1 | | |
| Hypoesthesia | 9 | 11 | 6 | 7 | 3 | 4 |
| Hypoesthesia oral | 2 | 3 | 1 | 1 | 1 | 2 |
| Hypotonic-hyporesponsive episode | 6 | 6 | 1 | 1 | 5 | 5 |

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|--|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Hypoxia | 1 | 1 |
| Illness | 1 | 1 |
| Inappropriate schedule of product administration | | 2 |
| Incorrect dose administered | | 1 |
| Inflammation | | 2 |
| Influenza like illness | 2 | 5 |
| Initial insomnia | | 1 |
| Insomnia | 2 | 4 |
| Iritis | | 1 |
| Joint range of motion decreased | | 1 |
| Joint swelling | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Lip swelling | 1 | 1 |
| Lividity | 2 | 2 |
| Loss of consciousness | 7 | 7 |
| Lung disorder | 1 | 1 |
| Lymphadenopathy | 10 | 12 |
| Lymph node pain | 5 | 5 |
| Malaise | 14 | 18 |
| Maternal exposure during pregnancy | 1 | 2 |
| Mental disorder | 1 | 1 |
| Migraine | | 1 |
| Monoparesis | 1 | 1 |
| Movement disorder | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal chest pain | 1 | 1 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | 2 | 3 |
| Myalgia | 26 | 37 |
| Nasal congestion | 1 | 1 |
| Nasopharyngitis | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| | 2 | | |
| | 1 | | |
| | 2 | | |
| 2 | 5 | | |
| | 1 | | |
| 2 | 4 | | |
| | 1 | | |
| | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 7 | 7 |
| 1 | 1 | | |
| 5 | 7 | 5 | 5 |
| 2 | 2 | 3 | 3 |
| 12 | 16 | 2 | 2 |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 3 | | |
| 21 | 31 | 5 | 6 |
| 1 | 1 | | |
| 1 | 1 | | |

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|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nausea | 14 | 21 | 11 | 18 | 3 | 3 |
| Neck pain | 5 | 8 | 4 | 6 | 1 | 2 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Nodule | 1 | 1 | 1 | 1 | | |
| Oedema | | 1 | | 1 | | |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 8 | 1 | 7 | | 1 |
| Oropharyngeal pain | 1 | 3 | | 2 | 1 | 1 |
| Oxygen saturation decreased | 1 | 3 | | 1 | 1 | 2 |
| Pain | 4 | 6 | 4 | 5 | | 1 |
| Painful respiration | | 1 | | 1 | | |
| Pain in extremity | 17 | 31 | 15 | 27 | 2 | 4 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Pain of skin | | 1 | | 1 | | |
| Pallor | 2 | 4 | | 1 | 2 | 3 |
| Palpitations | 2 | 2 | 2 | 2 | | |
| Pancreatitis acute | | 1 | | | | 1 |
| Paraesthesia | 2 | 3 | 2 | 3 | | |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Paralysis | | 1 | | | | 1 |
| Paresis | | 1 | | | | 1 |
| Parosmia | 1 | 1 | 1 | 1 | | |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | | 1 | | 1 | | |
| Petechiae | 3 | 3 | 1 | 1 | 2 | 2 |
| Pharyngeal swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Pneumonia | | 1 | | | | 1 |
| Poor quality product administered | 1 | 1 | 1 | 1 | | |
| Presyncope | | 1 | | 1 | | |
| Product temperature excursion issue | 1 | 1 | 1 | 1 | | |
| Product use issue | 2 | 9 | 2 | 8 | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pulpitis dental | | 1 | | 1 | | |
| Pyrexia | 40 | 63 | 28 | 47 | 12 | 16 |
| Rash | 1 | 1 | 1 | 1 | | |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory tract oedema | 1 | 1 | | | 1 | 1 |
| Retching | | 1 | | 1 | | |
| Rhinitis | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 4 | 5 | 4 | 5 | | |
| SARS-CoV-2 ant body test negative | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test negative | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Seizure | 8 | 8 | | | 8 | 8 |
| Shock symptom | 1 | 1 | | | 1 | 1 |
| Sinus headache | 1 | 1 | | | 1 | 1 |
| Sinusitis | | 1 | | 1 | | |
| Skin hypertrophy | 1 | 1 | 1 | 1 | | |
| Somnolence | 2 | 4 | 1 | 3 | 1 | 1 |
| Speech disorder | 2 | 2 | | | 2 | 2 |
| Spinal pain | | 2 | | 1 | | 1 |
| Suppressed lactation | | 2 | | 1 | | 1 |
| Suspected COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| Swelling | | 1 | | | | 1 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Swollen tongue | 2 | 2 | | | 2 | 2 |
| Syncope | 7 | 7 | | | 7 | 7 |
| Tachycardia | 5 | 7 | 2 | 2 | 3 | 5 |
| Taste disorder | 2 | 4 | 2 | 4 | | |
| Temperature intolerance | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | 1 | 2 | 1 | 2 | | |
| Thirst | 1 | 1 | 1 | 1 | | |
| Thrombosis | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tinnitus | 4 | 4 | 4 | 4 | | |
| Toothache | | 1 | | 1 | | |
| Tracheal oedema | 1 | 1 | | | 1 | 1 |
| Tremor | | 2 | | 1 | | 1 |
| Urticaria | 2 | 3 | | 1 | 2 | 2 |
| Vaccination complication | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 4 | 8 | 2 | 6 | 2 | 2 |
| Vaccination site extravasation | | 1 | | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site macule | | 1 | | 1 | | |
| Vaccination site movement impairment | 1 | 3 | 1 | 3 | | |
| Vaccination site oedema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 26 | 46 | 22 | 41 | 4 | 5 |
| Vaccination site pruritus | 1 | 5 | 1 | 5 | | |
| Vaccination site reaction | 5 | 11 | 1 | 7 | 4 | 4 |
| Vaccination site swelling | 5 | 9 | 4 | 8 | 1 | 1 |
| Vaccination site warmth | 1 | 2 | 1 | 2 | | |
| Vein disorder | 1 | 1 | 1 | 1 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 4 | 4 | 1 | 1 | 3 | 3 |
| Viral infection | 1 | 1 | 1 | 1 | | |
| Vision blurred | | 1 | | 1 | | |
| Visual field defect | | 1 | | 1 | | |
| Visual impairment | 1 | 1 | 1 | 1 | | |
| Vomiting | 2 | 7 | 1 | 6 | 1 | 1 |
| | 598 | 940 | 367 | 651 | 231 | 289 |

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MALE

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|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anosmia | 1 | 1 | 1 | 1 | | |
| Antibody test abnormal | 1 | 1 | 1 | 1 | | |
| Arthralgia | 5 | 5 | 5 | 5 | | |
| Asthenia | 8 | 13 | 7 | 12 | 1 | 1 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | | 1 | | | | 1 |
| Back pain | 1 | 2 | 1 | 2 | | |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Bone pain | 2 | 2 | 2 | 2 | | |
| Cardiac arrest | 2 | 2 | | | 2 | 2 |
| Cerebral haematoma | 1 | 1 | | | 1 | 1 |
| Chills | 5 | 7 | 4 | 6 | 1 | 1 |
| Cough | | 1 | | 1 | | |
| COVID-19 | 6 | 9 | 2 | 2 | 4 | 7 |
| Death | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 2 | 1 | 2 | | |
| Disease progression | 1 | 1 | | | 1 | 1 |
| Disease recurrence | | 1 | | | | 1 |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Drug ineffective | 4 | 8 | | | 4 | 8 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |

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|---|------------------------------------|--------------------------------------|
| Fatigue | 3 | 4 |
| Febrile convulsion | 2 | 2 |
| Feeling cold | 1 | 1 |
| Feeling hot | 1 | 1 |
| Flatulence | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Gastrointestinal disorder | 1 | 1 |
| Gastrointestinal haemorrhage | 1 | 1 |
| Haemoptysis | 1 | 1 |
| Headache | 3 | 10 |
| Heart rate increased | 1 | 1 |
| Herpes virus infection | | 1 |
| Herpes zoster | | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 1 | 1 |
| Hypersensitivity | 1 | 2 |
| Hypertension | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 |
| Incorrect route of product administration | | 1 |
| Increased upper airway secretion | 1 | 1 |
| Infection | 1 | 1 |
| Influenza | | 1 |
| Influenza like illness | 1 | 1 |
| Insomnia | 4 | 4 |
| Laryngospasm | 1 | 1 |
| Loss of consciousness | 1 | 1 |
| Lymphadenopathy | 2 | 5 |
| Lymph node pain | 2 | 2 |
| Malaise | 4 | 4 |
| Middle insomnia | 1 | 1 |
| Muscle tightness | | 1 |
| Muscular weakness | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 4 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 3 | 10 | | |
| | | 1 | 1 |
| | | 1 | |
| | | 1 | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 4 | 4 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 4 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 3 | 3 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myalgia | 6 | 10 | 6 | 10 | | |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 3 | 1 | 3 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 2 | 1 | 2 | | |
| Pain in extremity | 2 | 4 | 2 | 4 | | |
| Pallor | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 1 | 1 | 1 | | |
| Paraparesis | | 1 | | | | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Prostatitis | 1 | 1 | | | 1 | 1 |
| Pruritus | | 1 | | 1 | | |
| Pyrexia | 9 | 16 | 6 | 13 | 3 | 3 |
| Rash | 1 | 2 | | 1 | 1 | 1 |
| Rash macular | | 1 | | 1 | | |
| Rash papular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Ulnar nerve palsy | 1 | 1 | 1 | 1 | | |
| Urinary tract inflammation | 1 | 1 | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Urticaria | | 1 | | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site infection | | 1 | | 1 | | |
| Vaccination site pain | 3 | 18 | 3 | 18 | | |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | | 1 | | 1 | | |
| Vaccination site scab | | 1 | | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaccination site vesicles | | 1 | | 1 | | |
| Visual field defect | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 145 | 224 | 88 | 157 | 57 | 67 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | | | 2 | 2 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Antibody test abnormal | 11 | 11 | 11 | 11 | | |
| Anxiety | 1 | 2 | | 1 | 1 | 1 |
| Aortic aneurysm rupture | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 11 | 17 | 8 | 14 | 3 | 3 |
| Arthropathy | | 1 | | 1 | | |
| Asthenia | 15 | 18 | 4 | 7 | 11 | 11 |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 |
| Axillary pain | | 1 | | 1 | | |
| Back pain | 3 | 5 | 2 | 4 | 1 | 1 |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bone pain | 3 | 3 | | | 3 | 3 |
| Burning sensation | | 1 | | 1 | | |
| Cardiac death | 1 | 1 | | | 1 | 1 |
| Chest pain | 2 | 2 | | | 2 | 2 |
| Chills | 14 | 17 | 8 | 11 | 6 | 6 |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 3 | | 1 | 2 | 2 |
| COVID-19 | 4 | 4 | | | 4 | 4 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Crying | | 1 | | 1 | | |
| Deafness | 2 | 2 | | | 2 | 2 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Death | 5 | 5 |
| Decreased appetite | 1 | 1 |
| Dermatitis allergic | 1 | 1 |
| Diarrhoea | 3 | 5 |
| Disorientation | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 4 | 5 |
| Drug ineffective | 5 | 5 |
| Dysgeusia | 2 | 3 |
| Dyspnoea | 3 | 3 |
| Ear pain | | 1 |
| Encephalopathy | 1 | 1 |
| Erythema | 2 | 2 |
| Erythema multiforme | 1 | 1 |
| Exposure via breast milk | | 7 |
| Eye pain | 2 | 2 |
| Facial paralysis | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 1 | 1 |
| Febrile convulsion | 3 | 3 |
| Feeling cold | 3 | 3 |
| Feeling hot | 1 | 1 |
| Formication | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Goitre | 1 | 1 |
| Headache | 13 | 13 |
| Hot flush | | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 2 | 2 |
| Hypertension | 1 | 1 |
| Hypoaesthesia | 5 | 6 |
| Hypoaesthesia eye | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 4 | 4 |
| | | 5 | 5 |
| | 1 | 2 | 2 |
| | | 3 | 3 |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 7 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 10 | 10 |
| | 1 | | |
| | | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 2 | 4 | 4 |
| | | 1 | 1 |

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|---|--|--|
| Hypoaesthesia oral | 1 | 2 |
| Hypopnoea | 1 | 1 |
| Hypotension | 1 | 1 |
| Hypotonic-hyporesponsive episode | 4 | 4 |
| Incorrect route of product administration | | 1 |
| Insomnia | 1 | 1 |
| Joint effusion | 1 | 1 |
| Joint swelling | 1 | 1 |
| Laryngospasm | 1 | 1 |
| Loss of consciousness | 5 | 5 |
| Lymphadenopathy | 11 | 12 |
| Lymph node pain | 8 | 9 |
| Malaise | 9 | 13 |
| Musculoskeletal pain | 1 | 1 |
| Musculoskeletal stiffness | | 1 |
| Myalgia | 17 | 22 |
| Myocardial hypoxia | 1 | 1 |
| Nausea | 6 | 7 |
| Neck pain | 1 | 1 |
| Needle issue | | 1 |
| Oedema | 1 | 1 |
| Off label use | 1 | 2 |
| Oropharyngeal pain | 1 | 2 |
| Oxygen saturation decreased | 3 | 3 |
| Pain | 2 | 2 |
| Pain in extremity | 6 | 8 |
| Paraesthesia | 2 | 2 |
| Paresis | | 1 |
| Parosmia | 2 | 2 |
| Parotitis | 1 | 1 |
| Pneumonia | 1 | 1 |
| Poor quality product administered | 3 | 3 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 5 | 5 |
| 4 | 5 | 7 | 7 |
| 3 | 4 | 5 | 5 |
| 8 | 12 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 8 | 13 | 9 | 9 |
| | | 1 | 1 |
| 2 | 3 | 4 | 4 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 2 | | |
| | 1 | 1 | 1 |
| | | 3 | 3 |
| | | 2 | 2 |
| 1 | 3 | 5 | 5 |
| | | 2 | 2 |
| | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| 3 | 3 | | |

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|-------------------------------|------------------------------------|--------------------------------------|
| Poor quality sleep | | 1 |
| Product label confusion | | 2 |
| Product preparation error | 1 | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 1 | 1 |
| Pulmonary oedema | 1 | 1 |
| Pyrexia | 30 | 35 |
| Rash | | 1 |
| Rash rubelliform | 1 | 1 |
| Respiratory arrest | 1 | 1 |
| Seizure | 1 | 1 |
| Somnolence | 2 | 3 |
| Spinal pain | 1 | 1 |
| Swelling | | 2 |
| Syncope | 6 | 6 |
| Tachycardia | 4 | 4 |
| Taste disorder | 1 | 1 |
| Tension headache | 1 | 1 |
| Throat irritation | | 1 |
| Thyroiditis | 1 | 1 |
| Thyroid pain | 1 | 1 |
| Tonsillar hypertrophy | | 1 |
| Tremor | 2 | 2 |
| Vaccination site erythema | 2 | 2 |
| Vaccination site induration | | 1 |
| Vaccination site inflammation | 1 | 1 |
| Vaccination site oedema | 1 | 1 |
| Vaccination site pain | 5 | 8 |
| Vaccination site reaction | 13 | 13 |
| Vaccination site swelling | | 2 |
| Vaccination site warmth | | 1 |
| Vertigo | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 9 | 14 | 21 | 21 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| | | 6 | 6 |
| | | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 12 | 12 |
| | 2 | | |
| | 1 | | |
| | | 1 | 1 |

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|--------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 8 | 8 | 1 | 1 | 7 | 7 |
| Walking disability | 1 | 1 | | | 1 | 1 |
| Yellow skin | 1 | 1 | | | 1 | 1 |
| | 340 | 417 | 98 | 175 | 242 | 242 |

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Country Where Event Occurred

PORTUGAL

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 2 | 3 | | | 2 | 3 |
| Abdominal pain | 8 | 9 | | | 8 | 9 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 5 | 5 | 1 | 1 | 4 | 4 |
| Abnormal faeces | 1 | 1 | | | 1 | 1 |
| Ageusia | 2 | 2 | | | 2 | 2 |
| Allergy to vaccine | 1 | 3 | | | 1 | 3 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Amnesia | | 1 | | 1 | | |
| Amylase increased | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 6 | 7 | | | 6 | 7 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anaphylactoid reaction | 2 | 2 | | | 2 | 2 |
| Angioedema | 8 | 8 | | | 8 | 8 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety | 3 | 4 | | 1 | 3 | 3 |
| Aphthous ulcer | 2 | 2 | | | 2 | 2 |
| Arrhythmia | 3 | 3 | | | 3 | 3 |
| Arthralgia | 61 | 61 | 3 | 3 | 58 | 58 |
| Asthenia | 49 | 49 | 2 | 2 | 47 | 47 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| Autophony | 1 | 1 | | | 1 | 1 |
| Axillary pain | 8 | 8 | | | 8 | 8 |
| Back pain | 10 | 10 | 1 | 1 | 9 | 9 |
| Balance disorder | 3 | 3 | | | 3 | 3 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 4 | 5 | 1 | 1 | 3 | 4 |
| Body temperature increased | 2 | 3 | | 1 | 2 | 2 |
| Bone pain | | 1 | | 1 | | |
| Bradycardia | 3 | 3 | | | 3 | 3 |
| Bradyphrenia | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|----------------------------------|--|--|
| Breast pain | 3 | 3 |
| Breast swelling | 1 | 1 |
| Bronchospasm | 3 | 3 |
| Burning sensation | 2 | 2 |
| Cardio-respiratory arrest | 1 | 2 |
| Cerebral venous sinus thrombosis | 1 | 1 |
| Chest discomfort | 8 | 9 |
| Chest pain | 12 | 13 |
| Chills | 71 | 75 |
| Choking sensation | 1 | 1 |
| Choroiditis | 1 | 1 |
| Circumoral oedema | | 1 |
| Cold sweat | 3 | 3 |
| Condition aggravated | 2 | 2 |
| Confusional state | 1 | 1 |
| Conjunctival irritation | 1 | 1 |
| Cough | 15 | 17 |
| COVID-19 | 17 | 23 |
| Crohn's disease | 1 | 1 |
| Crying | 1 | 1 |
| Cyanosis | 1 | 1 |
| Deafness transitory | 1 | 1 |
| Decreased appetite | 8 | 9 |
| Depressed level of consciousness | 1 | 1 |
| Depressed mood | 1 | 1 |
| Dermatitis allergic | | 1 |
| Diarrhoea | 23 | 23 |
| Discomfort | 1 | 1 |
| Disease recurrence | 1 | 1 |
| Dizziness | 46 | 46 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 13 | 19 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 2 | 2 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 2 | 2 |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | 7 | 8 |
| | | 12 | 13 |
| 2 | 3 | 69 | 72 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 3 | 3 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 11 | 13 |
| 4 | 4 | 13 | 19 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 7 | 7 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 2 | 2 | 21 | 21 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | 42 | 42 |
| | | 1 | 1 |
| | | 13 | 19 |

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Gender

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|---------------------------|------------------------------------|--------------------------------------|
| Drug interaction | 1 | 1 |
| Dry eye | | 1 |
| Dry mouth | 3 | 3 |
| Dry throat | 1 | 1 |
| Dysarthria | 4 | 5 |
| Dysgeusia | 5 | 6 |
| Dyskinesia | 1 | 1 |
| Dyslexia | 1 | 1 |
| Dyspepsia | 1 | 1 |
| Dysphagia | 6 | 7 |
| Dysphonia | 3 | 3 |
| Dyspnoea | 19 | 19 |
| Dyspnoea at rest | 2 | 2 |
| Dysstasia | 1 | 1 |
| Ear pain | 3 | 3 |
| Eczema | 1 | 1 |
| Eructation | | 1 |
| Erythema | 9 | 13 |
| Exophthalmos | | 1 |
| Exposure during pregnancy | 1 | 1 |
| Exposure to SARS-CoV-2 | 1 | 1 |
| Exposure via breast milk | | 1 |
| Eye disorder | 1 | 1 |
| Eye irritation | 2 | 3 |
| Eyelid myokymia | 1 | 1 |
| Eyelid oedema | 3 | 3 |
| Eye movement disorder | | 1 |
| Eye pain | | 1 |
| Eye paraesthesia | | 1 |
| Eye pruritus | 1 | 1 |
| Eye swelling | 1 | 1 |
| Face oedema | 10 | 11 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | 1 | 4 | 4 |
| | | 5 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 6 | 7 |
| 1 | 1 | 2 | 2 |
| 2 | 2 | 17 | 17 |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | 1 | | |
| | 1 | 9 | 12 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 3 | 3 |
| | | | 1 |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 10 | 11 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Facial paralysis | 3 | 4 |
| Faeces soft | 1 | 1 |
| Fall | 1 | 1 |
| Fatigue | 59 | 66 |
| Feeling abnormal | 1 | 2 |
| Feeling cold | 4 | 4 |
| Feeling hot | 11 | 12 |
| Feeling of body temperature change | 1 | 1 |
| Flatulence | 2 | 2 |
| Flushing | 4 | 6 |
| Gait disturbance | 1 | 1 |
| Gait inability | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 2 |
| Gonorrhoea | 1 | 1 |
| Haematoma | 1 | 1 |
| Haemoptysis | 1 | 1 |
| Headache | 192 | 202 |
| Head discomfort | 1 | 1 |
| Heart rate increased | 2 | 2 |
| Hot flush | 4 | 4 |
| Hyperaesthesia | 1 | 1 |
| Hyperglycaemia | 3 | 3 |
| Hyperhidrosis | 12 | 12 |
| Hypersensitivity | 3 | 4 |
| Hypertension | 14 | 14 |
| Hypertensive crisis | 2 | 2 |
| Hyperthermia | 6 | 6 |
| Hypoaesthesia | 5 | 6 |
| Hypoaesthesia oral | 4 | 8 |
| Hypoglycaemia | 3 | 3 |
| Hypokalaemia | 3 | 3 |
| Hypoperfusion | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 7 | 57 | 59 |
| 1 | 2 | | |
| | | 4 | 4 |
| | | 11 | 12 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 4 | 6 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 11 | 18 | 181 | 184 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 11 | 11 |
| | | 3 | 4 |
| | | 14 | 14 |
| | | 2 | 2 |
| 1 | 1 | 5 | 5 |
| | 1 | 5 | 5 |
| | 1 | 4 | 7 |
| | | 3 | 3 |
| | | 3 | 3 |
| | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Hypotension | 9 | 9 |
| Hypothyroidism | | 1 |
| Illness | 1 | 1 |
| Impaired work ability | 2 | 2 |
| Inappropriate schedule of product administration | 2 | 2 |
| Incorrect route of product administration | 12 | 14 |
| Inflammation | 1 | 1 |
| Influenza | 2 | 2 |
| Influenza like illness | 1 | 1 |
| Injected limb mobility decreased | | 1 |
| Insomnia | 6 | 6 |
| Inspiratory capacity decreased | 1 | 1 |
| Joint range of motion decreased | 1 | 1 |
| Lacrimation increased | 1 | 1 |
| Laryngeal oedema | 4 | 6 |
| Leukocyturia | 1 | 1 |
| Limb discomfort | 1 | 1 |
| Lipase increased | 1 | 1 |
| Lip oedema | 5 | 7 |
| Lip pruritus | | 1 |
| Lip swelling | 1 | 1 |
| Localised oedema | 4 | 5 |
| Loss of personal independence in daily activities | 2 | 2 |
| Lymphadenitis | 3 | 4 |
| Lymphadenopathy | 66 | 72 |
| Lymph node pain | 1 | 1 |
| Macule | 1 | 1 |
| Malaise | 29 | 29 |
| Mastitis | 1 | 1 |
| Maternal exposure during pregnancy | 1 | 2 |
| Metrorrhagia | 1 | 1 |
| Migraine | 4 | 6 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 9 | 9 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| 2 | 2 | | |
| 12 | 14 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 6 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 7 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | 4 | 4 |
| 1 | 1 | 1 | 1 |
| | 1 | 3 | 3 |
| 2 | 6 | 64 | 66 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 28 | 28 |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 3 | 5 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Motor dysfunction | 1 | 1 | | | 1 | 1 |
| Muscle fatigue | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle tightness | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 2 | 3 | | | 2 | 3 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 217 | 228 | 11 | 17 | 206 | 211 |
| Myalgia intercostal | 1 | 1 | | | 1 | 1 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Myelosuppression | 1 | 1 | | | 1 | 1 |
| Myoclonus | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 4 | 4 | 1 | 1 | 3 | 3 |
| Nasal discomfort | 1 | 1 | 1 | 1 | | |
| Nasal dryness | 1 | 1 | 1 | 1 | | |
| Nasal obstruction | | 1 | | | | 1 |
| Nausea | 72 | 79 | 4 | 7 | 68 | 72 |
| Neck mass | 1 | 1 | 1 | 1 | | |
| Neck pain | 2 | 2 | | | 2 | 2 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Nystagmus | 2 | 3 | | | 2 | 3 |
| Ocular discomfort | | 1 | | 1 | | |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Odynophagia | 9 | 10 | 2 | 2 | 7 | 8 |
| Oedema | 2 | 2 | | | 2 | 2 |
| Oedema mouth | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 5 | 5 | 1 | 1 | 4 | 4 |
| Oesophageal pain | 1 | 1 | | | 1 | 1 |
| Oesophageal stenosis | 1 | 1 | | | 1 | 1 |
| Off label use | 6 | 8 | 6 | 8 | | |
| Oral candidiasis | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 11 | 17 | 206 | 211 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | | 1 |
| 4 | 7 | 68 | 72 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | 1 | | |
| | | 1 | 1 |
| 2 | 2 | 7 | 8 |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 6 | 8 | | |
| | | 1 | 1 |

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|--|------------------------------------|--------------------------------------|
| Oral herpes | 1 | 1 |
| Oral pain | 1 | 1 |
| Oropharyngeal discomfort | 5 | 6 |
| Oropharyngeal oedema | | 1 |
| Oropharyngeal pain | 3 | 3 |
| Overdose | 1 | 5 |
| Oxygen saturation decreased | 2 | 2 |
| Pain | 14 | 15 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 17 | 18 |
| Pallor | 4 | 4 |
| Palmar-plantar erythrodysesthesia syndrome | | 1 |
| Palpitations | 5 | 6 |
| Paraesthesia | 26 | 31 |
| Paraesthesia oral | 6 | 8 |
| Paralysis | 1 | 1 |
| Perineal pain | 1 | 1 |
| Peripheral coldness | 2 | 3 |
| Peripheral swelling | 1 | 1 |
| Petechiae | 1 | 1 |
| Pharyngeal erythema | 1 | 1 |
| Pharyngeal inflammation | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 3 |
| Phlebitis | 1 | 1 |
| Phonophobia | 1 | 1 |
| Photophobia | 2 | 3 |
| Piloerection | 2 | 2 |
| Pleuritic pain | 1 | 1 |
| Pneumonia | 1 | 1 |
| Pneumonia aspiration | 1 | 1 |
| Polydipsia | 3 | 3 |
| Poor quality sleep | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 4 | 5 |
| | | | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 5 | | |
| | | 2 | 2 |
| 1 | 2 | 13 | 13 |
| | | 1 | 1 |
| 2 | 2 | 15 | 16 |
| | | 4 | 4 |
| | | | 1 |
| | 1 | 5 | 5 |
| 2 | 5 | 24 | 26 |
| | | 6 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 2 | 2 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Postural orthostatic tachycardia syndrome | 1 | 1 | | | 1 | 1 |
| Presyncope | 13 | 16 | | 2 | 13 | 14 |
| Product administered at inappropriate site | 1 | 1 | 1 | 1 | | |
| Product use issue | 6 | 8 | 6 | 8 | | |
| Proteinuria | 1 | 1 | 1 | 1 | | |
| Pruritus | 17 | 22 | | 2 | 17 | 20 |
| Pyrexia | 155 | 159 | 3 | 4 | 152 | 155 |
| Rash | 21 | 26 | 1 | 3 | 20 | 23 |
| Rash erythematous | 3 | 3 | | | 3 | 3 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 1 | 2 | | 1 | 1 | 1 |
| Rash papular | 2 | 2 | | | 2 | 2 |
| Rash pruritic | 2 | 2 | | | 2 | 2 |
| Renal disorder | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Rhinitis | 2 | 2 | 1 | 1 | 1 | 1 |
| Rhinorrhoea | 11 | 12 | 3 | 3 | 8 | 9 |
| SARS-CoV-2 test positive | 3 | 6 | | | 3 | 6 |
| Scar | | 1 | | 1 | | |
| Seizure | 3 | 3 | | | 3 | 3 |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Sensory loss | 4 | 4 | | | 4 | 4 |
| Sinusitis | 1 | 1 | 1 | 1 | | |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Skin lesion | 1 | 1 | | | 1 | 1 |
| Sleep disorder | 1 | 1 | | | 1 | 1 |
| Somnolence | 7 | 9 | | 2 | 7 | 7 |
| Stiff tongue | 1 | 1 | | | 1 | 1 |
| Stomatitis | 1 | 2 | | 1 | 1 | 1 |
| Swelling | 2 | 2 | | | 2 | 2 |
| Syncope | 7 | 7 | | | 7 | 7 |
| Synovial cyst | 4 | 4 | | | 4 | 4 |

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|--------------------------------|------------------------------------|--------------------------------------|
| Tachyarrhythmia | 2 | 2 |
| Tachycardia | 25 | 26 |
| Tachypnoea | 1 | 2 |
| Takayasu's arteritis | 1 | 1 |
| Taste disorder | 4 | 4 |
| Tenosynovitis | | 1 |
| Terminal ileitis | 1 | 1 |
| Throat irritation | 5 | 6 |
| Throat tightness | 2 | 3 |
| Thrombocytopenia | 1 | 1 |
| Thrombophlebitis | 1 | 1 |
| Thyroid function test abnormal | | 1 |
| Tinnitus | 1 | 1 |
| Tongue dry | | 1 |
| Tongue eruption | 1 | 2 |
| Tongue oedema | 7 | 9 |
| Tongue pruritus | | 1 |
| Tremor | 15 | 16 |
| Trichoglossia | 1 | 1 |
| Trismus | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urticaria | 3 | 4 |
| Urticaria papular | 1 | 1 |
| Vaccination complication | 1 | 1 |
| Vaccination failure | 1 | 1 |
| Vaccination site erythema | 14 | 16 |
| Vaccination site induration | 2 | 2 |
| Vaccination site inflammation | 6 | 6 |
| Vaccination site oedema | 12 | 13 |
| Vaccination site pain | 91 | 106 |
| Vaccination site paraesthesia | 2 | 2 |
| Vaccination site pruritus | 8 | 8 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 25 | 26 |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 4 | 4 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | 5 | 5 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 2 |
| | | 7 | 9 |
| | | | 1 |
| | 1 | 15 | 15 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | 14 | 14 |
| | | 2 | 2 |
| | | 6 | 6 |
| | | 12 | 13 |
| 11 | 20 | 80 | 86 |
| 1 | 1 | 1 | 1 |
| | | 8 | 8 |

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|--------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 9 | 10 | | 1 | 9 | 9 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 6 | 6 | | | 6 | 6 |
| Vasculitis | 1 | 1 | | | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 6 | 6 | | | 6 | 6 |
| Vertigo positional | | 1 | | | | 1 |
| Vision blurred | 2 | 3 | | 1 | 2 | 2 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 21 | 22 | 1 | 1 | 20 | 21 |
| Vulvovaginal burning sensation | 1 | 1 | | | 1 | 1 |
| Vulvovaginal swelling | 1 | 1 | | | 1 | 1 |
| Weight decreased | | 1 | | 1 | | |
| Wheezing | 1 | 1 | | | 1 | 1 |
| Wound | 1 | 1 | 1 | 1 | | |
| | 2,023 | 2,231 | 150 | 242 | 1873 | 1989 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | | 1 | | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 5 | 5 | | | 5 | 5 |
| Arthritis reactive | | 1 | | | | 1 |
| Asthenia | 13 | 13 | 1 | 1 | 12 | 12 |
| Axillary pain | 2 | 2 | | | 2 | 2 |
| Back pain | 2 | 2 | | | 2 | 2 |
| Balance disorder | | 1 | | | | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chillblains | | 1 | | 1 | | |
| Chills | 15 | 17 | 1 | 2 | 14 | 15 |
| Cough | 3 | 3 | 1 | 1 | 2 | 2 |
| COVID-19 | 5 | 9 | 2 | 3 | 3 | 6 |
| Cutaneous vasculitis | 1 | 1 | | | 1 | 1 |
| Death | 2 | 4 | | | 2 | 4 |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Diarrhoea | 3 | 3 | | | 3 | 3 |
| Dizziness | 5 | 6 | | | 5 | 6 |
| Drug ineffective | 1 | 4 | | | 1 | 4 |
| Dysphagia | 2 | 2 | | | 2 | 2 |
| Dyspnoea | 2 | 2 | | | 2 | 2 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Embolism | | 1 | | | | 1 |
| Erythema | 1 | 2 | | | 1 | 2 |
| Exposure via breast milk | | 1 | | 1 | | |
| Eyelid oedema | | 1 | | | | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Fatigue | 4 | 5 | 1 | 1 | 3 | 4 |
| Feeling cold | 2 | 2 | | | 2 | 2 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Flushing | 1 | 1 | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Functional gastrointestinal disorder | | 1 |
| General symptom | 1 | 1 |
| Headache | 28 | 32 |
| Hemianaesthesia | 1 | 1 |
| Hemidysaesthesia | 1 | 1 |
| Hyperhidrosis | 2 | 3 |
| Hypersensitivity | | 1 |
| Hypertension | 1 | 1 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia oral | | 1 |
| Hypotension | 3 | 3 |
| Inappropriate schedule of product administration | 1 | 2 |
| Incorrect route of product administration | 2 | 2 |
| Insomnia | 3 | 3 |
| Intercostal neuralgia | 1 | 2 |
| L bido decreased | 1 | 1 |
| Lip oedema | 1 | 1 |
| Lymphadenopathy | 7 | 9 |
| Malaise | 4 | 7 |
| Motor dysfunction | 2 | 2 |
| Muscle contractions involuntary | 1 | 1 |
| Muscle fatigue | 1 | 1 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Myalgia | 37 | 43 |
| Myocarditis | 2 | 2 |
| Nasal congestion | 1 | 1 |
| Nausea | 5 | 6 |
| Occupational exposure to SARS-CoV-2 | 1 | 1 |
| Odynophagia | 1 | 3 |
| Off label use | 2 | 3 |
| Ophthalmic herpes simplex | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 1 | 1 |
| | 3 | 28 | 29 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 3 | 3 |
| 1 | 2 | | |
| 2 | 2 | | |
| 1 | 1 | 2 | 2 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | 7 | 8 |
| | 1 | 4 | 6 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 5 | 36 | 38 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 5 | 6 |
| 1 | 1 | | |
| | 1 | 1 | 2 |
| 2 | 3 | | |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Oropharyngeal pain | 1 | 2 |
| Oxygen saturation decreased | 2 | 2 |
| Pain | 3 | 3 |
| Pain in extremity | 2 | 2 |
| Pallor | | 2 |
| Paraesthesia | 4 | 4 |
| Paraesthesia oral | 1 | 1 |
| Pharyngeal hypoesthesia | | 1 |
| Pharyngeal inflammation | 1 | 1 |
| Piloerection | 1 | 1 |
| Pleuritic pain | 1 | 1 |
| Presyncope | 3 | 3 |
| Procedural haemorrhage | 1 | 1 |
| Productive cough | | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 2 | 3 |
| Pyrexia | 26 | 30 |
| Rash | 4 | 6 |
| Renal colic | 1 | 1 |
| Respiratory tract congestion | | 1 |
| Rhabdomyolysis | 1 | 1 |
| Rhinorrhoea | 1 | 2 |
| SARS-CoV-2 test positive | 1 | 1 |
| Sinus tachycardia | | 1 |
| Skin exfoliation | 1 | 1 |
| Skin reaction | 1 | 1 |
| Sleep disorder | 1 | 1 |
| Somnolence | 2 | 4 |
| Syncope | 2 | 2 |
| Tachycardia | 1 | 3 |
| Taste disorder | 1 | 1 |
| Throat irritation | | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| 1 | 1 | 1 | 1 |
| | | 3 | 3 |
| | | 2 | 2 |
| | 1 | | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| | | 2 | 3 |
| | 3 | 26 | 27 |
| | | 4 | 6 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 4 |
| | | 2 | 2 |
| | 1 | 1 | 2 |
| | | 1 | 1 |
| | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tongue coated | 1 | 1 | | | 1 | 1 |
| Tongue discomfort | 1 | 1 | | | 1 | 1 |
| Tongue dry | 1 | 1 | | | 1 | 1 |
| Tonsillar hypertrophy | 1 | 1 | | | 1 | 1 |
| Tremor | 3 | 3 | | | 3 | 3 |
| Upper-airway cough syndrome | | 1 | | | | 1 |
| Urticaria | 2 | 3 | | 1 | 2 | 2 |
| Vaccination site discomfort | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | | 1 | | 1 | | |
| Vaccination site pain | 11 | 17 | 1 | 7 | 10 | 10 |
| Vaccination site pruritus | | 1 | | | | 1 |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 282 | 359 | 22 | 55 | 260 | 304 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Abdominal discomfort | | 1 | | 1 | | | |
| Abdominal pain upper | | 1 | | 1 | | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 | |
| Arthralgia | 4 | 4 | | | 4 | 4 | |
| Asthenia | 1 | 2 | | 1 | 1 | 1 | |
| Bronchospasm | 1 | 1 | | | 1 | 1 | |
| Chest pain | | 2 | | 1 | | 1 | |
| Chills | 3 | 4 | | 1 | 3 | 3 | |
| COVID-19 | 1 | 7 | | | 1 | 7 | |
| Cyanosis | 1 | 1 | | | 1 | 1 | |
| Decreased appetite | | 1 | | 1 | | | |
| Diarrhoea | 1 | 3 | | 2 | 1 | 1 | |
| Dizziness | 4 | 6 | | 2 | 4 | 4 | |
| Drug ineffective | 1 | 8 | | | 1 | 8 | |
| Dysgeusia | | 1 | | 1 | | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 | |
| Eructation | | 1 | | 1 | | | |
| Erythema | | 3 | | 2 | | 1 | |
| Exposure via breast milk | 1 | 3 | 1 | 3 | | | |
| Face oedema | | 3 | | 1 | | 2 | |
| Fatigue | 2 | 2 | | | 2 | 2 | |
| Flushing | 1 | 1 | | | 1 | 1 | |
| Groin pain | 1 | 1 | | | 1 | 1 | |
| Headache | 17 | 24 | | 6 | 17 | 18 | |
| Hemiparaesthesia | 1 | 1 | | | 1 | 1 | |
| Hyperaemia | 1 | 1 | | | 1 | 1 | |
| Hyperglycaemia | | 1 | | | | 1 | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 | |
| Hypersensitivity | | 5 | | 4 | | 1 | |
| Hypertension | 1 | 1 | | | 1 | 1 | |
| Hypoaesthesia | 1 | 2 | | 1 | 1 | 1 | |
| Hypoaesthesia oral | | 1 | | | | 1 | |

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Gender

UNKNOWN

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------|--|--|
| Hypotension | 1 | 1 |
| Laryngeal oedema | 4 | 6 |
| Leukaemoid reaction | 1 | 1 |
| Lip oedema | 1 | 3 |
| Lip swelling | 1 | 1 |
| Lymphadenopathy | 2 | 2 |
| Malaise | | 4 |
| Migraine | | 2 |
| Myalgia | 17 | 21 |
| Nausea | 7 | 11 |
| Odynophagia | | 1 |
| Oedema mouth | 1 | 1 |
| Oedema mucosal | 1 | 1 |
| Oral disorder | | 1 |
| Oropharyngeal discomfort | 1 | 1 |
| Oropharyngeal oedema | | 1 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | | 1 |
| Pain in jaw | | 1 |
| Pallor | 1 | 2 |
| Paraesthesia | 4 | 5 |
| Paraesthesia oral | 2 | 4 |
| Presyncope | 1 | 2 |
| Productive cough | | 1 |
| Pruritus | 1 | 2 |
| Pyrexia | 14 | 18 |
| Rash | 4 | 10 |
| Rash maculo-papular | | 1 |
| Rash pruritic | | 2 |
| Rhinorrhoea | 2 | 3 |
| SARS-CoV-2 test positive | | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 4 | 6 |
| | | 1 | 1 |
| | | 1 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 4 | | |
| | 1 | | 1 |
| | 4 | 17 | 17 |
| | 4 | 7 | 7 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | 1 | 1 | 1 |
| | | 4 | 5 |
| | 1 | 2 | 3 |
| | 1 | 1 | 1 |
| | | | 1 |
| | | 1 | 2 |
| | 4 | 14 | 14 |
| | 5 | 4 | 5 |
| | 1 | | |
| | 2 | | |
| | | 2 | 3 |
| | | | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Sensory loss | | 1 | | | | 1 |
| Somnolence | | 2 | | 1 | | 1 |
| Stomatitis | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 2 | 4 | 1 | 3 | 1 | 1 |
| Taste disorder | | 2 | | 2 | | |
| Throat irritation | 1 | 2 | | 1 | 1 | 1 |
| Tongue discomfort | 1 | 1 | | | 1 | 1 |
| Tongue disorder | | 1 | | 1 | | |
| Tongue oedema | 2 | 3 | | | 2 | 3 |
| Tremor | 3 | 4 | | 1 | 3 | 3 |
| Urticaria | 1 | 2 | | | 1 | 2 |
| Urticaria cholinergic | | 1 | | 1 | | |
| Vaccination site erythema | 3 | 4 | | 1 | 3 | 3 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site oedema | | 1 | | | | 1 |
| Vaccination site pain | 3 | 20 | | 16 | 3 | 4 |
| Vaccination site swelling | 1 | 2 | | 1 | 1 | 1 |
| Varicella | 1 | 1 | | | 1 | 1 |
| Vomiting | 3 | 5 | | 1 | 3 | 4 |
| | 140 | 270 | 3 | 90 | 137 | 180 |

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Country Where Event Occurred

PUERTO RICO

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 2 | 3 | 2 | 3 | | |
| Abdominal pain | | 1 | | 1 | | |
| Antinuclear antibody positive | 1 | 1 | 1 | 1 | | |
| Arthralgia | 2 | 4 | 2 | 4 | | |
| Asthenia | | 1 | | 1 | | |
| Axillary pain | | 1 | | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bone disorder | | 1 | | 1 | | |
| Bone neoplasm | | 1 | | 1 | | |
| Bone pain | | 1 | | 1 | | |
| Burning sensation | | 2 | | 2 | | |
| Chills | | 2 | | 2 | | |
| Decreased appetite | | 1 | | 1 | | |
| Diarrhoea | | 3 | | 3 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dry mouth | | 1 | | 1 | | |
| Dyskinesia | | 1 | | | | 1 |
| Dyspepsia | | 1 | | 1 | | |
| Dysphonia | | 1 | | 1 | | |
| Erythema | | 1 | | 1 | | |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 2 | | | 1 | 2 |
| Fatigue | 2 | 7 | 2 | 7 | | |
| Gingival bleeding | | 1 | | 1 | | |
| Haematoma | | 1 | | 1 | | |
| Headache | 5 | 14 | 5 | 14 | | |
| Heart rate decreased | | 1 | | | | 1 |
| Hypoaesthesia | 1 | 5 | 1 | 5 | | |
| Inappropriate schedule of product administration | 1 | 2 | 1 | 2 | | |
| Inflammation | | 1 | | 1 | | |
| Joint range of motion decreased | | 1 | | 1 | | |
| Loss of personal independence in daily activities | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphadenopathy | 1 | 3 | 1 | 3 | | |
| Malaise | | 1 | | 1 | | |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Migraine | | 1 | | | | 1 |
| Movement disorder | | 1 | | 1 | | |
| Muscle twitching | 1 | 1 | 1 | 1 | | |
| Myalgia | 4 | 6 | 4 | 6 | | |
| Nausea | 1 | 4 | 1 | 4 | | |
| Neck pain | | 1 | | 1 | | |
| Night sweats | | 1 | | | | 1 |
| Nodule | | 1 | | 1 | | |
| Off label use | | 2 | | 2 | | |
| Pain | 2 | 4 | 2 | 4 | | |
| Pain in extremity | | 5 | | 5 | | |
| Palpitations | | 1 | | 1 | | |
| Paraesthesia | 1 | 2 | 1 | 2 | | |
| Photophobia | | 1 | | 1 | | |
| Pruritus | | 1 | | 1 | | |
| Puncture site swelling | | 1 | | 1 | | |
| Pyrexia | 2 | 7 | 2 | 7 | | |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| Sinus arrhythmia | | 1 | | | | 1 |
| Speech disorder | | 1 | | 1 | | |
| Stress | 1 | 1 | 1 | 1 | | |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swelling face | | 1 | | 1 | | |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Taste disorder | | 2 | | 2 | | |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 3 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 4 | 6 | | |
| 1 | 4 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | 2 | | |
| 2 | 4 | | |
| | 5 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 2 | 7 | | |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |

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Gender

FEMALE

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|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site inflammation | | 1 | | 1 | | |
| Vaccination site pain | 2 | 6 | 2 | 6 | | |
| Vaccination site swelling | | 2 | | 2 | | |
| | 37 | 133 | 36 | 126 | 1 | 7 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Abdominal discomfort | | 1 | | 1 |
| Antibody test abnormal | 1 | 1 | 1 | 1 |
| Arthralgia | 1 | 2 | 1 | 2 |
| Blood test abnormal | 1 | 1 | 1 | 1 |
| Chills | | 1 | | 1 |
| Dehydration | 1 | 1 | 1 | 1 |
| Depression | | 1 | | 1 |
| Dizziness | 1 | 1 | 1 | 1 |
| Dyspnoea | | 1 | | 1 |
| Fatigue | 1 | 4 | 1 | 4 |
| Flatulence | 1 | 1 | 1 | 1 |
| Gait disturbance | | 1 | | 1 |
| Headache | 2 | 3 | 2 | 3 |
| Head discomfort | | 1 | | 1 |
| Hypertension | | 1 | | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| Limb discomfort | | 1 | | 1 |
| Lymphadenitis | 1 | 1 | 1 | 1 |
| Muscle spasms | | 1 | | 1 |
| Musculoskeletal stiffness | | 1 | | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Neuralgia | | 1 | | 1 |
| Pain | 1 | 2 | 1 | 2 |
| Pain in extremity | 1 | 1 | 1 | 1 |
| Paraesthesia | | 1 | | 1 |
| Pyrexia | 1 | 3 | 1 | 3 |
| Rash | | 1 | | 1 |
| Tachycardia | | 1 | | 1 |
| Thirst | 1 | 1 | 1 | 1 |
| | 16 | 38 | 16 | 38 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Chills | | 1 | | 1 |
| Poor quality product administered | 10 | 10 | 10 | 10 |
| Pyrexia | | 1 | | 1 |
| | 10 | 12 | 10 | 12 |

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Country Where Event Occurred

QATAR

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | | 1 | | | | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspepsia | 2 | 2 | 2 | 2 | | |
| Erythema | | 1 | | | | 1 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Mood altered | 1 | 1 | 1 | 1 | | |
| Nausea | | 1 | | | | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| | 6 | 9 | 6 | 6 | | 3 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Myalgia | | 1 | | 1 | | |
| Overdose | | 1 | | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product preparation error | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| | 9 | 12 | 3 | 6 | 6 | 6 |

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Country Where Event Occurred

ROMANIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Administration site pain | 1 | 1 | | | 1 | 1 |
| Ageusia | | 1 | | 1 | | |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Angle closure glaucoma | | 1 | | | | 1 |
| Anosmia | | 1 | | 1 | | |
| Anxiety | | 3 | | 1 | | 2 |
| Arthralgia | 9 | 16 | 3 | 8 | 6 | 8 |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthenia | 7 | 15 | 3 | 10 | 4 | 5 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrioventricular block | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 2 | 1 | 2 | | |
| Balance disorder | | 1 | | | | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 3 | 3 | | | 3 | 3 |
| Body temperature abnormal | 1 | 1 | 1 | 1 | | |
| Bone pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Breast pain | | 1 | | 1 | | |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Cardiac fibrillation | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 3 | | 2 | 1 | 1 |
| Chest pain | 3 | 4 | | | 3 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chills | 17 | 31 | 8 | 20 | 9 | 11 |
| Circumoral oedema | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | 1 | 1 | | |
| Cough | 3 | 5 | | | 3 | 5 |
| COVID-19 | 12 | 18 | | | 12 | 18 |
| Crying | | 1 | | 1 | | |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 2 | | 1 | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Dizziness | 9 | 12 | 4 | 7 | 5 | 5 |
| Drug eruption | 2 | 2 | | | 2 | 2 |
| Drug ineffective | 12 | 20 | | | 12 | 20 |
| Dry mouth | | 1 | | | | 1 |
| Dysgeusia | | 1 | | | | 1 |
| Dysphagia | | 1 | | | | 1 |
| Dysphonia | | 1 | | 1 | | |
| Dyspnoea | 6 | 8 | 1 | 1 | 5 | 7 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Emotional distress | | 1 | | 1 | | |
| Epiglottic oedema | | 1 | | | | 1 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Erythema | 6 | 10 | 2 | 5 | 4 | 5 |
| Erythema nodosum | 1 | 2 | | 1 | 1 | 1 |
| Exposure during pregnancy | | 1 | | 1 | | |
| Extensive swelling of vaccinated limb | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |
| Eyelid ptosis | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 8 | 20 | 9 | 11 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 5 |
| | | 12 | 18 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| 4 | 7 | 5 | 5 |
| | | 2 | 2 |
| | | 12 | 20 |
| | | | 1 |
| | | | 1 |
| | 1 | | |
| 1 | 1 | 5 | 7 |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| 2 | 5 | 4 | 5 |
| | 1 | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Face oedema | 2 | 2 |
| Facial neuralgia | 1 | 1 |
| Facial paralysis | 2 | 5 |
| Faeces soft | 1 | 1 |
| Fatigue | 5 | 16 |
| Fear | | 1 |
| Feeling abnormal | 1 | 1 |
| Feeling cold | | 1 |
| Feeling hot | | 1 |
| Flushing | | 1 |
| Foaming at mouth | 1 | 1 |
| General physical health deterioration | | 1 |
| Headache | 26 | 45 |
| Heart rate increased | 6 | 6 |
| Hot flush | 1 | 1 |
| Hyperaemia | 1 | 1 |
| Hyperhidrosis | 4 | 6 |
| Hyperpyrexia | 1 | 1 |
| Hypersensitivity | 3 | 4 |
| Hypertension | 7 | 12 |
| Hypertensive crisis | | 1 |
| Hypoaesthesia | 4 | 5 |
| Hypocalcaemia | | 1 |
| Hypokinesia | 1 | 1 |
| Hypotension | 3 | 3 |
| Illness | 1 | 1 |
| Incorrect route of product administration | 2 | 2 |
| Inflammation | 1 | 2 |
| Influenza like illness | | 1 |
| Injected limb mobility decreased | 2 | 4 |
| Insomnia | 1 | 1 |
| Intracranial pressure increased | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 5 |
| | | 1 | 1 |
| 2 | 11 | 3 | 5 |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 8 | 24 | 18 | 21 |
| | | 6 | 6 |
| 1 | 1 | | |
| | | 1 | 1 |
| 2 | 3 | 2 | 3 |
| | | 1 | 1 |
| 1 | 2 | 2 | 2 |
| 1 | 1 | 6 | 11 |
| | | | 1 |
| 2 | 2 | 2 | 3 |
| | | | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 2 | | |
| | 1 | | |
| 1 | 3 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

FEMALE

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|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint ankylosis | | 1 | | | | 1 |
| Laryngeal oedema | | 1 | | | | 1 |
| Limb injury | | 1 | | | | 1 |
| Lipase increased | 1 | 1 | 1 | 1 | | |
| Lip oedema | 3 | 6 | | 2 | 3 | 4 |
| Lip swelling | | 1 | | | | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 5 | 10 | | 5 | 5 | 5 |
| Lymph node pain | | 1 | | 1 | | |
| Malaise | 4 | 7 | 1 | 4 | 3 | 3 |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Memory impairment | 1 | 1 | | | 1 | 1 |
| Migraine | | 2 | | 1 | | 1 |
| Monoplegia | 1 | 1 | | | 1 | 1 |
| Muscle contractions involuntary | | 1 | | 1 | | |
| Musculoskeletal chest pain | 1 | 1 | | | 1 | 1 |
| Myalgia | 16 | 34 | 3 | 19 | 13 | 15 |
| Myoclonus | 1 | 1 | | | 1 | 1 |
| Nasal discomfort | 1 | 2 | 1 | 2 | | |
| Nasal dryness | 1 | 1 | | | 1 | 1 |
| Nasal oedema | | 1 | | | | 1 |
| Nausea | 12 | 22 | 5 | 13 | 7 | 9 |
| Nephropathy | 1 | 1 | | | 1 | 1 |
| Nervous system disorder | 2 | 2 | 2 | 2 | | |
| Nystagmus | | 1 | | 1 | | |
| Odynophagia | | 1 | | 1 | | |
| Oedema peripheral | | 1 | | | | 1 |
| Oedematous pancreatitis | 1 | 1 | | | 1 | 1 |
| Off label use | | 1 | | 1 | | |
| Oropharyngeal discomfort | 1 | 2 | | | 1 | 2 |
| Overdose | 1 | 1 | 1 | 1 | | |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | | 1 |
| | | | 1 |
| 1 | 1 | | |
| | 2 | 3 | 4 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 5 | 5 | 5 |
| | 1 | | |
| 1 | 4 | 3 | 3 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | 1 |
| | | 1 | 1 |
| | 1 | | |
| 3 | 19 | 13 | 15 |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 1 |
| | | | 1 |
| 5 | 13 | 7 | 9 |
| | | 1 | 1 |
| 2 | 2 | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 2 |
| 1 | 1 | | |

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Gender

FEMALE

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Pain | 1 | 6 | 1 | 6 | | |
| Pain in extremity | 1 | 17 | 1 | 16 | | 1 |
| Palpitations | | 2 | | | | 2 |
| Paraesthesia | 9 | 11 | 4 | 5 | 5 | 6 |
| Paraesthesia oral | | 1 | | 1 | | |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Paraplegia | 1 | 1 | | | 1 | 1 |
| Parosmia | 1 | 1 | 1 | 1 | | |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | | 1 | | 1 | | |
| Polyuria | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 3 | 1 | 3 | | |
| Product use issue | | 1 | | 1 | | |
| Pruritus | 4 | 8 | 1 | 4 | 3 | 4 |
| Pulse abnormal | 2 | 2 | 1 | 1 | 1 | 1 |
| Pyrexia | 18 | 33 | 7 | 22 | 11 | 11 |
| Rash | 3 | 8 | | 5 | 3 | 3 |
| Rash erythematous | 1 | 3 | | | 1 | 3 |
| Rash pruritic | 2 | 3 | | 1 | 2 | 2 |
| Raynaud's phenomenon | 1 | 1 | | | 1 | 1 |
| Renal pain | 2 | 2 | | | 2 | 2 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Rhinalgia | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 3 | 4 | 1 | 1 | 2 | 3 |
| Scar pain | | 1 | | 1 | | |
| Seizure | | 1 | | | | 1 |
| Sensory loss | 1 | 1 | 1 | 1 | | |
| Sinus tachycardia | 2 | 2 | | | 2 | 2 |
| Skin plaque | 1 | 1 | | | 1 | 1 |
| Somnolence | 3 | 7 | 1 | 5 | 2 | 2 |

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Gender

FEMALE

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|--------------------------------------|------------------------------------|--------------------------------------|
| Speech disorder | 1 | 1 |
| Spinal pain | | 1 |
| Suffocation feeling | 1 | 1 |
| Suppressed lactation | | 1 |
| Suspected COVID-19 | | 1 |
| Swelling | 1 | 1 |
| Syncope | 3 | 3 |
| Systolic hypertension | | 1 |
| Tachycardia | 7 | 12 |
| Taste disorder | 1 | 1 |
| Thirst | | 1 |
| Tinnitus | 1 | 1 |
| Tongue oedema | | 1 |
| Tongue spasm | 1 | 1 |
| Tremor | 1 | 2 |
| Urticaria | 4 | 5 |
| Urticaria papular | | 1 |
| Vaccination failure | 1 | 1 |
| Vaccination site erythema | 4 | 6 |
| Vaccination site induration | 1 | 3 |
| Vaccination site inflammation | 1 | 1 |
| Vaccination site lymphadenopathy | | 2 |
| Vaccination site movement impairment | | 3 |
| Vaccination site pain | 20 | 41 |
| Vaccination site paraesthesia | 1 | 1 |
| Vaccination site pruritus | 1 | 2 |
| Vaccination site reaction | 4 | 5 |
| Vaccination site swelling | 2 | 3 |
| Ventricular extrasystoles | | 1 |
| Vertigo | 6 | 8 |
| Vestibular disorder | | 1 |
| Visual impairment | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | | 1 |
| 3 | 5 | 4 | 7 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | 1 | 4 | 4 |
| | 1 | | |
| | | 1 | 1 |
| 2 | 4 | 2 | 2 |
| | 2 | 1 | 1 |
| | | 1 | 1 |
| | 2 | | |
| | 3 | | |
| 9 | 30 | 11 | 11 |
| 1 | 1 | | |
| 1 | 2 | | |
| 4 | 5 | | |
| 2 | 3 | | |
| | 1 | | |
| | 1 | 6 | 7 |
| | 1 | | |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 5 | 8 | 1 | 3 | 4 | 5 |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 397 | 703 | 112 | 331 | 285 | 372 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 2 | | 1 | | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | | 1 | | 1 | | |
| Angina pectoris | | 1 | | | | 1 |
| Anosmia | | 1 | | | | 1 |
| Anxiety | | 3 | | 3 | | |
| Arthralgia | 1 | 3 | | 2 | 1 | 1 |
| Asthenia | 1 | 3 | | 2 | 1 | 1 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Back pain | | 2 | | 2 | | |
| Blood pressure increased | | 1 | | 1 | | |
| Body temperature abnormal | | 1 | | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| Chills | 4 | 10 | | 6 | 4 | 4 |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| COVID-19 | 8 | 12 | | | 8 | 12 |
| Diarrhoea | | 1 | | 1 | | |
| Disturbance in attention | | 1 | | 1 | | |
| Dizziness | 2 | 6 | | 4 | 2 | 2 |
| Drug ineffective | 10 | 16 | | | 10 | 16 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Ear pain | | 1 | | 1 | | |
| Erythema | 1 | 4 | | 3 | 1 | 1 |
| Eyelid oedema | | 1 | | 1 | | |
| Eyelid ptosis | 1 | 1 | 1 | 1 | | |
| Facial pain | | 1 | | 1 | | |
| Fatigue | 2 | 8 | 1 | 7 | 1 | 1 |
| Feeling abnormal | | 1 | | 1 | | |
| General physical health deterioration | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 13 | 1 | 12 | 1 | 1 |

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Gender

MALE

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|---|------------------------------------|--------------------------------------|
| Horner's syndrome | | 1 |
| Hyperhidrosis | | 2 |
| Hypersensitivity | | 1 |
| Hyperthermia | | 1 |
| Hypoaesthesia | | 1 |
| Hypotension | 1 | 1 |
| Incorrect route of product administration | | 1 |
| Insomnia | | 1 |
| Localised oedema | 1 | 1 |
| Lymphadenopathy | | 2 |
| Malaise | | 1 |
| Medication error | | 1 |
| Muscle swelling | | 1 |
| Muscular weakness | | 2 |
| Myalgia | 3 | 9 |
| Nausea | 2 | 4 |
| Nervous system disorder | 1 | 1 |
| No adverse event | 1 | 1 |
| Oedema | | 1 |
| Off label use | | 1 |
| Pain | | 1 |
| Pain in extremity | | 5 |
| Pallor | 1 | 1 |
| Panic attack | | 2 |
| Paraesthesia | 1 | 6 |
| Paraesthesia ear | | 1 |
| Presyncope | | 1 |
| Product preparation issue | | 1 |
| Product use issue | | 1 |
| Pruritus | 1 | 2 |
| Pyrexia | 5 | 13 |
| Rash | | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 6 | 3 | 3 |
| | 2 | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 5 | | |
| 1 | 1 | | |
| | 2 | | |
| | 5 | 1 | 1 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | 1 | 1 |
| 1 | 9 | 4 | 4 |
| | 2 | | |

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Gender

MALE

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|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test negative | 2 | 2 | 2 | 2 | | |
| SARS-CoV-2 test positive | | 2 | | | | 2 |
| Skin discolouration | | 1 | | 1 | | |
| Skin irritation | 1 | 1 | | | 1 | 1 |
| Somnolence | | 1 | | 1 | | |
| Suspected COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| Syncope | 2 | 3 | | | 2 | 3 |
| Syringe issue | | 1 | | 1 | | |
| Tongue disorder | | 1 | | 1 | | |
| Transaminases increased | | 1 | | 1 | | |
| Tremor | | 1 | | 1 | | |
| Urticaria | | 2 | | 2 | | |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 17 | 3 | 17 | | |
| Vertigo | | 1 | | 1 | | |
| Wrong technique in product usage process | | 2 | | 2 | | |
| | 69 | 214 | 17 | 145 | 52 | 69 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | | 5 | | 5 | | |
| Blood pressure abnormal | | 1 | | 1 | | |
| Chills | | 1 | | 1 | | |
| Circumstance or information capable of leading to medication error | | 3 | | 3 | | |
| Cough | | 1 | | 1 | | |
| COVID-19 | 8 | 9 | 1 | 1 | 7 | 8 |
| Drug ineffective | 8 | 13 | 1 | 1 | 7 | 12 |
| Erythema | | 3 | | 3 | | |
| Exposure via breast milk | 1 | 1 | 1 | 1 | | |
| Fatigue | | 1 | | 1 | | |
| Feeling cold | | 1 | | 1 | | |
| Feeling hot | | 1 | | 1 | | |
| Headache | | 3 | | 3 | | |
| Heart rate increased | | 1 | | 1 | | |
| Incorrect route of product administration | | 1 | | 1 | | |
| Injected limb mobility decreased | | 1 | | 1 | | |
| Intercepted medication error | | 1 | | 1 | | |
| Lymphadenopathy | | 2 | | 2 | | |
| Malaise | | 1 | | 1 | | |
| Medication error | | 2 | | 2 | | |
| Myalgia | | 2 | | 2 | | |
| Nausea | | 1 | | 1 | | |
| Off label use | | 1 | | 1 | | |
| Pain | | 1 | | 1 | | |
| Pain in extremity | | 6 | | 6 | | |
| Paraesthesia | | 1 | | 1 | | |
| Product preparation error | | 11 | | 11 | | |
| Product preparation issue | | 5 | | 5 | | |
| Product quality issue | | 1 | | 1 | | |
| Pyrexia | | 9 | | 9 | | |
| SARS-CoV-2 ant body test negative | 2 | 2 | 2 | 2 | | |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test negative | | 1 | | 1 | | |
| SARS-CoV-2 test positive | | 4 | | | | 4 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Underdose | | 1 | | 1 | | |
| Vaccination site discomfort | | 3 | | 3 | | |
| Vaccination site erythema | | 12 | | 12 | | |
| Vaccination site inflammation | | 1 | | 1 | | |
| Vaccination site nodule | | 1 | | 1 | | |
| Vaccination site pain | | 16 | | 16 | | |
| Vaccination site warmth | | 1 | | 1 | | |
| Wrong technique in product usage process | 1 | 11 | 1 | 11 | | |
| | 23 | 146 | 7 | 120 | 16 | 26 |

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Country Where Event Occurred

SAUDI ARABIA

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 3 | 2 | 3 | | |
| Hyperhidrosis | 1 | 2 | 1 | 2 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Mastication disorder | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 2 | 2 | 2 | 2 | | |
| Mouth ulceration | | 1 | | 1 | | |
| Movement disorder | | 1 | | 1 | | |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | 1 | 2 | 1 | 2 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Pain in jaw | 1 | 1 | 1 | 1 | | |
| Pain of skin | | 1 | | 1 | | |
| Pyrexia | 1 | 2 | 1 | 2 | | |
| Sciatica | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | |
| Vaginal infection | | 1 | | 1 | | |
| | 23 | 34 | 22 | 33 | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Arthralgia | | 1 | | 1 | | |
| Asthenia | 1 | 1 | 1 | 1 | | |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Dizziness | | 1 | | 1 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Fatigue | | 3 | | 3 | | |
| Headache | | 1 | | 1 | | |
| Herpes zoster | | 1 | | 1 | | |
| Hyperhidrosis | | 1 | | 1 | | |
| Hypotension | | 1 | | | | 1 |
| Injection site pain | | 1 | | 1 | | |
| Malaise | | 1 | | 1 | | |
| Mobility decreased | 2 | 2 | 2 | 2 | | |
| Myalgia | | 1 | | 1 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Pain | 2 | 3 | 2 | 3 | | |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | | 1 | | 1 | | |
| Pollakiuria | | 1 | | 1 | | |
| Pyrexia | 1 | 3 | 1 | 3 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| Sciatica | 1 | 1 | 1 | 1 | | |
| Syncope | | 1 | | | | 1 |
| Vaccination site pain | 1 | 3 | 1 | 3 | | |
| | 12 | 35 | 8 | 29 | 4 | 6 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 1 | 1 | 1 | 1 |
| Asthenia | 1 | 1 | 1 | 1 |
| C-reactive protein increased | 1 | 1 | 1 | 1 |
| Fatigue | | 1 | | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Pain in extremity | 1 | 2 | 1 | 2 |
| Peripheral coldness | 1 | 1 | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 |
| | 9 | 11 | 9 | 11 |

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Country Where Event Occurred

SERBIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | | 1 | | 1 | | |
| Anaphylactoid reaction | | 1 | | | | 1 |
| Anosmia | | 1 | | 1 | | |
| Anxiety | | 1 | | 1 | | |
| Arthralgia | 3 | 7 | 3 | 7 | | |
| Asphyxia | | 1 | | | | 1 |
| Asthenia | | 4 | | 4 | | |
| Axillary pain | | 1 | | 1 | | |
| Back pain | | 1 | | 1 | | |
| Blood pressure increased | | 1 | | 1 | | |
| Body temperature increased | 1 | 3 | 1 | 3 | | |
| Bone pain | | 1 | | 1 | | |
| Bronchospasm | | 1 | | | | 1 |
| Burning sensation | | 1 | | 1 | | |
| Chest pain | | 1 | | 1 | | |
| Chills | | 3 | | 3 | | |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Cough | | 1 | | | | 1 |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| Decreased appetite | | 1 | | 1 | | |
| Disease recurrence | | 1 | | 1 | | |
| Dizziness | | 1 | | 1 | | |
| Dry mouth | | 1 | | 1 | | |
| Erythema | 1 | 4 | 1 | 4 | | |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Eyelid ptosis | 1 | 1 | 1 | 1 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fall | | 1 | | 1 | | |
| Fatigue | | 3 | | 3 | | |
| Fear of death | | 1 | | 1 | | |
| Feeling cold | | 1 | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Headache | 5 | 9 |
| Herpes zoster | | 1 |
| Huntington's disease | | 1 |
| Hyperhidrosis | | 1 |
| Hypersensitivity | | 1 |
| Hypertension | 1 | 3 |
| Inflammatory marker increased | | 1 |
| Influenza like illness | | 1 |
| Insomnia | | 1 |
| Joint stiffness | 1 | 1 |
| Malaise | 1 | 4 |
| Muscular weakness | | 1 |
| Musculoskeletal stiffness | 1 | 1 |
| Myalgia | 2 | 8 |
| Nausea | | 2 |
| Oedema mucosal | | 1 |
| Oedema peripheral | | 1 |
| Oropharyngeal pain | | 1 |
| Pain | 1 | 1 |
| Pain in extremity | | 5 |
| Pallor | 1 | 1 |
| Palpitations | | 1 |
| Paraesthesia | | 1 |
| Pruritus | | 1 |
| Pyrexia | 5 | 17 |
| Rash | | 2 |
| Rash macular | | 2 |
| SARS-CoV-2 test positive | | 1 |
| Sleep disorder | | 1 |
| Superficial vein prominence | | 1 |
| Swelling | 1 | 1 |
| Swelling of eyelid | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 5 | 9 | | |
| | 1 | | |
| | | | 1 |
| | 1 | | |
| | | | 1 |
| 1 | 2 | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 4 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 8 | | |
| | 2 | | |
| | | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| 5 | 17 | | |
| | 1 | | 1 |
| | | | 2 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | | 1 | | | | 1 |
| Tinnitus | | 1 | | 1 | | |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination complication | 2 | 2 | 2 | 2 | | |
| Vaccination site erythema | 1 | 2 | 1 | 2 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site oedema | 1 | 2 | 1 | 2 | | |
| Vaccination site pain | 2 | 8 | 2 | 8 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| | 39 | 146 | 36 | 131 | 3 | 15 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abscess | | 1 | | | | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | | 1 | | 1 | | |
| Axillary pain | | 1 | | | | 1 |
| Body temperature increased | | 2 | | 1 | | 1 |
| Bone pain | | 1 | | 1 | | |
| Bronchospasm | 1 | 1 | 1 | 1 | | |
| Chest discomfort | | 1 | | 1 | | |
| Chills | 1 | 2 | 1 | 1 | | 1 |
| Confusional state | | 1 | | 1 | | |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Fatigue | | 2 | | 2 | | |
| Headache | 3 | 5 | 2 | 4 | 1 | 1 |
| Hyperhidrosis | 1 | 2 | 1 | 2 | | |
| Hypersensitivity | | 1 | | 1 | | |
| Intraocular pressure increased | | 1 | | | | 1 |
| Loss of consciousness | | 1 | | | | 1 |
| Lymphadenitis | | 1 | | | | 1 |
| Lymphadenopathy | | 2 | | 1 | | 1 |
| Malaise | 4 | 5 | 4 | 5 | | |
| Monocyte count increased | | 1 | | 1 | | |
| Muscular weakness | | 1 | | 1 | | |
| Myalgia | 2 | 3 | 1 | 2 | 1 | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nausea | 2 | 7 | 1 | 6 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Pain | | 1 | | | | 1 |
| Pain in extremity | | 2 | | 2 | | |
| Pain in jaw | | 1 | | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pancreatitis acute | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | | 1 | | | | 1 |
| Phlebitis | | 1 | | | | 1 |
| Pyrexia | 3 | 9 | 2 | 7 | 1 | 2 |
| Rash | | 1 | | 1 | | |
| Skin reaction | | 1 | | | | 1 |
| Swelling | | 1 | | | | 1 |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Urticaria | | 1 | | 1 | | |
| Vaccination site haematoma | | 1 | | | | 1 |
| Vaccination site pain | 1 | 6 | 1 | 6 | | |
| Vomiting | | 2 | | 2 | | |
| | 27 | 81 | 20 | 59 | 7 | 22 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Nausea | 1 | 1 | | | 1 | 1 |
| Pyrexia | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 7 | 7 | 4 | 4 | 3 | 3 |

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Country Where Event Occurred
SINGAPORE

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | | 2 | | | | 2 |
| Anaphylactic shock | | 3 | | | | 3 |
| Angioedema | | 1 | | | | 1 |
| Chest discomfort | | 1 | | | | 1 |
| Chills | | 1 | | 1 | | |
| Cough | | 2 | | 1 | | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Dizziness | | 1 | | | | 1 |
| Dysphonia | | 1 | | 1 | | |
| Dyspnoea | | 2 | | 1 | | 1 |
| Enlarged uvula | | 1 | | 1 | | |
| Head discomfort | | 1 | | 1 | | |
| Heart rate increased | | 1 | | 1 | | |
| Hypertension | | 1 | | 1 | | |
| Lip swelling | | 1 | | | | 1 |
| Malaise | | 1 | | 1 | | |
| Palpitations | | 1 | | 1 | | |
| Pruritus | | 1 | | | | 1 |
| Rash macular | | 1 | | | | 1 |
| Urticaria | | 2 | | 1 | | 1 |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | 1 | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 2 | 29 | 2 | 15 | | 14 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Abdominal pain | | 1 | | 1 |
| Anaphylactic shock | | 1 | | 1 |
| Angioedema | | 1 | | 1 |
| Diarrhoea | | 1 | | 1 |
| Dysphonia | | 1 | | 1 |
| Enlarged uvula | | 1 | | 1 |
| Lip swelling | | 1 | | 1 |
| Nausea | | 1 | | 1 |
| Palpitations | | 1 | | 1 |
| Periorbital swelling | | 1 | | 1 |
| Rash macular | | 1 | | 1 |
| Throat tightness | | 1 | | 1 |
| | | 12 | | 12 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Anaphylactic shock | | 1 | | | | 1 |
| Chills | | 1 | | 1 | | |
| Eye swelling | | 1 | | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Urticaria | | 1 | | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 3 | 8 | 3 | 7 | | 1 |

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Country Where Event Occurred

SLOVAKIA

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Gender

FEMALE

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|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal dreams | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 3 | 3 | 3 | | |
| Asthenia | 9 | 10 | 8 | 9 | 1 | 1 |
| Axillary pain | | 1 | | 1 | | |
| Axillary vein thrombosis | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Body temperature increased | 2 | 3 | 2 | 3 | | |
| Burning sensation | 1 | 2 | 1 | 2 | | |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 2 | 2 | 2 | | |
| Chills | 9 | 14 | 7 | 12 | 2 | 2 |
| Cough | | 2 | | 2 | | |
| COVID-19 | 2 | 6 | | 2 | 2 | 4 |
| Diplopia | | 1 | | 1 | | |
| Dizziness | 4 | 6 | 3 | 5 | 1 | 1 |
| Drug ineffective | 1 | 3 | | | 1 | 3 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | 1 | 2 | | |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Erythema | 2 | 2 | 2 | 2 | | |
| Eye allergy | 1 | 1 | 1 | 1 | | |
| Eye irritation | 1 | 1 | 1 | 1 | | |
| Eye oedema | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Fatigue | 5 | 6 | 5 | 6 | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 10 | 14 | 10 | 14 | | |
| Hot flush | 3 | 3 | 2 | 2 | 1 | 1 |

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Gender

FEMALE

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|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hyperhidrosis | 3 | 4 | 1 | 2 | 2 | 2 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypertension | 2 | 4 | 1 | 3 | 1 | 1 |
| Hypoaesthesia | | 1 | | 1 | | |
| Influenza like illness | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Insulin resistance | 1 | 1 | | | 1 | 1 |
| Limb discomfort | | 1 | | 1 | | |
| Lip oedema | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | 2 | 2 | | | 2 | 2 |
| Lymphadenopathy | | 2 | | 2 | | |
| Malaise | 3 | 3 | 3 | 3 | | |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Movement disorder | 1 | 1 | 1 | 1 | | |
| Myalgia | 5 | 6 | 5 | 6 | | |
| Myocardial ischaemia | 1 | 1 | | | 1 | 1 |
| Nausea | 5 | 5 | 3 | 3 | 2 | 2 |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Oedema | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | 1 | 1 | 1 | 1 | | |
| Oral discomfort | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | | 1 | | 1 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Pain in extremity | 6 | 10 | 6 | 10 | | |
| Palpitations | 1 | 2 | 1 | 2 | | |
| Paraesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Presyncope | 3 | 3 | 1 | 1 | 2 | 2 |
| Product administered at inappropriate site | 1 | 1 | 1 | 1 | | |
| Pruritus | 3 | 3 | 3 | 3 | | |
| Pyrexia | 6 | 10 | 5 | 9 | 1 | 1 |
| Rash | 2 | 2 | 2 | 2 | | |

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Gender

FEMALE

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|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Restlessness | 1 | 1 | | | 1 | 1 |
| Rhinitis | | 1 | | 1 | | |
| SARS-CoV-2 ant body test positive | | 1 | | | | 1 |
| SARS-CoV-2 test positive | | 1 | | | | 1 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Subclavian vein thrombosis | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 2 | | | 1 | 2 |
| Synovitis | 1 | 1 | 1 | 1 | | |
| Tachycardia | | 1 | | 1 | | |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat irritation | 1 | 2 | 1 | 2 | | |
| Throat tightness | | 1 | | 1 | | |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 1 | | | 1 | 1 |
| Tryptase decreased | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site joint movement impairment | | 1 | | 1 | | |
| Vaccination site pain | 12 | 16 | 12 | 16 | | |
| Venous thrombosis limb | 1 | 1 | | | 1 | 1 |
| Vertigo | 2 | 2 | 2 | 2 | | |
| Vomiting | 1 | 2 | | 1 | 1 | 1 |
| | 155 | 213 | 117 | 168 | 38 | 45 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Asthenia | 4 | 4 | 2 | 2 | 2 | 2 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | | | 2 | 2 |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 6 | 7 | 5 | 6 | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 | 1 | 1 | | |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Dizziness | 2 | 2 | 1 | 1 | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 1 | 1 | 1 | | |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Incorrect dose administered | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Medication error | 1 | 1 | 1 | 1 | | |
| Micturition urgency | 1 | 1 | | | 1 | 1 |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Mydriasis | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Pain in extremity | | 1 | | 1 | | |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Paraesthesia | 2 | 2 | 1 | 1 | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Petechiae | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Pyrexia | 5 | 5 | 4 | 4 | 1 | 1 |
| Rash | | 1 | | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| SARS-CoV-2 test positive | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vaccination site urticaria | | 1 | | 1 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 58 | 66 | 38 | 46 | 20 | 20 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Body temperature increased | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Erythema | | 1 | | 1 |
| Headache | | 1 | | 1 |
| Paraesthesia | | 1 | | 1 |
| Pruritus | | 1 | | 1 |
| Vaccination site pain | | 1 | | 1 |
| Vaccination site swelling | | 1 | | 1 |
| | | 8 | | 8 |

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Country Where Event Occurred
SLOVENIA

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 3 | 3 | 3 | 3 | | |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | | 2 | | 2 | | |
| Aura | 1 | 1 | 1 | 1 | | |
| Autoimmune thyroiditis | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Blindness unilateral | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 3 | 3 | 3 | 3 | | |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | 4 | 4 | | |
| Death | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 4 | 4 | 4 | 4 | | |
| Disease recurrence | | 1 | | | | 1 |
| Dizziness | 3 | 3 | 2 | 2 | 1 | 1 |
| Dysgeusia | 2 | 2 | 2 | 2 | | |
| Ear pain | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fatigue | 11 | 12 | 9 | 10 | 2 | 2 |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Headache | 11 | 11 | 10 | 10 | 1 | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Hypertension | 1 | 2 | | | 1 | 2 |
| Hypoesthesia | 1 | 1 | 1 | 1 | | |
| Hyposmia | 2 | 2 | 2 | 2 | | |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Lymphadenitis | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Lymphadenopathy | 4 | 4 |
| Malaise | 3 | 3 |
| Myalgia | 4 | 4 |
| Nasopharyngitis | 2 | 2 |
| Nausea | 3 | 4 |
| Neurological symptom | 1 | 1 |
| Off label use | 1 | 1 |
| Oral herpes | 1 | 1 |
| Pain | 1 | 1 |
| Pain in extremity | 1 | 1 |
| Paraesthesia | 2 | 2 |
| Paraesthesia oral | 2 | 2 |
| Peripheral coldness | 1 | 1 |
| Pyrexia | 5 | 5 |
| Rash pruritic | 2 | 2 |
| Restlessness | 1 | 1 |
| Sensory disturbance | 1 | 1 |
| Somnolence | 5 | 5 |
| Speech disorder | 1 | 1 |
| Suffocation feeling | 1 | 1 |
| Syncope | 1 | 1 |
| Tachycardia | 2 | 2 |
| Thinking abnormal | 1 | 1 |
| Throat tightness | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 |
| Vaccination site erythema | 9 | 10 |
| Vaccination site oedema | 3 | 4 |
| Vaccination site pain | 31 | 32 |
| Vaccination site pruritus | 3 | 3 |
| Vertigo | 1 | 2 |
| Vomiting | 2 | 3 |
| White blood cell count increased | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 4 | | |
| 3 | 3 | | |
| 4 | 4 | | |
| 2 | 2 | | |
| 2 | 2 | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| 4 | 4 | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 9 | 10 | | |
| 3 | 4 | | |
| 29 | 30 | 2 | 2 |
| 3 | 3 | | |
| | | 1 | 2 |
| 2 | 2 | | 1 |
| | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 161 | 174 | 137 | 144 | 24 | 30 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrial tachycardia | 1 | 1 | | | 1 | 1 |
| B-cell lymphoma | 1 | 1 | | | 1 | 1 |
| B-cell type acute leukaemia | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | | 1 | | | | 1 |
| Cerebral thrombosis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Headache | 3 | 3 | 2 | 2 | 1 | 1 |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 2 | | | 2 | 2 |
| Miosis | 1 | 1 | | | 1 | 1 |
| Myalgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Skin disorder | 1 | 1 | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sudden death | | 1 | | | | 1 |
| Syncope | 2 | 2 | | | 2 | 2 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Tongue biting | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 4 | 4 | 3 | 3 | 1 | 1 |
| | 47 | 49 | 6 | 6 | 41 | 43 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 1 | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 |
| Nightmare | 1 | 1 | 1 | 1 |
| Wrong technique in product usage process | | 1 | | 1 |
| | 3 | 4 | 3 | 4 |

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Country Where Event Occurred

SPAIN

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 3 | 6 | | 2 | 3 | 4 |
| Abdominal pain upper | 2 | 3 | 1 | 2 | 1 | 1 |
| Acute kidney injury | 2 | 2 | | | 2 | 2 |
| Acute leukaemia | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 2 | 5 | | | 2 | 5 |
| Ageusia | 2 | 2 | | | 2 | 2 |
| Allergic oedema | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 4 | 4 | | | 4 | 4 |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anal sphincter atony | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 28 | 30 | | | 28 | 30 |
| Anaphylactic shock | 2 | 4 | | | 2 | 4 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Angioedema | 17 | 18 | | | 17 | 18 |
| Angular cheilitis | | 1 | | 1 | | |
| Anosmia | 2 | 2 | | | 2 | 2 |
| Anxiety | 2 | 4 | 2 | 4 | | |
| Aortic dissection | 1 | 1 | | | 1 | 1 |
| Aphasia | 3 | 3 | | | 3 | 3 |
| Aphonia | 2 | 2 | | | 2 | 2 |
| Aphthous ulcer | 1 | 2 | | 1 | 1 | 1 |
| Appendicitis | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 17 | 23 | 5 | 10 | 12 | 13 |
| Asphyxia | 2 | 2 | | | 2 | 2 |
| Asthenia | 24 | 27 | 6 | 9 | 18 | 18 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Asthma | 2 | 2 | | | 2 | 2 |
| Asymptomatic COVID-19 | 5 | 5 | | | 5 | 5 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 2 | 2 | | | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Atrophic glossitis | 1 | 1 | | | 1 | 1 |
| Autoantibody negative | 1 | 1 | | | 1 | 1 |
| Autoimmune demyelinating disease | 1 | 1 | | | 1 | 1 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 6 | 6 | 3 | 3 | 3 | 3 |
| Balance disorder | 4 | 5 | | 1 | 4 | 4 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood fibrinogen increased | 1 | 1 | 1 | 1 | | |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure diastolic decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 7 | 7 | 6 | 6 | 1 | 1 |
| Blood pressure systolic increased | 1 | 1 | 1 | 1 | | |
| Body temperature abnormal | 1 | 1 | | | 1 | 1 |
| Body temperature increased | | 1 | | 1 | | |
| Brachial plexus injury | 1 | 1 | | | 1 | 1 |
| Bradycardia | 4 | 4 | | | 4 | 4 |
| Bradykinesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Bradyphrenia | 3 | 3 | 1 | 1 | 2 | 2 |
| Breast oedema | 1 | 1 | | | 1 | 1 |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Bronchial hyperreactivity | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 8 | 8 | | | 8 | 8 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Burning sensation mucosal | | 1 | | 1 | | |
| Butterfly rash | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 2 | 2 | | | 2 | 2 |
| Cardiac failure acute | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory distress | | 1 | | | | 1 |
| Carotid bruit | 2 | 2 | | | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| 3 | 3 | 3 | 3 |
| | 1 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 6 | 6 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 8 | 8 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cellulitis | 3 | 3 | | | 3 | 3 |
| Cerebrovascular accident | 3 | 3 | | | 3 | 3 |
| Cheilitis | 3 | 3 | | | 3 | 3 |
| Chest discomfort | 10 | 11 | 1 | 1 | 9 | 10 |
| Chest pain | 9 | 12 | 2 | 4 | 7 | 8 |
| Chills | 16 | 23 | 5 | 12 | 11 | 11 |
| Choking sensation | 2 | 2 | | | 2 | 2 |
| Circumoral swelling | | 1 | | 1 | | |
| Circumstance or information capable of leading to medication error | 1 | 1 | 1 | 1 | | |
| Citrobacter infection | 1 | 1 | | | 1 | 1 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| Condition aggravated | 2 | 2 | 1 | 1 | 1 | 1 |
| Confusional state | 3 | 3 | 1 | 1 | 2 | 2 |
| Conjunctival haemorrhage | 5 | 5 | | | 5 | 5 |
| Contusion | 2 | 2 | 1 | 1 | 1 | 1 |
| Cough | 12 | 14 | 1 | 3 | 11 | 11 |
| COVID-19 | 26 | 29 | 4 | 4 | 22 | 25 |
| COVID-19 pneumonia | 2 | 2 | | | 2 | 2 |
| C-reactive protein increased | 2 | 2 | 2 | 2 | | |
| Cyanosis | 2 | 2 | | | 2 | 2 |
| Deafness | 1 | 1 | | | 1 | 1 |
| Death | 2 | 3 | | | 2 | 3 |
| Decreased appetite | 2 | 2 | | | 2 | 2 |
| Deep vein thrombosis | 2 | 2 | | | 2 | 2 |
| Dehydration | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 6 | 6 | | | 6 | 6 |
| Depressed mood | | 1 | | 1 | | |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Dermatitis bullous | 2 | 2 | | | 2 | 2 |
| Diabetes mellitus | 1 | 1 | | | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--------------------------|--|--|
| Diarrhoea | 20 | 31 |
| Diarrhoea haemorrhagic | 1 | 1 |
| Diplopia | 1 | 1 |
| Discomfort | 3 | 6 |
| Disease recurrence | 1 | 1 |
| Disorientation | 1 | 1 |
| Disturbance in attention | 1 | 1 |
| Dizziness | 56 | 65 |
| Drug hypersensitivity | 2 | 2 |
| Drug ineffective | 20 | 23 |
| Drug interaction | | 1 |
| Dry mouth | 1 | 2 |
| Dry throat | 1 | 2 |
| Dysaesthesia | 2 | 2 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 3 | 6 |
| Dysphagia | 3 | 4 |
| Dysphonia | 3 | 3 |
| Dyspnoea | 29 | 34 |
| Dystonia | 1 | 1 |
| Ear infection | 1 | 1 |
| Ear pain | 2 | 2 |
| Ecchymosis | 1 | 1 |
| Eczema | 1 | 1 |
| Eczema herpeticum | 1 | 1 |
| Encephalitis | 2 | 2 |
| Encephalopathy | 1 | 1 |
| Epidermal necrosis | 1 | 1 |
| Epigastric discomfort | 1 | 1 |
| Epiglottitis | 1 | 1 |
| Epilepsy | 1 | 1 |
| Erythema | 25 | 28 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 5 | 14 | 15 | 17 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 4 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 12 | 20 | 44 | 45 |
| | | 2 | 2 |
| | | 20 | 23 |
| | 1 | | |
| | 1 | 1 | 1 |
| | 1 | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 3 | 2 | 3 |
| 1 | 1 | 2 | 3 |
| | | 3 | 3 |
| | | 29 | 34 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 4 | 24 | 24 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Essential tremor | 1 | 1 | | | 1 | 1 |
| Euphoric mood | 1 | 2 | | 1 | 1 | 1 |
| Exposure during pregnancy | | 1 | | 1 | | |
| Extensor plantar response | 1 | 1 | 1 | 1 | | |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 4 | 4 | 1 | 1 | 3 | 3 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 2 | 3 | | 1 | 2 | 2 |
| Face oedema | 8 | 8 | | | 8 | 8 |
| Facial paralysis | 15 | 16 | | | 15 | 16 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 16 | 24 | 3 | 9 | 13 | 15 |
| Feeling abnormal | 2 | 2 | | | 2 | 2 |
| Feeling cold | 2 | 3 | | | 2 | 3 |
| Feeling drunk | | 1 | | 1 | | |
| Feeling hot | 6 | 7 | 1 | 2 | 5 | 5 |
| Fibrin D dimer increased | 1 | 1 | | | 1 | 1 |
| Flatulence | | 1 | | | | 1 |
| Flushing | 2 | 2 | | | 2 | 2 |
| Formication | 1 | 2 | | 1 | 1 | 1 |
| Gait inability | 1 | 1 | | | 1 | 1 |
| Gamma-glutamyltransferase increased | 1 | 1 | 1 | 1 | | |
| Gastroenteritis | | 1 | | | | 1 |
| Gastrooesophageal reflux disease | 1 | 1 | 1 | 1 | | |
| Generalised oedema | 2 | 2 | | | 2 | 2 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Genital ulceration | 1 | 1 | | | 1 | 1 |
| Glossitis | | 1 | | | | 1 |
| Glossodynia | 1 | 1 | | | 1 | 1 |
| Groin pain | 1 | 1 | | | 1 | 1 |
| Haematochezia | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haematocrit decreased | 1 | 1 | 1 | 1 | | |
| Haematoma | 3 | 3 | 1 | 1 | 2 | 2 |
| Haematoma muscle | | 1 | | | | 1 |
| Haemoglobin decreased | 1 | 1 | 1 | 1 | | |
| Haemorrhage | 1 | 1 | | | 1 | 1 |
| Haemorrhagic diathesis | 1 | 1 | | | 1 | 1 |
| Headache | 76 | 103 | 20 | 43 | 56 | 60 |
| Head injury | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hemiparaesthesia | 3 | 3 | | | 3 | 3 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hepatitis | 1 | 1 | | | 1 | 1 |
| Hepatitis acute | 1 | 1 | | | 1 | 1 |
| Herpes virus infection | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 10 | 10 | | | 10 | 10 |
| Herpes zoster cutaneous disseminated | 1 | 1 | | | 1 | 1 |
| Herpes zoster oticus | 1 | 1 | | | 1 | 1 |
| Herpes zoster reactivation | 2 | 2 | | | 2 | 2 |
| Hyperdynamic left ventricle | 1 | 1 | | | 1 | 1 |
| Hyperf brinogenaemia | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | | 1 | | 1 | | |
| Hyperhidrosis | 6 | 7 | 1 | 2 | 5 | 5 |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 11 | 12 | 1 | 1 | 10 | 11 |
| Hypersexuality | 1 | 1 | | | 1 | 1 |
| Hypertension | 21 | 21 | 6 | 6 | 15 | 15 |
| Hypertensive crisis | 10 | 10 | | | 10 | 10 |
| Hypertensive urgency | 1 | 1 | | | 1 | 1 |
| Hypertransaminasaemia | 1 | 1 | | | 1 | 1 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Hypoacusis | 2 | 2 | | | 2 | 2 |
| Hypoaesthesia | 11 | 12 | 1 | 2 | 10 | 10 |

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|--|------------------------------------|--------------------------------------|
| Hypoaesthesia oral | 2 | 3 |
| Hypocalcaemia | 1 | 1 |
| Hypoglycaemia | 2 | 2 |
| Hypokalaemia | 1 | 1 |
| Hypophosphataemia | 1 | 1 |
| Hypotension | 7 | 10 |
| Hypothermia | 2 | 2 |
| Hypoxia | 5 | 5 |
| Ileus paralytic | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 |
| Immunisation reaction | | 1 |
| Inappropriate schedule of product administration | 2 | 2 |
| Incorrect route of product administration | | 1 |
| Induration | 1 | 1 |
| Inflammation | 2 | 2 |
| Inflammatory bowel disease | 1 | 1 |
| Influenza | 3 | 3 |
| Influenza like illness | 2 | 2 |
| Insomnia | 1 | 1 |
| Insulin resistance | | 1 |
| Interstitial lung disease | 1 | 1 |
| Intestinal obstruction | 1 | 1 |
| Iron deficiency | 1 | 1 |
| Ischaemic stroke | 4 | 4 |
| Jaw disorder | | 1 |
| Joint contracture | | 1 |
| Joint range of motion decreased | | 1 |
| Joint swelling | 1 | 1 |
| Joint warmth | 1 | 1 |
| Lacrimation increased | 3 | 3 |
| Laryngeal oedema | 4 | 6 |
| Leukopenia | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | 6 | 8 |
| | | 2 | 2 |
| | | 5 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 3 | 3 |
| 1 | 1 | 1 | 1 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 4 | 4 |
| | | | |
| | 1 | | |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 4 | 6 |
| | | 1 | 1 |

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|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lichen planus | 1 | 1 | | | 1 | 1 |
| Limb immobilisation | 1 | 1 | | | 1 | 1 |
| Lip oedema | 6 | 7 | | 1 | 6 | 6 |
| Lip pruritus | 2 | 3 | | 1 | 2 | 2 |
| Lip swelling | 2 | 2 | | | 2 | 2 |
| Lividity | 1 | 1 | | | 1 | 1 |
| Localised infection | 1 | 1 | | | 1 | 1 |
| Localised oedema | 1 | 1 | | | 1 | 1 |
| Local reaction | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 4 | 4 | | | 4 | 4 |
| Lymphadenitis | 4 | 4 | 1 | 1 | 3 | 3 |
| Lymphadenopathy | 20 | 22 | 2 | 4 | 18 | 18 |
| Lymphangitis | 1 | 1 | | | 1 | 1 |
| Lymphopenia | 1 | 1 | 1 | 1 | | |
| Macroglossia | 1 | 1 | | | 1 | 1 |
| Malaise | 38 | 48 | 10 | 18 | 28 | 30 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Mental impairment | 2 | 2 | | | 2 | 2 |
| Migraine | 2 | 4 | | 1 | 2 | 3 |
| Migraine with aura | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 3 | 4 | 1 | 1 | 2 | 3 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Movement disorder | | 1 | | 1 | | |
| Mucosal dryness | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | | 1 | | | | 1 |
| Muscle contracture | 1 | 1 | 1 | 1 | | |
| Muscle rigidity | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle tightness | | 1 | | 1 | | |
| Muscular weakness | 3 | 5 | 1 | 3 | 2 | 2 |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal discomfort | 2 | 2 | | | 2 | 2 |

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| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Musculoskeletal pain | 8 | 9 | 1 | 2 | 7 | 7 |
| Musculoskeletal stiffness | | 2 | | 1 | | 1 |
| Myalgia | 35 | 49 | 8 | 22 | 27 | 27 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Myositis | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 3 | 5 | 1 | 3 | 2 | 2 |
| Nausea | 38 | 50 | 11 | 20 | 27 | 30 |
| Neck pain | | 1 | | | | 1 |
| Necrosis | 1 | 1 | | | 1 | 1 |
| Neoplasm | 1 | 1 | 1 | 1 | | |
| Nervousness | | 1 | | 1 | | |
| Nervous system disorder | 1 | 1 | | | 1 | 1 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Neurosensory hypoacusis | 1 | 1 | | | 1 | 1 |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Noninfective gingivitis | 1 | 1 | | | 1 | 1 |
| Nuchal rigidity | | 1 | | | | 1 |
| Ocular hyperaemia | 1 | 1 | | | 1 | 1 |
| Odynophagia | 5 | 5 | | | 5 | 5 |
| Oedema | 3 | 3 | 2 | 2 | 1 | 1 |
| Oedema peripheral | 5 | 5 | | | 5 | 5 |
| Off label use | 7 | 9 | 7 | 9 | | |
| Oral candidiasis | 1 | 1 | | | 1 | 1 |
| Oral discomfort | | 1 | | 1 | | |
| Oral herpes | 2 | 2 | | | 2 | 2 |
| Oral pruritus | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 3 | 3 | | | 3 | 3 |
| Oropharyngeal oedema | 2 | 2 | | | 2 | 2 |
| Oropharyngeal pain | 1 | 2 | | 1 | 1 | 1 |

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| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Overdose | 1 | 2 | 1 | 2 | | |
| Oxygen saturation decreased | 3 | 3 | | | 3 | 3 |
| Pain | 8 | 10 | 2 | 4 | 6 | 6 |
| Pain in extremity | 9 | 18 | 3 | 10 | 6 | 8 |
| Palatal oedema | 7 | 8 | | | 7 | 8 |
| Palatal swelling | 1 | 1 | | | 1 | 1 |
| Pallor | 4 | 4 | 1 | 1 | 3 | 3 |
| Palpitations | 7 | 10 | | 2 | 7 | 8 |
| Pancytopenia | 1 | 1 | | | 1 | 1 |
| Panic reaction | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 21 | 25 | 3 | 7 | 18 | 18 |
| Paraesthesia oral | 6 | 7 | | 1 | 6 | 6 |
| Paraparesis | 1 | 1 | | | 1 | 1 |
| Parotitis | 2 | 2 | | | 2 | 2 |
| Partial seizures | 1 | 1 | | | 1 | 1 |
| Pelvic pain | | 1 | | 1 | | |
| Periorbital oedema | | 1 | | 1 | | |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Peripheral ischaemia | 1 | 2 | | | 1 | 2 |
| Peripheral swelling | 1 | 3 | 1 | 2 | | 1 |
| Persistent depressive disorder | 1 | 1 | | | 1 | 1 |
| Pertussis | 2 | 2 | | | 2 | 2 |
| Petechiae | 2 | 2 | 1 | 1 | 1 | 1 |
| Petit mal epilepsy | 2 | 2 | | | 2 | 2 |
| Pharyngeal erythema | 1 | 1 | | | 1 | 1 |
| Pharyngeal inflammation | 1 | 1 | | | 1 | 1 |
| Pharyngeal oedema | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 1 | 1 | | | 1 | 1 |
| Phlebitis | 1 | 1 | 1 | 1 | | |
| Photophobia | 2 | 2 | | | 2 | 2 |
| Photopsia | 1 | 1 | 1 | 1 | | |
| Platelet count increased | 1 | 1 | 1 | 1 | | |

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|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pleural effusion | | 1 | | | | 1 |
| Pneumonia | 3 | 3 | | | 3 | 3 |
| Presyncope | 7 | 7 | 2 | 2 | 5 | 5 |
| Productive cough | 1 | 1 | | | 1 | 1 |
| Product use issue | 6 | 8 | 6 | 8 | | |
| Prothrombin time prolonged | 1 | 1 | 1 | 1 | | |
| Pruritus | 35 | 40 | 1 | 5 | 34 | 35 |
| Psoriasis | 1 | 1 | | | 1 | 1 |
| Psychomotor hyperactivity | | 1 | | 1 | | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pulmonary thrombosis | 1 | 1 | | | 1 | 1 |
| Pulse abnormal | 1 | 1 | | | 1 | 1 |
| Purpura | 1 | 1 | | | 1 | 1 |
| Pyrexia | 76 | 114 | 16 | 52 | 60 | 62 |
| Rash | 20 | 26 | | 6 | 20 | 20 |
| Rash erythematous | 3 | 3 | | | 3 | 3 |
| Rash maculo-papular | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash papular | 2 | 2 | | | 2 | 2 |
| Rash pruritic | 2 | 3 | 1 | 1 | 1 | 2 |
| Raynaud's phenomenon | 1 | 1 | | | 1 | 1 |
| Reaction to excipient | 1 | 1 | | | 1 | 1 |
| Rectal haemorrhage | | 1 | | | | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 | | |
| Renal impairment | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | | 1 | | | | 1 |
| Respiratory distress | 5 | 6 | | | 5 | 6 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Rhinitis | | 1 | | 1 | | |
| Rhinorrhoea | 2 | 4 | 1 | 3 | 1 | 1 |
| SARS-CoV-2 ant body test positive | 3 | 3 | 3 | 3 | | |
| Seizure | 3 | 3 | | | 3 | 3 |

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|---------------------------------|------------------------------------|--------------------------------------|
| Sensation of foreign body | 3 | 3 |
| Sense of oppression | 1 | 1 |
| Sensory loss | 1 | 2 |
| Sinus bradycardia | 1 | 1 |
| Skin exfoliation | 1 | 1 |
| Skin lesion | | 1 |
| Skin necrosis | 2 | 2 |
| Skin odour abnormal | 1 | 1 |
| Skin ulcer | 1 | 1 |
| Slow speech | 1 | 1 |
| Somnolence | 4 | 8 |
| Speech disorder | 2 | 2 |
| Spinal cord injury | 1 | 1 |
| Status epilepticus | 1 | 1 |
| Stomatitis | | 3 |
| Stridor | 1 | 1 |
| Subcutaneous abscess | 1 | 1 |
| Sudden death | 2 | 5 |
| Suffocation feeling | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling | 1 | 1 |
| Swelling face | 3 | 3 |
| Swollen tongue | 4 | 4 |
| Syncope | 23 | 23 |
| Tachyarrhythmia | 1 | 1 |
| Tachycardia | 32 | 33 |
| Tachycardia paroxysmal | 1 | 1 |
| Tachypnoea | 3 | 3 |
| Temperature regulation disorder | 7 | 9 |
| Tension headache | 2 | 3 |
| Throat irritation | 6 | 9 |
| Throat tightness | 2 | 3 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 3 | 3 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 6 | 2 | 2 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 2 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 4 | 4 |
| | | 23 | 23 |
| | | 1 | 1 |
| 5 | 6 | 27 | 27 |
| | | 1 | 1 |
| | | 3 | 3 |
| 3 | 5 | 4 | 4 |
| | 1 | 2 | 2 |
| | 3 | 6 | 6 |
| | | 2 | 3 |

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|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Thunderclap headache | 1 | 1 | | | 1 | 1 |
| Tinnitus | 2 | 2 | | | 2 | 2 |
| Tongue discomfort | | 1 | | 1 | | |
| Tongue eruption | | 1 | | 1 | | |
| Tongue erythema | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 3 | 4 | | 1 | 3 | 3 |
| Tongue pruritus | 2 | 4 | | 1 | 2 | 3 |
| Tongue ulceration | | 1 | | 1 | | |
| Tonic clonic movements | 1 | 1 | | | 1 | 1 |
| Tonsillitis | 1 | 1 | | | 1 | 1 |
| Transient global amnesia | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 2 | 2 | | | 2 | 2 |
| Tremor | 3 | 3 | | | 3 | 3 |
| Troponin T increased | | 1 | | | | 1 |
| Tunnel vision | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 2 | | 1 | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Urticaria | 19 | 21 | 2 | 3 | 17 | 18 |
| Uterine haemorrhage | 2 | 2 | | | 2 | 2 |
| Vaccination complication | 1 | 2 | | 1 | 1 | 1 |
| Vaccination failure | 3 | 3 | | | 3 | 3 |
| Vaccination site cellulitis | 2 | 2 | | | 2 | 2 |
| Vaccination site erosion | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 5 | 6 | 1 | 2 | 4 | 4 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site inflammation | 6 | 13 | 1 | 7 | 5 | 6 |
| Vaccination site joint erythema | 4 | 5 | | 1 | 4 | 4 |
| Vaccination site joint inflammation | 2 | 2 | | | 2 | 2 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | 3 | 3 |
| | 1 | 2 | 3 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 3 | 3 |
| | | | 1 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 2 | 3 | 17 | 18 |
| | | 2 | 2 |
| | 1 | 1 | 1 |
| | | 3 | 3 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 2 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 7 | 5 | 6 |
| | 1 | 4 | 4 |
| | | 2 | 2 |

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|--|------------------------------------|--------------------------------------|-------------|-----|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site joint movement impairment | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site oedema | 2 | 2 | | | 2 | 2 |
| Vaccination site pain | 29 | 53 | 6 | 29 | 23 | 24 |
| Vaccination site paraesthesia | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site pruritus | 4 | 5 | 1 | 2 | 3 | 3 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 1 | 1 | | | 1 | 1 |
| Vaccination site swelling | 3 | 5 | 1 | 3 | 2 | 2 |
| Vaccination site warmth | 4 | 5 | | 1 | 4 | 4 |
| Vaginal haemorrhage | | 1 | | 1 | | |
| Vasculitis | 1 | 1 | | | 1 | 1 |
| Vertigo | 6 | 6 | 2 | 2 | 4 | 4 |
| Vision blurred | 6 | 6 | 2 | 2 | 4 | 4 |
| Visual acuity reduced | 1 | 1 | | | 1 | 1 |
| Vitreous detachment | 1 | 1 | | | 1 | 1 |
| Vomiting | 28 | 36 | 5 | 11 | 23 | 25 |
| Wheezing | 6 | 6 | | | 6 | 6 |
| White blood cell count decreased | 1 | 1 | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| Wrong technique in product usage process | | 1 | | 1 | | |
| | 1,597 | 1,975 | 260 | 553 | 1337 | 1422 |

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|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | | 1 | | 1 | | |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain lower | 1 | 1 | 1 | 1 | | |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Allergic reaction to excipient | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 3 | 3 | | | 3 | 3 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angioedema | 3 | 4 | | | 3 | 4 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 3 | | | 3 | 3 |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Aspiration | | 1 | | | | 1 |
| Asthenia | 7 | 7 | 1 | 1 | 6 | 6 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 2 | 3 | | 1 | 2 | 2 |
| Blood chloride decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | | 1 | | | | 1 |
| Blood sodium decreased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Bruxism | | 1 | | 1 | | |
| Bursitis | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardiac failure acute | 3 | 3 | | | 3 | 3 |
| Cardio-respiratory arrest | 2 | 2 | | | 2 | 2 |

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|--|------------------------------------|--------------------------------------|
| Catarrh | 1 | 1 |
| Cellulitis | 1 | 1 |
| Cervicobrachial syndrome | 1 | 1 |
| Chest discomfort | 2 | 2 |
| Chest pain | 4 | 5 |
| Chills | 10 | 11 |
| Chronic respiratory failure | 1 | 1 |
| Cold sweat | 1 | 1 |
| Condition aggravated | 1 | 1 |
| Confusional state | 1 | 2 |
| Contusion | 1 | 1 |
| Cough | 4 | 4 |
| COVID-19 | 16 | 16 |
| COVID-19 pneumonia | 3 | 3 |
| C-reactive protein increased | 1 | 1 |
| Deafness unilateral | 1 | 1 |
| Decreased appetite | 1 | 1 |
| Dehydration | 1 | 1 |
| Depressed level of consciousness | 6 | 6 |
| Depressed mood | | 1 |
| Diarrhoea | 12 | 16 |
| Discomfort | 1 | 1 |
| Disturbance in attention | 2 | 2 |
| Dizziness | 5 | 7 |
| Drowning | 1 | 1 |
| Drug ineffective | 11 | 12 |
| Drug interaction | 1 | 1 |
| Dry mouth | | 1 |
| Dysarthria | 1 | 2 |
| Dyspnoea | 14 | 16 |
| Electrocardiogram QRS complex prolonged | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 4 | 5 |
| 2 | 3 | 8 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| 1 | 1 | | |
| 2 | 2 | 2 | 2 |
| 1 | 1 | 15 | 15 |
| | | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 6 | 6 |
| | 1 | | |
| 2 | 6 | 10 | 10 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | 5 | 6 |
| | | 1 | 1 |
| | | 11 | 12 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | 13 | 15 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Electrocardiogram ST-T change | 1 | 1 |
| Epilepsy | 2 | 2 |
| Erythema | 1 | 1 |
| Erythema nodosum | 1 | 1 |
| Extrapyramidal disorder | 1 | 1 |
| Face oedema | 2 | 3 |
| Facial bones fracture | 1 | 1 |
| Facial paralysis | 4 | 4 |
| Fall | 1 | 1 |
| Fatigue | 5 | 7 |
| Febrile convulsion | 1 | 1 |
| Feeling abnormal | 1 | 2 |
| Feeling hot | 2 | 2 |
| Flushing | 1 | 1 |
| Formication | | 1 |
| Gait disturbance | 2 | 2 |
| Gastroenteritis | 1 | 1 |
| Gastrooesophageal reflux disease | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 |
| General physical health deterioration | 1 | 1 |
| Gingivitis | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematuria | 1 | 1 |
| Haemophagocytic lymphohistiocytosis | 1 | 1 |
| Haemorrhage | 1 | 1 |
| Haemorrhagic stroke | 1 | 1 |
| Headache | 12 | 20 |
| Head injury | 1 | 1 |
| Hepatic failure | 1 | 1 |
| Hepatitis acute | 1 | 1 |
| Herpes zoster | 7 | 7 |
| Hyperhidrosis | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 1 | | |
| 3 | 4 | 2 | 3 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| | 1 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 8 | 11 | 12 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 7 | 7 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypertensive crisis | 2 | 2 | | | 2 | 2 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypotension | 2 | 4 | 1 | 2 | 1 | 2 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Hypoxia | 5 | 6 | | | 5 | 6 |
| Inappropriate schedule of product administration | 2 | 3 | 2 | 3 | | |
| Incorrect dose administered | | 1 | | 1 | | |
| Increased bronchial secretion | 1 | 1 | | | 1 | 1 |
| Infection | 1 | 1 | | | 1 | 1 |
| Influenza like illness | | 1 | | 1 | | |
| Intestinal ischaemia | | 1 | | | | 1 |
| Intestinal obstruction | 1 | 1 | | | 1 | 1 |
| Ischaemic stroke | 3 | 3 | | | 3 | 3 |
| Jaw fracture | 1 | 1 | | | 1 | 1 |
| Laryngeal erythema | 1 | 1 | | | 1 | 1 |
| Laryngeal oedema | 1 | 1 | | | 1 | 1 |
| Leukoencephalopathy | 1 | 1 | | | 1 | 1 |
| Lip oedema | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | | 1 | | | | 1 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Lung infiltration | 2 | 2 | 2 | 2 | | |
| Lymphadenopathy | 4 | 4 | | | 4 | 4 |
| Lymphocyte percentage decreased | 1 | 1 | 1 | 1 | | |
| Malaise | 11 | 16 | 3 | 7 | 8 | 9 |
| Mental impairment | 1 | 1 | | | 1 | 1 |
| Migraine with aura | 1 | 1 | | | 1 | 1 |
| Mononeuropathy | 1 | 1 | | | 1 | 1 |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 2 | 1 | 2 |
| | | 1 | 1 |
| | | 5 | 6 |
| 2 | 3 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 4 | 4 |
| 1 | 1 | | |
| 3 | 7 | 8 | 9 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Muscle contractions involuntary | | 1 |
| Muscle contracture | 1 | 2 |
| Muscle spasms | 1 | 1 |
| Muscular weakness | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal pain | 3 | 3 |
| Myalgia | 7 | 7 |
| Myocardial infarction | 1 | 1 |
| Myocarditis | 1 | 1 |
| Myoclonic dystonia | 1 | 1 |
| Myoclonus | | 1 |
| Nasal congestion | 2 | 2 |
| Nasopharyngitis | | 2 |
| Nausea | 1 | 2 |
| Neck pain | 1 | 1 |
| Neuralgia | 1 | 1 |
| Neurogenic shock | 1 | 1 |
| Neutrophil count increased | 1 | 1 |
| Neutrophil percentage increased | 1 | 1 |
| Odynophagia | 1 | 1 |
| Oedema | 1 | 1 |
| Oedema mouth | 1 | 1 |
| Oedema peripheral | 1 | 1 |
| Off label use | 2 | 2 |
| Oral dysaesthesia | 1 | 1 |
| Oral pruritus | 1 | 1 |
| Oxygen saturation decreased | 3 | 3 |
| Pain | | 2 |
| Pain in jaw | 1 | 1 |
| Palatal oedema | 3 | 3 |
| Palatal swelling | 1 | 1 |
| Palpitations | | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 2 |
| 1 | 1 | 6 | 6 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| | 2 | | |
| | | 1 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 3 | 3 |
| | 2 | | |
| 1 | 1 | | |
| | | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Panniculitis | 1 | 1 |
| Paraesthesia | 4 | 7 |
| Paraesthesia oral | 2 | 2 |
| Paraparesis | 1 | 1 |
| Pericarditis | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngotonsillitis | 1 | 1 |
| Pleuritic pain | 1 | 1 |
| Pneumonia | 4 | 5 |
| Presyncope | 1 | 2 |
| Productive cough | 1 | 1 |
| Product use issue | 1 | 1 |
| Pruritus | 2 | 3 |
| Pulmonary embolism | 1 | 1 |
| Pyrexia | 34 | 43 |
| Rash | 1 | 2 |
| Rectal haemorrhage | 1 | 1 |
| Renal failure | 1 | 1 |
| Renal impairment | 1 | 1 |
| Respiratory distress | 1 | 2 |
| Respiratory failure | 1 | 2 |
| Respiratory tract infection | 1 | 1 |
| Restlessness | 1 | 1 |
| Rhinalgia | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 2 |
| Sensation of foreign body | 1 | 1 |
| Sepsis | | 1 |
| Shock | 1 | 1 |
| Skin lesion | 1 | 1 |
| Skin reaction | 1 | 1 |
| Slow speech | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 3 | 4 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 5 |
| | | 1 | 2 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 3 |
| | | 1 | 1 |
| 8 | 16 | 26 | 27 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 1 | 2 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | | 1 |
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| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Somnolence | 2 | 2 |
| Speech disorder | | 1 |
| Sudden death | 2 | 2 |
| Swelling face | 1 | 1 |
| Syncope | 6 | 6 |
| Tachycardia | 1 | 3 |
| Tachypnoea | 1 | 1 |
| Temperature regulation disorder | 2 | 2 |
| Tension headache | | 1 |
| Throat irritation | 2 | 2 |
| Thrombophlebitis superficial | 1 | 1 |
| Tic | 1 | 1 |
| Tongue oedema | | 1 |
| Transaminases increased | 1 | 1 |
| Tremor | 4 | 4 |
| Trigeminal neuralgia | 1 | 1 |
| Type IV hypersensitivity reaction | 1 | 1 |
| Urinary retention | 1 | 1 |
| Urinary sediment present | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urticaria | 3 | 3 |
| Vaccination complication | 1 | 2 |
| Vaccination site erythema | 1 | 2 |
| Vaccination site induration | 1 | 1 |
| Vaccination site pain | 5 | 7 |
| Vaccination site paraesthesia | 1 | 1 |
| Venous thrombosis limb | 1 | 1 |
| Ventricular extrasystoles | 1 | 1 |
| Vertigo | 1 | 1 |
| Vision blurred | 1 | 1 |
| Vitreous detachment | 1 | 1 |
| Volvulus | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 6 | 6 |
| | | 1 | 3 |
| 1 | 1 | | |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 3 |
| | | 1 | 2 |
| 1 | 2 | | |
| | | 1 | 1 |
| 2 | 4 | 3 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vomiting | 5 | 7 | 1 | 2 | 4 | 5 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| | 427 | 515 | 72 | 124 | 355 | 391 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | | 2 | | | | 2 |
| Diarrhoea | | 2 | | 2 | | |
| Drug ineffective | | 2 | | | | 2 |
| Exposure via breast milk | 1 | 2 | 1 | 2 | | |
| Petechiae | | 1 | | 1 | | |
| Underdose | | 1 | | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 1 | 11 | 1 | 7 | | 4 |

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Country Where Event Occurred

SWEDEN

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 6 | 8 | 5 | 7 | 1 | 1 |
| Abdominal pain lower | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | | 1 | | 1 | | |
| Acne | 1 | 1 | 1 | 1 | | |
| Acute left ventricular failure | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Ageusia | 4 | 4 | 2 | 2 | 2 | 2 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Allodynia | 1 | 1 | 1 | 1 | | |
| Amnesia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 12 | 13 | | | 12 | 13 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Anosmia | 3 | 3 | 2 | 2 | 1 | 1 |
| Anxiety | 5 | 5 | 4 | 4 | 1 | 1 |
| Areflexia | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arteriosclerosis | | 1 | | | | 1 |
| Arthralgia | 16 | 20 | 12 | 15 | 4 | 5 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Asthenia | 8 | 9 | 4 | 5 | 4 | 4 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Autonomic nervous system imbalance | 1 | 1 | | | 1 | 1 |
| Axillary pain | 5 | 6 | 3 | 4 | 2 | 2 |
| Back pain | 7 | 7 | 5 | 5 | 2 | 2 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blindness | 1 | 1 | | | 1 | 1 |
| Blindness transient | 1 | 1 | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blister | 1 | 1 | 1 | 1 | | |
| Blood glucose increased | 2 | 2 | | | 2 | 2 |
| Blood pressure abnormal | | 1 | | | | 1 |
| Blood pressure decreased | 4 | 4 | 2 | 2 | 2 | 2 |
| Blood pressure fluctuation | | 1 | | | | 1 |
| Blood pressure increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure systolic increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Body temperature decreased | 2 | 2 | | | 2 | 2 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bone disorder | 1 | 1 | 1 | 1 | | |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cachexia | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 2 | 3 | | | 2 | 3 |
| Cardiac disorder | | 1 | | | | 1 |
| Cardiac failure | 4 | 4 | | | 4 | 4 |
| Cardiac failure acute | | 1 | | | | 1 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cerebral infarction | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 2 | 2 | | | 2 | 2 |
| Chest discomfort | 6 | 6 | 2 | 2 | 4 | 4 |
| Chest pain | 7 | 7 | 4 | 4 | 3 | 3 |
| Chills | 29 | 38 | 20 | 28 | 9 | 10 |
| Chronic obstructive pulmonary disease | 4 | 4 | | | 4 | 4 |
| Chronic respiratory failure | | 1 | | | | 1 |
| Circulatory collapse | 1 | 2 | | | 1 | 2 |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Cold sweat | 3 | 3 | 2 | 2 | 1 | 1 |
| Condition aggravated | 4 | 5 | | | 4 | 5 |
| Confusional state | 5 | 5 | | | 5 | 5 |
| Cough | 11 | 12 | 6 | 7 | 5 | 5 |
| COVID-19 | 5 | 6 | | | 5 | 6 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| C-reactive protein increased | 1 | 1 | 1 | 1 | | |
| Crepitations | 1 | 2 | | 1 | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | 16 | 20 | | | 16 | 20 |
| Decreased appetite | 8 | 8 | 3 | 3 | 5 | 5 |
| Deep vein thrombosis | 2 | 2 | | | 2 | 2 |
| Dehydration | | 1 | | | | 1 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 4 | 4 | | | 4 | 4 |
| Diarrhoea | 15 | 18 | 10 | 13 | 5 | 5 |
| Discomfort | 5 | 5 | 3 | 3 | 2 | 2 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dissociation | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 2 | 2 | 2 | 2 | | |
| Diverticulitis | 1 | 1 | | | 1 | 1 |
| Dizziness | 30 | 33 | 16 | 18 | 14 | 15 |
| Drug eruption | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 5 | 6 | | | 5 | 6 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysgeusia | 5 | 5 | 2 | 2 | 3 | 3 |
| Dyspepsia | | 1 | | 1 | | |
| Dysphagia | 3 | 3 | | | 3 | 3 |
| Dysphonia | 4 | 4 | 4 | 4 | | |
| Dyspnoea | 30 | 34 | 5 | 5 | 25 | 29 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Eczema | 1 | 1 | 1 | 1 | | |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Epistaxis | | 1 | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Erysipelas | 1 | 2 |
| Erythema | 20 | 21 |
| Extrasystoles | 1 | 1 |
| Eye disorder | 1 | 1 |
| Eye pain | 1 | 1 |
| Eye pruritus | 2 | 2 |
| Eye swelling | 1 | 1 |
| Facial neuralgia | 1 | 1 |
| Facial paralysis | 2 | 3 |
| Facial paresis | 5 | 6 |
| Fatigue | 77 | 84 |
| Feeling abnormal | 4 | 6 |
| Feeling cold | 9 | 9 |
| Feeling hot | 13 | 14 |
| Feeling of body temperature change | 2 | 2 |
| Fibromyalgia | | 1 |
| Flank pain | 1 | 1 |
| Flatulence | 1 | 1 |
| Fluid retention | 1 | 1 |
| Flushing | 2 | 2 |
| Food refusal | 1 | 1 |
| Formication | | 1 |
| Furuncle | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Generalised oedema | 1 | 1 |
| General physical health deterioration | 16 | 20 |
| Glossodynia | 1 | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematoma | 2 | 2 |
| Haemoglobin decreased | 1 | 1 |
| Hallucination | 1 | 1 |
| Hallucination, visual | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 2 |
| 12 | 13 | 8 | 8 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 5 | 6 |
| 45 | 51 | 32 | 33 |
| | 2 | 4 | 4 |
| 7 | 7 | 2 | 2 |
| 6 | 7 | 7 | 7 |
| | | 2 | 2 |
| | | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 5 | 12 | 15 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Headache | 80 | 94 |
| Head discomfort | 1 | 1 |
| Head injury | 1 | 1 |
| Heart rate decreased | 2 | 2 |
| Heart rate increased | 5 | 6 |
| Hemiparesis | 5 | 5 |
| Herpes zoster | 4 | 4 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 3 | 3 |
| Hypernatraemia | 1 | 1 |
| Hypersensitivity | 25 | 25 |
| Hypersomnia | 1 | 1 |
| Hypertension | 4 | 5 |
| Hypoaesthesia | 19 | 21 |
| Hypoaesthesia oral | 7 | 8 |
| Hypoglycaemia | 2 | 2 |
| Hypokalaemia | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hypophagia | 1 | 1 |
| Hypotension | 6 | 7 |
| Hypothermia | 1 | 1 |
| Illness | 1 | 1 |
| Immunisation reaction | 1 | 1 |
| Incorrect route of product administration | 4 | 4 |
| Increased upper airway secretion | 1 | 1 |
| Infection | 3 | 4 |
| Influenza like illness | 2 | 2 |
| Infrequent bowel movements | 1 | 1 |
| Injected limb mobility decreased | 1 | 2 |
| Insomnia | 2 | 2 |
| Ischaemic stroke | | 2 |
| Jaw disorder | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 62 | 75 | 18 | 19 |
| | | 1 | 1 |
| 1 | 1 | | |
| 2 | 2 | | |
| 2 | 2 | 3 | 4 |
| | | 5 | 5 |
| 1 | 1 | 3 | 3 |
| 1 | 1 | | |
| 3 | 3 | | |
| | | 1 | 1 |
| 4 | 4 | 21 | 21 |
| | | 1 | 1 |
| 3 | 3 | 1 | 2 |
| 10 | 11 | 9 | 10 |
| 2 | 3 | 5 | 5 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 4 | | |
| 1 | 1 | | |
| | | 3 | 4 |
| 2 | 2 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 2 | 2 | | |
| | | | 2 |
| | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint range of motion decreased | | 1 | | 1 | | |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Lethargy | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Limb discomfort | 1 | 1 | | | 1 | 1 |
| Lip pruritus | 1 | 1 | | | 1 | 1 |
| Lip swelling | 5 | 6 | 1 | 1 | 4 | 5 |
| Local reaction | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | 5 | 5 | | | 5 | 5 |
| Lymphadenopathy | 5 | 6 | 5 | 5 | | 1 |
| Lymph node pain | 5 | 5 | 4 | 4 | 1 | 1 |
| Malaise | 22 | 23 | 14 | 15 | 8 | 8 |
| Memory impairment | 2 | 3 | 1 | 1 | 1 | 2 |
| Meningitis herpes | 1 | 1 | | | 1 | 1 |
| Mental fatigue | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 3 | 1 | 3 | | |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Muscle contractions involuntary | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 3 | 3 | | | 3 | 3 |
| Muscle tone disorder | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 3 | 4 | 2 | 3 | 1 | 1 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 4 | 4 | 4 | 4 | | |
| Myalgia | 34 | 41 | 22 | 28 | 12 | 13 |
| Myelosuppression | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 2 | 3 | | | 2 | 3 |
| Myocardial ischaemia | | 1 | | | | 1 |
| Myocardial rupture | | 1 | | | | 1 |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Nail discolouration | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 5 | 5 | 1 | 1 | 4 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nasopharyngitis | 2 | 2 | | | 2 | 2 |
| Nausea | 35 | 42 | 22 | 28 | 13 | 14 |
| Neck pain | 4 | 5 | 4 | 5 | | |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Neurological symptom | 1 | 1 | | | 1 | 1 |
| Nightmare | 1 | 1 | | | 1 | 1 |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Nodule | 1 | 1 | 1 | 1 | | |
| Obstructive airways disorder | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Oral discomfort | 1 | 1 | | | 1 | 1 |
| Oral herpes | 2 | 2 | 2 | 2 | | |
| Oral pain | 1 | 1 | 1 | 1 | | |
| Oral pruritus | 5 | 6 | 3 | 3 | 2 | 3 |
| Oropharyngeal discomfort | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 12 | 13 | 10 | 11 | 2 | 2 |
| Oropharyngeal spasm | | 1 | | | | 1 |
| Overdose | 1 | 1 | 1 | 1 | | |
| Oxygen saturation abnormal | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 6 | 7 | | 1 | 6 | 6 |
| Pain | 19 | 22 | 11 | 13 | 8 | 9 |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 36 | 44 | 29 | 37 | 7 | 7 |
| Pain in jaw | 1 | 1 | | | 1 | 1 |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Palpitations | 7 | 10 | 1 | 4 | 6 | 6 |
| Panic reaction | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 17 | 20 | 4 | 6 | 13 | 14 |
| Paraesthesia ear | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 6 | 7 | 2 | 3 | 4 | 4 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Paresis | 1 | 1 | | | 1 | 1 |
| Parosmia | 1 | 1 | | | 1 | 1 |
| Pericardial haemorrhage | | 1 | | | | 1 |
| Periorbital oedema | 1 | 1 | | | 1 | 1 |
| Periorbital pain | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Peripheral coldness | 2 | 3 | | 1 | 2 | 2 |
| Peripheral swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorder | 1 | 1 | | | 1 | 1 |
| Pharyngeal erythema | 2 | 2 | 1 | 1 | 1 | 1 |
| Pharyngeal hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Pharyngeal paraesthesia | 2 | 2 | | | 2 | 2 |
| Pharyngeal swelling | 5 | 6 | | 1 | 5 | 5 |
| Pharyngitis | | 1 | | 1 | | |
| Pleural effusion | 2 | 2 | | | 2 | 2 |
| Pleurisy | 1 | 1 | | | 1 | 1 |
| Poor quality product administered | | 5 | | 5 | | |
| Postoperative wound complication | 1 | 1 | | | 1 | 1 |
| Post viral fatigue syndrome | | 1 | | 1 | | |
| Presyncope | 3 | 3 | | | 3 | 3 |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Product colour issue | | 5 | | 5 | | |
| Productive cough | 1 | 1 | | | 1 | 1 |
| Product preparation issue | 3 | 3 | 3 | 3 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pruritus | 12 | 12 | 6 | 6 | 6 | 6 |
| Pulmonary artery thrombosis | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pulmonary oedema | 2 | 4 | | | 2 | 4 |
| Pulse abnormal | 2 | 3 | 2 | 2 | | 1 |
| Pulse pressure decreased | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

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|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pyrexia | 93 | 104 | 63 | 71 | 30 | 33 |
| Rash | 11 | 11 | 5 | 5 | 6 | 6 |
| Rash erythematous | 3 | 3 | 1 | 1 | 2 | 2 |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 3 | 3 | 2 | 2 | 1 | 1 |
| Reading disorder | 1 | 1 | | | 1 | 1 |
| Renal failure | | 1 | | | | 1 |
| Renal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 5 | 5 | | | 5 | 5 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory rate increased | 2 | 3 | | | 2 | 3 |
| Restless legs syndrome | 1 | 1 | | | 1 | 1 |
| Rhinalgia | 1 | 1 | 1 | 1 | | |
| Rhinitis | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 9 | 9 | 9 | 9 | | |
| Seizure | 3 | 3 | | | 3 | 3 |
| Seizure like phenomena | 1 | 1 | | | 1 | 1 |
| Sensation of foreign body | | 1 | | | | 1 |
| Sensory disturbance | 2 | 2 | 1 | 1 | 1 | 1 |
| Sepsis | 1 | 2 | | | 1 | 2 |
| Sinus congestion | 1 | 1 | 1 | 1 | | |
| Sinus disorder | 1 | 1 | 1 | 1 | | |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |
| Skin discolouration | 1 | 1 | | | 1 | 1 |
| Skin reaction | 1 | 1 | 1 | 1 | | |
| Skin ulcer | 1 | 2 | | | 1 | 2 |
| Skin warm | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 1 | 1 | | | 1 | 1 |
| Sleep paralysis | 1 | 1 | | | 1 | 1 |
| Sleep talking | | 1 | | | | 1 |
| Sneezing | 1 | 1 | 1 | 1 | | |

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|--|------------------------------------|--------------------------------------|
| Somnolence | 4 | 4 |
| Stevens-Johnson syndrome | 1 | 1 |
| Sudden death | | 2 |
| Swelling | 1 | 2 |
| Swelling face | 5 | 7 |
| Swollen tongue | 6 | 6 |
| Syncope | 6 | 6 |
| Tachycardia | 2 | 2 |
| Tachypnoea | 1 | 1 |
| Taste disorder | 1 | 1 |
| Throat irritation | 5 | 6 |
| Throat tightness | 1 | 2 |
| Tinnitus | 1 | 1 |
| Tongue discomfort | 1 | 1 |
| Tongue pruritus | 2 | 3 |
| Toxic epidermal necrolysis | 1 | 1 |
| Transient ischaemic attack | 2 | 2 |
| Tremor | 5 | 5 |
| Underdose | 2 | 3 |
| Upper gastrointestinal haemorrhage | 1 | 1 |
| Upper respiratory tract congestion | | 1 |
| Urinary retention | 1 | 1 |
| Urinary tract infection | 1 | 1 |
| Urine output decreased | 1 | 1 |
| Urosepsis | 1 | 1 |
| Urticaria | 16 | 17 |
| Vaccination site discomfort | 1 | 1 |
| Vaccination site erythema | 20 | 23 |
| Vaccination site haematoma | 1 | 1 |
| Vaccination site hypoesthesia | | 1 |
| Vaccination site induration | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | | 2 |
| | 1 | 1 | 1 |
| 1 | 3 | 4 | 4 |
| | | 6 | 6 |
| | | 6 | 6 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | 3 | 4 |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | 4 | 4 |
| 2 | 3 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 9 | 10 | 7 | 7 |
| | | 1 | 1 |
| 13 | 15 | 7 | 8 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site movement impairment | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site pain | 63 | 71 | 56 | 63 | 7 | 8 |
| Vaccination site pruritus | 6 | 7 | 4 | 5 | 2 | 2 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site reaction | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site swelling | 22 | 27 | 14 | 18 | 8 | 9 |
| Vaccination site urticaria | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 4 | 7 | 4 | 6 | | 1 |
| Vaginal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vascular dementia | 1 | 1 | | | 1 | 1 |
| Vertigo positional | | 1 | | 1 | | |
| Vision blurred | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual field defect | 2 | 2 | | | 2 | 2 |
| Visual impairment | 2 | 2 | 1 | 1 | 1 | 1 |
| Vomiting | 17 | 18 | 5 | 6 | 12 | 12 |
| Wheezing | 3 | 3 | | | 3 | 3 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| | 1,412 | 1,625 | 698 | 835 | 714 | 790 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Abnormal behaviour | 1 | 2 | | 1 | 1 | 1 |
| Acute kidney injury | | 1 | | | | 1 |
| Acute myocardial infarction | | 1 | | | | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Angioedema | 2 | 2 | | | 2 | 2 |
| Anxiety | 4 | 5 | | | 4 | 5 |
| Apnoea | | 1 | | | | 1 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Arthralgia | 3 | 3 | 2 | 2 | 1 | 1 |
| Ascites | | 1 | | | | 1 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 2 | 3 | | | 2 | 3 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bronchitis | 1 | 1 | | | 1 | 1 |
| Bundle branch block left | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 1 | 4 | | | 1 | 4 |
| Cardiac failure | 2 | 3 | | | 2 | 3 |
| Cardiac failure acute | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 3 | 4 | | | 3 | 4 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 6 | 6 | 3 | 3 | 3 | 3 |
| Chronic obstructive pulmonary disease | | 1 | | | | 1 |
| Circulatory collapse | 1 | 2 | | | 1 | 2 |
| Cold sweat | 1 | 1 | | | 1 | 1 |

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MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Condition aggravated | 1 | 1 |
| Confusional state | 3 | 4 |
| Constipation | 1 | 1 |
| Cough | 3 | 5 |
| COVID-19 | 1 | 1 |
| C-reactive protein increased | 1 | 2 |
| Death | 3 | 5 |
| Decreased appetite | 1 | 1 |
| Decubitus ulcer | | 1 |
| Deep vein thrombosis | 1 | 1 |
| Dehydration | 2 | 2 |
| Delusional disorder, unspecified type | 1 | 1 |
| Depressed level of consciousness | 7 | 8 |
| Depressed mood | 1 | 1 |
| Dermatitis | 1 | 2 |
| Diarrhoea | 3 | 5 |
| Disorganised speech | 1 | 1 |
| Disorientation | 1 | 1 |
| Dizziness | 3 | 4 |
| Drug ineffective | 1 | 1 |
| Dysphagia | 3 | 4 |
| Dyspnoea | 12 | 15 |
| Dysstasia | | 1 |
| Epistaxis | 1 | 1 |
| Escherichia infection | 1 | 1 |
| Escherichia sepsis | | 1 |
| Eye disorder | 1 | 1 |
| Face injury | 1 | 1 |
| Facial paralysis | 4 | 4 |
| Facial paresis | 2 | 2 |
| Fall | 2 | 2 |
| Fatigue | 14 | 18 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| | | 3 | 4 |
| 1 | 1 | | |
| 2 | 2 | 1 | 3 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| | | 3 | 5 |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 7 | 8 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 2 | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | 3 | 3 |
| | | 1 | 1 |
| 2 | 3 | 1 | 1 |
| 2 | 2 | 10 | 13 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 2 | 2 |
| | | 2 | 2 |
| 8 | 10 | 6 | 8 |

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MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---------------------------------------|--|--|
| Feeling hot | 2 | 2 |
| Fluid intake reduced | 1 | 1 |
| Gait disturbance | 1 | 1 |
| General physical health deterioration | 1 | 2 |
| Goitre | | 1 |
| Haematemesis | 1 | 1 |
| Haemoptysis | 1 | 1 |
| Hallucination | 2 | 2 |
| Headache | 10 | 10 |
| Head discomfort | 1 | 1 |
| Head injury | 1 | 1 |
| Heart rate increased | 2 | 2 |
| Heart rate irregular | 1 | 1 |
| Hiccups | 1 | 1 |
| Hyperglycaemia | 1 | 1 |
| Hyperhidrosis | 2 | 2 |
| Hypersensitivity | 2 | 3 |
| Hypoaesthesia | 4 | 4 |
| Hypoaesthesia oral | 1 | 1 |
| Hypokinesia | 1 | 1 |
| Hypotension | 2 | 3 |
| Incontinence | 1 | 1 |
| Infection | 1 | 3 |
| Insomnia | | 2 |
| Intestinal haemorrhage | | 1 |
| Intestinal ischaemia | | 1 |
| Lacrimation increased | 1 | 1 |
| Lactic acidosis | 1 | 1 |
| Loss of consciousness | | 1 |
| Malaise | 4 | 4 |
| Muscle spasms | 1 | 1 |
| Muscle twitching | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| 7 | 7 | 3 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 2 | 3 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 1 | | |
| | | 1 | 3 |
| | 2 | | |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |

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MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Muscular weakness | 1 | 1 |
| Musculoskeletal stiffness | 2 | 2 |
| Myalgia | 5 | 6 |
| Myocardial infarction | 2 | 2 |
| Nasal congestion | 1 | 1 |
| Nasopharyngitis | 1 | 1 |
| Nausea | 7 | 8 |
| Neoplasm progression | | 1 |
| Obstructive airways disorder | 1 | 1 |
| Ocular discomfort | 1 | 1 |
| Oropharyngeal pain | 4 | 5 |
| Oxygen saturation decreased | 2 | 5 |
| Pain | 3 | 4 |
| Pain in extremity | 2 | 5 |
| Pallor | 1 | 1 |
| Palpitations | 1 | 1 |
| Paraesthesia | 1 | 1 |
| Peripheral swelling | 1 | 1 |
| Pharyngeal swelling | 1 | 1 |
| Pneumonia | 3 | 5 |
| Pneumonia aspiration | 1 | 1 |
| Pneumonia bacterial | | 1 |
| Pneumonia pneumococcal | 1 | 1 |
| Pneumonia streptococcal | 1 | 1 |
| Poor quality product administered | | 2 |
| Product colour issue | | 2 |
| Productive cough | | 2 |
| Product preparation issue | 1 | 1 |
| Pruritus | 1 | 2 |
| Psoriasis | 1 | 1 |
| Pulmonary embolism | 1 | 1 |
| Pulmonary oedema | 2 | 3 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 2 | 2 |
| 3 | 3 | 2 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | 6 | 6 |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 3 | 1 | 2 |
| | 1 | 2 | 4 |
| 1 | 1 | 2 | 3 |
| 1 | 4 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 5 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 2 | | |
| | 2 | | |
| | | | 2 |
| 1 | 1 | | |
| | | 1 | 2 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 2 | 3 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Pyrexia | 15 | 18 |
| Rash | 1 | 1 |
| Rash erythematous | 2 | 2 |
| Respiratory arrest | 1 | 1 |
| Respiratory distress | 2 | 4 |
| Respiratory rate increased | 2 | 2 |
| Rhinorrhoea | 2 | 3 |
| Seizure | 1 | 1 |
| Sepsis | 4 | 4 |
| Sinus tachycardia | 1 | 1 |
| Slow speech | 1 | 1 |
| Somnolence | 1 | 1 |
| Speech disorder | 1 | 1 |
| Streptococcal bacteraemia | 1 | 1 |
| Stress | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 |
| Swelling | 1 | 1 |
| Swelling face | 1 | 1 |
| Swollen tongue | 1 | 1 |
| Syncope | 1 | 1 |
| Systemic inflammatory response syndrome | | 1 |
| Tachycardia | 1 | 2 |
| Tachypnoea | | 1 |
| Throat irritation | 1 | 1 |
| Throat tightness | 1 | 1 |
| Thrombosis | 1 | 1 |
| Tongue discomfort | 1 | 1 |
| Transient ischaemic attack | 1 | 1 |
| Tremor | 1 | 1 |
| Underdose | 1 | 2 |
| Upper respiratory tract infection | 1 | 2 |
| Urinary incontinence | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 6 | 7 | 9 | 11 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 1 |
| | | 2 | 4 |
| | | 2 | 2 |
| 2 | 3 | | |
| | | 1 | 1 |
| | | 4 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | |
| | | 1 | 2 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|---|-----|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Urinary tract infection | | 1 | | | | | 1 |
| Urosepsis | | 2 | | | | | 2 |
| Urticaria | 2 | 2 | | | 2 | | 2 |
| Vaccination site induration | 1 | 1 | 1 | 1 | | | |
| Vaccination site pain | 12 | 12 | 12 | 12 | | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | | |
| Vaccination site swelling | 1 | 1 | 1 | 1 | | | |
| Ventricular tachycardia | 1 | 1 | | | 1 | | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | | |
| Vomiting | 7 | 8 | 1 | 2 | 6 | | 6 |
| Wheezing | 1 | 2 | | 1 | 1 | | 1 |
| White blood cells urine positive | 1 | 1 | 1 | 1 | | | |
| | 295 | 382 | 85 | 111 | 210 | | 271 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circumstance or information capable of leading to medication error | | 29 | | 29 | | |
| COVID-19 | 19 | 19 | 18 | 18 | 1 | 1 |
| Death | 2 | 2 | | | 2 | 2 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | 2 | 2 | 2 | 2 | | |
| Myalgia | | 2 | | 2 | | |
| Poor quality product administered | | 28 | | 28 | | |
| Product colour issue | | 29 | | 29 | | |
| Pyrexia | 1 | 3 | 1 | 3 | | |
| Vaccination site joint movement impairment | 2 | 2 | 2 | 2 | | |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| | 29 | 119 | 25 | 115 | 4 | 4 |

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Country Where Event Occurred
SWITZERLAND

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | | | 1 |
| Acute myocardial infarction | | 1 | | | | 1 |
| Acute pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Aphasia | | 1 | | | | 1 |
| Arteriosclerosis | | 1 | | | | 1 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Asthma | 2 | 2 | | | 2 | 2 |
| Atrophy | | 1 | | | | 1 |
| Blindness transient | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | | 1 | | | | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 3 | 3 | 1 | 1 | 2 | 2 |
| Chronic obstructive pulmonary disease | | 1 | | | | 1 |
| Coma | 1 | 1 | | | 1 | 1 |
| COVID-19 | 2 | 2 | | | 2 | 2 |
| Death | 1 | 1 | | | 1 | 1 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Dizziness | 3 | 4 | 1 | 2 | 2 | 2 |
| Drug ineffective | 3 | 3 | | | 3 | 3 |
| Drug interaction | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Dysaesthesia | 1 | 1 |
| Dyspnoea | 1 | 1 |
| Embolism | | 1 |
| Erythema | 3 | 3 |
| Fall | | 1 |
| Fatigue | 1 | 2 |
| Feeling hot | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Gastric disorder | | 1 |
| Haemorrhagic stroke | 1 | 1 |
| Headache | 4 | 4 |
| Hemiplegia | | 1 |
| Hepatic cirrhosis | | 1 |
| Hypersensitivity | 2 | 2 |
| Hypertensive emergency | 1 | 1 |
| Hyperthermia | 1 | 1 |
| Influenza like illness | 1 | 1 |
| Lymphadenopathy | 1 | 1 |
| Malaise | 2 | 3 |
| Myalgia | 2 | 2 |
| Nausea | 2 | 3 |
| Oxygen saturation decreased | 1 | 1 |
| Pain | 1 | 1 |
| Paraesthesia | 1 | 1 |
| Peripheral vascular disorder | 1 | 1 |
| Platelet count increased | 1 | 1 |
| Pneumonia | | 1 |
| Presyncope | 1 | 1 |
| Pruritus | 3 | 3 |
| Pyrexia | 4 | 4 |
| Respiratory depression | 1 | 1 |
| Respiratory distress | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | 2 | 2 |
| | | | 1 |
| 1 | 2 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 2 | 2 | 2 | 2 |
| | | | 1 |
| | | | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 3 |
| | | 2 | 2 |
| | | 2 | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 1 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | 3 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |

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 * AE=Adverse Event
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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|-----------|-----------|-----------|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Respiratory failure | | 1 | | | | 1 | |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 | |
| SARS-CoV-2 test positive | 2 | 2 | | | 2 | 2 | |
| Somnolence | | 1 | | | | 1 | |
| Swelling face | 1 | 1 | 1 | 1 | | | |
| Swollen tongue | | 1 | | | | 1 | |
| Tachycardia | 1 | 2 | 1 | 1 | | 1 | |
| Type I hypersensitivity | | 1 | | | | 1 | |
| Urticaria | 1 | 1 | 1 | 1 | | | |
| Vaccination site erythema | 4 | 4 | 2 | 2 | 2 | 2 | |
| Vaccination site induration | 1 | 1 | | | 1 | 1 | |
| Vaccination site pain | 1 | 3 | 1 | 3 | | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | | |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 | |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 | |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 | |
| Vomiting | 3 | 3 | | | 3 | 3 | |
| | 93 | 119 | 29 | 33 | 64 | 86 | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Agitation | 1 | 1 | | | 1 | 1 |
| Anal haemorrhage | | 1 | | 1 | | |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Aphasia | 2 | 2 | | | 2 | 2 |
| Asthenia | | 1 | | 1 | | |
| Back pain | | 1 | | 1 | | |
| Blood pressure decreased | | 1 | | | | 1 |
| Central nervous system lesion | 1 | 1 | | | 1 | 1 |
| Chills | | 1 | | 1 | | |
| Coma | | 1 | | | | 1 |
| Confusional state | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | | 1 | | | | 1 |
| Death | | 2 | | | | 2 |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Encephalopathy | 1 | 1 | | | 1 | 1 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 2 | | 1 | 1 | 1 |
| Feeling cold | | 1 | | 1 | | |
| Gait disturbance | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 1 | 2 | | | 1 | 2 |
| Heart rate decreased | | 1 | | | | 1 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Malaise | | 1 | | 1 | | |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Muscle disorder | 1 | 1 | | | 1 | 1 |
| Myalgia | | 1 | | | | 1 |
| Oxygen saturation decreased | | 1 | | | | 1 |
| Pain in extremity | | 1 | | 1 | | |
| Pleocytosis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 2 | | | 1 | 2 |
| Sleep disorder | 1 | 1 | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Somnolence | 2 | 3 | | | 2 | 3 |
| Tachypnoea | | 1 | | | | 1 |
| Urinary incontinence | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 2 | | | 1 | 2 |
| Vaccination site pain | | 1 | | 1 | | |
| | 22 | 45 | 3 | 13 | 19 | 32 |

Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Dysgeusia | | 1 | | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Nausea | | 1 | | 1 | | |
| Underdose | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | | | 1 | 1 |
| Wrong product administered | 1 | 1 | 1 | 1 | | |
| | 7 | 9 | 4 | 6 | 3 | 3 |

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Country Where Event Occurred
TURKS AND CAICOS ISLANDS

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nodule | 1 | 1 | 1 | 1 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Tonic convulsion | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 3 | 3 | 2 | 2 |

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Country Where Event Occurred
UNITED ARAB EMIRATES

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 2 | 2 | 2 | 2 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Chest pain | | 1 | | | | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 1 | | | | 1 |
| Depressed level of consciousness | | 1 | | | | 1 |
| Depressed mood | | 1 | | | | 1 |
| Dizziness | 1 | 2 | 1 | 1 | | 1 |
| Drug ineffective | | 1 | | | | 1 |
| Facial paralysis | | 1 | | | | 1 |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 2 | 1 | 1 | | 1 |
| Hypertension | | 1 | | | | 1 |
| Hypoacusis | | 1 | | | | 1 |
| Hypoaesthesia | | 1 | | | | 1 |
| Injected limb mobility decreased | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Nausea | 4 | 5 | 4 | 4 | | 1 |
| Neurotoxicity | 1 | 1 | | | 1 | 1 |
| Off label use | | 1 | | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Product use issue | | 1 | | 1 | | |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 2 | 2 | 2 | | |
| Rash | 1 | 1 | 1 | 1 | | |
| Sciatica | 1 | 1 | 1 | 1 | | |
| Skin irritation | 1 | 1 | 1 | 1 | | |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| | 26 | 41 | 24 | 27 | 2 | 14 |

Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | | 1 | | 1 | | |
| Back pain | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| COVID-19 | 3 | 4 | | | 3 | 4 |
| Diarrhoea | | 1 | | 1 | | |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 3 | 4 | | | 3 | 4 |
| Erectile dysfunction | | 1 | | | | 1 |
| Fatigue | | 1 | | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 2 | 1 | 2 | | |
| Hypertension | | 1 | | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 3 | 1 | 3 | | |
| Rectal haemorrhage | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | | 1 | | 1 | | |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| | 15 | 26 | 7 | 15 | 8 | 11 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 1 | 1 | 2 | 2 |

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Country Where Event Occurred
UNITED KINGDOM

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Abdominal discomfort | 51 | 69 |
| Abdominal distension | 12 | 21 |
| Abdominal pain | 84 | 140 |
| Abdominal pain lower | 7 | 10 |
| Abdominal pain upper | 143 | 211 |
| Abdominal rigidity | 1 | 1 |
| Abdominal tenderness | 1 | 5 |
| Abnormal dreams | 3 | 11 |
| Abnormal faeces | | 1 |
| Abnormal sensation in eye | 3 | 6 |
| Abnormal weight gain | 1 | 1 |
| Abortion spontaneous | 6 | 8 |
| Abscess | 2 | 2 |
| Abscess oral | 2 | 2 |
| Accidental overdose | 1 | 2 |
| Acidosis | | 1 |
| Acrochordon | 1 | 1 |
| Acute abdomen | 1 | 1 |
| Acute febrile neutrophilic dermatosis | 1 | 1 |
| Acute kidney injury | 4 | 6 |
| Acute myocardial infarction | 3 | 6 |
| Acute respiratory failure | | 1 |
| Administration site joint movement impairment | 1 | 1 |
| Adnexa uteri pain | 3 | 3 |
| Adrenocortical insufficiency acute | 1 | 1 |
| Adverse drug reaction | 3 | 4 |
| Adverse event | 1 | 1 |
| Adverse reaction | | |
| Aerophagia | | 1 |
| African trypanosomiasis | | 1 |
| Age-related macular degeneration | | 1 |
| Ageusia | 26 | 48 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 2 | 2 | 5 | 13 | 46 | 56 |
| | | 3 | 7 | 9 | 14 |
| | | 14 | 43 | 70 | 97 |
| | | 1 | 3 | 6 | 7 |
| | | 12 | 38 | 131 | 173 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 3 |
| | | 1 | 7 | 2 | 4 |
| | | | 1 | | |
| | | | 1 | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 6 | 8 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 6 |
| | | | | 3 | 6 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 5 | 14 | 21 | 34 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Aggression | 1 | 1 |
| Agitation | 7 | 13 |
| Airway burns | 1 | 1 |
| Alanine aminotransferase increased | 1 | 4 |
| Alcohol interaction | | 1 |
| Allergic cough | | 1 |
| Allergic reaction to excipient | 2 | 2 |
| Allergy to vaccine | 7 | 24 |
| Allodynia | | 1 |
| Alopecia | 6 | 7 |
| Altered state of consciousness | 2 | 2 |
| Amblyopia | | 1 |
| Amnesia | 7 | 8 |
| Anaemia | 4 | 4 |
| Anal haemorrhage | 3 | 4 |
| Anal incontinence | 1 | 1 |
| Anal sphincter atony | 1 | 1 |
| Anaphylactic reaction | 82 | 143 |
| Anaphylactic shock | 4 | 5 |
| Anaphylactoid reaction | 3 | 8 |
| Anger | | 1 |
| Angina pectoris | 4 | 5 |
| Angioedema | 30 | 46 |
| Anisocytosis | 1 | 1 |
| Ankylosing spondylitis | 1 | 1 |
| Anorgasmia | | 1 |
| Anosmia | 9 | 22 |
| Anovulatory cycle | 1 | 1 |
| Antibody test abnormal | 1 | 1 |
| Antibody test positive | | 1 |
| Anticholinergic syndrome | | 1 |
| Anticoagulation drug level increased | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 3 | 6 | 10 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | 9 | 7 | 15 |
| | | | | | 1 |
| | | 2 | 2 | 4 | 5 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 1 | 2 | 6 | 6 |
| | | 2 | 2 | 2 | 2 |
| | | | | 3 | 4 |
| 1 | 1 | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 82 | 143 |
| | | | | 4 | 5 |
| | | | | 3 | 8 |
| | | | | | 1 |
| | | | | 4 | 5 |
| | | | | 30 | 46 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 9 | 8 | 13 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Anuria | | 1 |
| Anxiety | 43 | 76 |
| Aortic stenosis | 1 | 1 |
| Apathy | 1 | 2 |
| Aphasia | 4 | 6 |
| Aphonia | 5 | 10 |
| Aphthous ulcer | 1 | 2 |
| Apnoea | 1 | 1 |
| Appendicitis | | 1 |
| Appetite disorder | 1 | 2 |
| Arrhythmia | 8 | 11 |
| Arrhythmia supraventricular | | 2 |
| Arteritis | 1 | 1 |
| Arthralgia | 601 | 1,051 |
| Arthritis | 16 | 22 |
| Arthritis reactive | 2 | 3 |
| Arthropathy | 4 | 4 |
| Ascites | 2 | 2 |
| Aspiration | 2 | 2 |
| Asthenia | 201 | 308 |
| Asthenopia | 17 | 20 |
| Asthma | 35 | 53 |
| Asthma prophylaxis | | 1 |
| Asymptomatic COVID-19 | 1 | 2 |
| Ataxia | 1 | 1 |
| Atelectasis | | 1 |
| Atrial f brillation | 13 | 23 |
| Atrial flutter | 1 | 1 |
| Atrial tachycardia | 1 | 1 |
| Atypical femur fracture | 1 | 1 |
| Auditory disorder | 1 | 1 |
| Aura | | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 11 | 24 | 32 | 52 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | 2 | 2 | 2 | 4 |
| | | 1 | 2 | 4 | 8 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 8 | 11 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| 2 | 3 | 71 | 220 | 530 | 831 |
| | | | 2 | 16 | 20 |
| | | | | 2 | 3 |
| | | 1 | 1 | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| 1 | 1 | 50 | 89 | 151 | 219 |
| | | 1 | 3 | 16 | 17 |
| | | 5 | 9 | 30 | 44 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 3 | | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Auricular swelling | | 1 |
| Autoimmune disorder | 4 | 4 |
| Autoimmune haemolytic anaemia | 1 | 1 |
| Autonomic nervous system imbalance | 1 | 1 |
| Autoscopy | 1 | 1 |
| Axillary mass | 4 | 12 |
| Axillary pain | 76 | 143 |
| Bacille Calmette-Guerin scar reactivation | 1 | 1 |
| Back pain | 170 | 265 |
| Bacterial diarrhoea | 1 | 1 |
| Balance disorder | 36 | 49 |
| Bedridden | 3 | 3 |
| Behcet's syndrome | 2 | 2 |
| Binocular eye movement disorder | 1 | 1 |
| Bladder discomfort | | 1 |
| Bladder disorder | 2 | 2 |
| Bladder irritation | 1 | 1 |
| Bleeding time abnormal | 1 | 1 |
| Blepharitis | | 1 |
| Blepharospasm | 2 | 4 |
| Blindness | 8 | 8 |
| Blindness transient | 2 | 2 |
| Blister | 15 | 22 |
| Blood alkaline phosphatase increased | | 2 |
| Blood blister | 1 | 1 |
| Blood creatinine increased | 2 | 2 |
| Blood glucose decreased | 2 | 4 |
| Blood glucose fluctuation | 2 | 2 |
| Blood glucose increased | 6 | 13 |
| Blood ketone body increased | 1 | 1 |
| Blood ketone body present | | 1 |
| Blood lactic acid increased | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 5 | 4 | 7 |
| | | 18 | 45 | 58 | 98 |
| | | 1 | 1 | | |
| 2 | 2 | 21 | 57 | 149 | 208 |
| | | | | 1 | 1 |
| | | 5 | 7 | 31 | 42 |
| | | 1 | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 4 |
| | | | | 8 | 8 |
| | | | | 2 | 2 |
| | | 1 | 5 | 14 | 17 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 2 | 2 |
| | | | 1 | 6 | 12 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Blood magnesium decreased | 1 | 1 |
| Blood pH increased | | 1 |
| Blood potassium abnormal | | 1 |
| Blood potassium decreased | 1 | 1 |
| Blood pressure abnormal | 2 | 2 |
| Blood pressure decreased | 4 | 11 |
| Blood pressure fluctuation | 1 | 2 |
| Blood pressure increased | 38 | 82 |
| Blood pressure orthostatic abnormal | | 1 |
| Blood pressure orthostatic decreased | | 1 |
| Blood pressure systolic decreased | 1 | 2 |
| Blood pressure systolic increased | 3 | 5 |
| Blood sodium decreased | 1 | 1 |
| Blood test abnormal | | 1 |
| Blood testosterone increased | 1 | 1 |
| Blood urea increased | 1 | 1 |
| Blood urine present | 3 | 5 |
| Blue toe syndrome | 2 | 2 |
| Body temperature | 1 | 4 |
| Body temperature abnormal | 10 | 23 |
| Body temperature decreased | 13 | 16 |
| Body temperature fluctuation | 3 | 7 |
| Body temperature increased | 34 | 77 |
| Bone contusion | 1 | 1 |
| Bone pain | 34 | 52 |
| Bone swelling | 1 | 3 |
| Bowel movement irregularity | 1 | 1 |
| Bradycardia | 4 | 11 |
| Bradykinesia | 2 | 2 |
| Bradyphrenia | 2 | 3 |
| Brain injury | | 1 |
| Brain oedema | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 3 | 3 | 8 |
| | | | | 1 | 2 |
| 1 | 1 | 10 | 35 | 28 | 47 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | 2 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | | 2 | 3 | 3 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 3 |
| | | 4 | 7 | 6 | 16 |
| | | 1 | 3 | 12 | 13 |
| | | 1 | 3 | 2 | 4 |
| | 1 | 8 | 22 | 26 | 55 |
| | | 1 | 1 | | |
| | | 5 | 14 | 29 | 38 |
| | | 1 | 2 | | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 11 |
| | | | | 2 | 2 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Breast abscess | | 1 |
| Breast cancer | 1 | 1 |
| Breast cyst | 1 | 1 |
| Breast discomfort | 1 | 2 |
| Breast enlargement | 1 | 1 |
| Breast mass | 4 | 5 |
| Breast pain | 22 | 34 |
| Breast swelling | 9 | 13 |
| Breast tenderness | 6 | 6 |
| Breath odour | 1 | 2 |
| Bronchial disorder | 1 | 1 |
| Bronchiectasis | 1 | 1 |
| Bronchitis | 2 | 2 |
| Bronchopulmonary aspergillosis | 1 | 1 |
| Bronchospasm | 1 | 3 |
| Burning sensation | 29 | 52 |
| Burn oesophageal | 1 | 1 |
| Burns second degree | 1 | 1 |
| Bursitis | 3 | 3 |
| Candida infection | 1 | 1 |
| Cardiac arrest | 5 | 13 |
| Cardiac disorder | 1 | 2 |
| Cardiac failure | 2 | 4 |
| Cardiac failure congestive | 1 | 2 |
| Cardiac flutter | 8 | 11 |
| Cardiac murmur | 1 | 1 |
| Cardiopulmonary failure | | 1 |
| Cardiovascular disorder | 1 | 1 |
| Carpal tunnel syndrome | 1 | 1 |
| Cataplexy | | 1 |
| Catarrh | 1 | 2 |
| Cellulitis | 30 | 46 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 4 |
| | | 3 | 8 | 19 | 26 |
| | | 3 | 7 | 6 | 6 |
| | | 1 | 1 | 5 | 5 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | 5 | 9 | 24 | 43 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | 5 | 13 |
| | | | | 1 | 2 |
| | | | | 2 | 4 |
| | | | | 1 | 2 |
| | | | | 8 | 11 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 30 | 46 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Cerebellar stroke | | 1 |
| Cerebral disorder | 1 | 1 |
| Cerebral haemorrhage | 7 | 9 |
| Cerebral infarction | 2 | 3 |
| Cerebral venous sinus thrombosis | | 1 |
| Cerebrovascular accident | 21 | 32 |
| Chalazion | 1 | 1 |
| Chapped lips | 2 | 3 |
| Cheilitis | 2 | 3 |
| Chest crushing | 1 | 1 |
| Chest discomfort | 104 | 189 |
| Chest pain | 147 | 232 |
| Chest X-ray abnormal | 1 | 1 |
| Chillblains | | 1 |
| Chills | 713 | 1,315 |
| Choking | 3 | 3 |
| Choking sensation | 2 | 2 |
| Cholecystitis infective | | 1 |
| Choroidal neovascularisation | 2 | 2 |
| Chromaturia | 5 | 7 |
| Chronic fatigue syndrome | 3 | 4 |
| Chronic obstructive pulmonary disease | 2 | 2 |
| Chronic spontaneous urticaria | 1 | 1 |
| Circulatory collapse | 4 | 14 |
| Circumstance or information capable of leading to medication error | | 2 |
| Clonic convulsion | 1 | 1 |
| Clostridium difficile colitis | | 1 |
| Clostridium difficile infection | 1 | 1 |
| Clumsiness | | 1 |
| Cluster headache | 11 | 18 |
| Coccydynia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 7 | 9 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | | 21 | 32 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 16 | 43 | 88 | 146 |
| 1 | 1 | 13 | 40 | 134 | 192 |
| | | 1 | 1 | | |
| | | | | | 1 |
| 3 | 4 | 88 | 305 | 625 | 1010 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | 3 | 4 | 2 | 3 |
| | | | 1 | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 14 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 2 | 10 | 16 |
| | | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Cognitive disorder | 6 | 9 |
| Cold sweat | 48 | 92 |
| Colitis | 2 | 2 |
| Colitis microscopic | 1 | 1 |
| Colitis ulcerative | 2 | 2 |
| Coma | 1 | 1 |
| Communication disorder | 3 | 4 |
| Condition aggravated | 36 | 58 |
| Confusional state | 69 | 95 |
| Conjunctival haemorrhage | 3 | 6 |
| Conjunctivitis | 6 | 10 |
| Conjunctivitis bacterial | 1 | 1 |
| Consciousness fluctuating | 3 | 4 |
| Constipation | 10 | 13 |
| Contraindicated product administered | 1 | 3 |
| Contrast media reaction | 1 | 1 |
| Contusion | 28 | 40 |
| Coordination abnormal | 6 | 7 |
| Corneal abrasion | 1 | 1 |
| Coronary artery disease | | 2 |
| Coronary artery occlusion | 1 | 1 |
| Cortisol decreased | | 1 |
| Costochondritis | 4 | 6 |
| Costovertebral angle tenderness | | 1 |
| Cough | 157 | 265 |
| COVID-19 | 86 | 136 |
| COVID-19 pneumonia | 6 | 7 |
| Cranial nerve disorder | 1 | 1 |
| C-reactive protein increased | 1 | 2 |
| Crohn's disease | 3 | 3 |
| Crying | 8 | 11 |
| CT hypotension complex | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 5 | 8 |
| | | 8 | 23 | 40 | 69 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 3 |
| | | 5 | 13 | 31 | 45 |
| | | 10 | 15 | 59 | 80 |
| | | | | 3 | 6 |
| | | | 1 | 6 | 9 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | 1 | 3 | 9 | 10 |
| | | 1 | 2 | | 1 |
| | | | | 1 | 1 |
| | | 9 | 13 | 19 | 27 |
| | | 1 | 2 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 3 | 5 |
| | | | 1 | | |
| 1 | 1 | 19 | 55 | 138 | 210 |
| 1 | 1 | 4 | 6 | 82 | 130 |
| | | | | 6 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 3 | 3 |
| | | | 1 | 8 | 10 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Culture negative | | 1 |
| Cutaneous symptom | 1 | 1 |
| Cyanosis | 2 | 7 |
| Cyst | 1 | 1 |
| Cystitis | 5 | 5 |
| Deafness | 8 | 10 |
| Deafness neurosensory | 1 | 1 |
| Deafness unilateral | 1 | 1 |
| Death | 20 | 46 |
| Decreased appetite | 155 | 240 |
| Decreased immune responsiveness | 1 | 1 |
| Decreased interest | | 2 |
| Deep vein thrombosis | 3 | 7 |
| Defaecation urgency | 1 | 3 |
| Dehydration | 12 | 25 |
| Delirium | 9 | 16 |
| Delusion | | 1 |
| Depersonalisation/derealisation disorder | | 2 |
| Depressed level of consciousness | 1 | 4 |
| Depressed mood | 19 | 23 |
| Depression | 6 | 8 |
| Derealisation | | 1 |
| Dermatitis | 5 | 11 |
| Dermatitis allergic | 9 | 21 |
| Dermatitis atopic | 1 | 1 |
| Dermatitis bullous | 1 | 1 |
| Diabetes mellitus | 1 | 1 |
| Diabetes mellitus inadequate control | 1 | 2 |
| Diabetic complication | | 1 |
| Diabetic diet | 1 | 1 |
| Diabetic ketoacidosis | | 3 |
| Diarrhoea | 380 | 579 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 6 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | | | 8 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 20 | 46 |
| 2 | 2 | 32 | 54 | 123 | 186 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 3 | 7 |
| | | | | 1 | 3 |
| | | 1 | 8 | 11 | 17 |
| | | | | 9 | 16 |
| | | | | | 1 |
| | | | 1 | | 1 |
| | | | | 1 | 4 |
| | | 2 | 4 | 17 | 19 |
| | | | | 6 | 8 |
| | | | | | 1 |
| | | 1 | 5 | 4 | 6 |
| | | | 5 | 9 | 16 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | 38 | 118 | 342 | 461 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Diarrhoea haemorrhagic | 2 | 3 |
| Diplegia | 1 | 1 |
| Diplopia | 8 | 15 |
| Discharge | 1 | 1 |
| Discoloured vomit | | 2 |
| Discomfort | 31 | 46 |
| Disease recurrence | 34 | 43 |
| Disorganised speech | 1 | 2 |
| Disorientation | 29 | 39 |
| Dissociation | 2 | 4 |
| Disturbance in attention | 37 | 53 |
| Diverticulitis | 1 | 1 |
| Dizziness | 653 | 1,073 |
| Dizziness exertional | 5 | 6 |
| Dizziness postural | 47 | 78 |
| Drooling | 2 | 3 |
| Drug eruption | | 2 |
| Drug hypersensitivity | 4 | 7 |
| Drug ineffective | 119 | 236 |
| Drug withdrawal syndrome | 1 | 1 |
| Dry eye | 9 | 13 |
| Dry mouth | 42 | 72 |
| Dry skin | 7 | 12 |
| Dry throat | 14 | 24 |
| Duodenogastric reflux | 1 | 1 |
| Dysaesthesia | 1 | 1 |
| Dysarthria | 12 | 18 |
| Dyschezia | 1 | 1 |
| Dysgeusia | 67 | 129 |
| Dyshidrotic eczema | 1 | 1 |
| Dyskinesia | 5 | 7 |
| Dysmenorrhoea | 7 | 10 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | 4 | 8 | 11 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | 8 | 15 | 23 | 31 |
| | | 2 | 4 | 32 | 39 |
| | | | 1 | 1 | 1 |
| | | 2 | 4 | 27 | 35 |
| | | 1 | 3 | 1 | 1 |
| | | 4 | 10 | 33 | 43 |
| | | | | 1 | 1 |
| 3 | 4 | 87 | 263 | 566 | 810 |
| | | | 1 | 5 | 5 |
| | | 3 | 11 | 44 | 67 |
| | | | | 2 | 3 |
| | | | | | 2 |
| | | 1 | 2 | 3 | 5 |
| 1 | 1 | 1 | 2 | 118 | 234 |
| | | | | 1 | 1 |
| | | 2 | 5 | 7 | 8 |
| 1 | 1 | 6 | 20 | 36 | 52 |
| | | 1 | 6 | 6 | 6 |
| | | 3 | 5 | 11 | 19 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 11 | 17 |
| | | | | 1 | 1 |
| | | 12 | 52 | 55 | 77 |
| | | | | 1 | 1 |
| | | | | 5 | 7 |
| | | 3 | 5 | 4 | 5 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Dysmorphism | 1 | 1 |
| Dyspepsia | 16 | 24 |
| Dysphagia | 23 | 42 |
| Dysphonia | 9 | 21 |
| Dyspnoea | 281 | 445 |
| Dyspnoea at rest | 3 | 3 |
| Dyspnoea exertional | 11 | 18 |
| Dysstasia | 13 | 17 |
| Dystonia | 3 | 3 |
| Dysuria | 3 | 4 |
| Ear discomfort | 7 | 15 |
| Ear disorder | 2 | 2 |
| Ear infection | 5 | 7 |
| Ear infection bacterial | 1 | 1 |
| Ear pain | 48 | 77 |
| Ear pruritus | 1 | 3 |
| Ear swelling | 1 | 2 |
| Eating disorder | 2 | 3 |
| Eating disorder symptom | 1 | 1 |
| Eczema | 11 | 16 |
| Eczema weeping | 1 | 1 |
| Electric shock | 1 | 1 |
| Electrocardiogram abnormal | 2 | 2 |
| Electrocardiogram ST segment elevation | | 1 |
| Emotional disorder | 3 | 3 |
| Emotional distress | 7 | 7 |
| Encephalitis | 2 | 2 |
| Encephalopathy | 1 | 1 |
| Endometriosis | 1 | 1 |
| Enlarged uvula | 1 | 2 |
| Enuresis | | 2 |
| Eosinophil count increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 2 | 7 | 14 | 17 |
| | | 5 | 10 | 18 | 32 |
| | | 2 | 5 | 7 | 16 |
| | | 30 | 72 | 251 | 373 |
| | | | | 3 | 3 |
| | | 1 | 5 | 10 | 13 |
| | | 4 | 5 | 9 | 12 |
| | | | | 3 | 3 |
| | | | 1 | 3 | 3 |
| | | 1 | 7 | 6 | 8 |
| | | | | 2 | 2 |
| | | 1 | 2 | 4 | 5 |
| | | | | 1 | 1 |
| | | 6 | 18 | 42 | 59 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 2 | 3 | 9 | 13 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | 6 | 6 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | | 1 |
| | | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Eosinophilia | | 1 |
| Epicondylitis | 2 | 2 |
| Epigastric discomfort | 2 | 2 |
| Epilepsy | 7 | 11 |
| Epiphyses premature fusion | 1 | 1 |
| Episcleritis | 1 | 3 |
| Epistaxis | 29 | 46 |
| Epstein-Barr virus infection | 1 | 1 |
| Eructation | 6 | 9 |
| Erythema | 127 | 250 |
| Erythema annulare | 1 | 1 |
| Erythema multiforme | 5 | 7 |
| Erythema nodosum | 2 | 2 |
| Erythema of eyelid | 1 | 1 |
| Euphoric mood | 2 | 3 |
| Eustachian tube disorder | 1 | 1 |
| Excessive granulation tissue | 1 | 1 |
| Exercise tolerance decreased | | 1 |
| Exertional headache | 1 | 2 |
| Exfoliative rash | 1 | 1 |
| Expired product administered | | 1 |
| Exposure during pregnancy | 9 | 12 |
| Exposure to SARS-CoV-2 | 3 | 4 |
| Exposure via breast milk | 1 | 2 |
| Extensor plantar response | 1 | 1 |
| External ear cellulitis | 1 | 1 |
| External ear pain | 2 | 2 |
| Extraocular muscle paresis | 1 | 1 |
| Extrasystoles | 3 | 6 |
| Eye abscess | 1 | 1 |
| Eye allergy | | 1 |
| Eye complication associated with device | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 7 | 11 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | 3 | 11 | 26 | 35 |
| | | | | 1 | 1 |
| | | | | 6 | 9 |
| | | 24 | 90 | 103 | 160 |
| | | | | 1 | 1 |
| | | | | 5 | 7 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 2 | 2 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 8 | 11 | 1 | 1 |
| | | 1 | 1 | 2 | 3 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 2 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------|------------------------------------|--------------------------------------|
| Eye contusion | 2 | 5 |
| Eye discharge | 3 | 3 |
| Eye disorder | 6 | 16 |
| Eye haematoma | 1 | 1 |
| Eye haemorrhage | 2 | 3 |
| Eye infection | 1 | 1 |
| Eye inflammation | 2 | 2 |
| Eye injury | 1 | 2 |
| Eye irritation | 6 | 13 |
| Eyelid exfoliation | | 1 |
| Eyelid function disorder | 1 | 1 |
| Eyelid irritation | 1 | 2 |
| Eyelid oedema | 2 | 2 |
| Eyelid pain | 2 | 3 |
| Eyelid ptosis | 1 | 2 |
| Eyelid rash | 1 | 3 |
| Eyelids pruritus | | 2 |
| Eye movement disorder | | 3 |
| Eye oedema | 1 | 1 |
| Eye pain | 66 | 105 |
| Eye paraesthesia | | 1 |
| Eye pruritus | 12 | 26 |
| Eye swelling | 42 | 66 |
| Face crushing | | 1 |
| Face injury | 1 | 1 |
| Face oedema | 2 | 2 |
| Facial discomfort | 2 | 4 |
| Facial neuralgia | 3 | 4 |
| Facial pain | 19 | 34 |
| Facial paralysis | 61 | 88 |
| Facial paresis | 5 | 11 |
| Facial spasm | 1 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | | 1 | 2 | 4 |
| | | | | 3 | 3 |
| | | 2 | 6 | 4 | 10 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | 1 | 3 | 5 | 10 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 3 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 3 |
| | | | 1 | | 1 |
| | | | | | 3 |
| | | 1 | 1 | | |
| 1 | 1 | 8 | 20 | 58 | 85 |
| | | | 1 | | |
| 2 | 2 | 3 | 7 | 9 | 19 |
| 1 | 1 | 4 | 10 | 38 | 56 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 3 |
| | | | 1 | 3 | 3 |
| | | 3 | 8 | 16 | 26 |
| 1 | 1 | | 2 | 61 | 86 |
| | | | 2 | 5 | 9 |
| | | | 2 | 1 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Faeces discoloured | 3 | 5 |
| Faeces pale | 1 | 2 |
| Faeces soft | 1 | 1 |
| Fall | 34 | 46 |
| Familial hemiplegic migraine | 1 | 1 |
| Fatigue | 1,584 | 2,518 |
| Fear | 1 | 5 |
| Fear of injection | | 1 |
| Febrile convulsion | 1 | 1 |
| Feeding disorder | 14 | 18 |
| Feeling abnormal | 133 | 211 |
| Feeling cold | 127 | 217 |
| Feeling drunk | 7 | 15 |
| Feeling hot | 127 | 237 |
| Feeling jittery | 5 | 8 |
| Feeling of body temperature change | 42 | 75 |
| Feeling of despair | 1 | 1 |
| Femur fracture | 1 | 1 |
| Fibrin D dimer increased | 1 | 2 |
| Fibromyalgia | 8 | 10 |
| Flank pain | | 2 |
| Flatulence | 14 | 14 |
| Fluid intake reduced | | 2 |
| Fluid retention | 1 | 2 |
| Flushing | 47 | 96 |
| Folliculitis | | 2 |
| Food allergy | 2 | 2 |
| Food aversion | 2 | 2 |
| Food craving | 1 | 1 |
| Food poisoning | 1 | 1 |
| Food refusal | 2 | 2 |
| Forced expiratory volume increased | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 4 | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 12 | 15 | 22 | 31 |
| | | | | 1 | 1 |
| 21 | 25 | 232 | 590 | 1352 | 1928 |
| | | 1 | 2 | | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 8 | 10 | 10 |
| | | 28 | 62 | 105 | 149 |
| 1 | 1 | 30 | 65 | 97 | 152 |
| | | 1 | 3 | 6 | 12 |
| | | 37 | 97 | 90 | 140 |
| | | | 2 | 5 | 6 |
| | | 6 | 23 | 36 | 52 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | 7 | 9 |
| | | | 2 | | |
| | | 2 | 2 | 12 | 12 |
| | | | | | 2 |
| | | | 1 | 1 | 1 |
| | | 3 | 25 | 44 | 71 |
| | | | 1 | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Foreign body sensation in eyes | 4 | 5 |
| Formication | 4 | 5 |
| Fracture blisters | 1 | 1 |
| Frequent bowel movements | 4 | 8 |
| Frustration tolerance decreased | | 1 |
| Full blood count abnormal | 1 | 1 |
| Fungal skin infection | 1 | 1 |
| Furuncle | 1 | 1 |
| Gait disturbance | 41 | 59 |
| Gait inability | 13 | 16 |
| Gamma-glutamyltransferase increased | | 1 |
| Gastric antral vascular ectasia | 1 | 1 |
| Gastric disorder | 4 | 6 |
| Gastritis | 3 | 6 |
| Gastroenteritis | 3 | 4 |
| Gastroenteritis viral | 1 | 2 |
| Gastrointestinal disorder | 1 | 2 |
| Gastrointestinal haemorrhage | 2 | 2 |
| Gastrointestinal motility disorder | | 1 |
| Gastrointestinal pain | 10 | 13 |
| Gastrointestinal sounds abnormal | 3 | 3 |
| Gastrointestinal stoma complication | | 1 |
| Gastroesophageal reflux disease | 8 | 13 |
| Generalised tonic-clonic seizure | 3 | 9 |
| General physical health deterioration | 3 | 4 |
| Genital ulceration | 1 | 1 |
| Giant cell arteritis | 1 | 1 |
| Gingival bleeding | | 3 |
| Gingival blister | | 1 |
| Gingival discomfort | 1 | 2 |
| Gingival pain | 5 | 12 |
| Gingivitis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 3 | 4 |
| | | | | 4 | 5 |
| | | 1 | 1 | | |
| | | | 2 | 4 | 6 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 5 | 11 | 36 | 48 |
| 1 | 1 | | 2 | 13 | 14 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 3 | 4 | 1 | 2 |
| | | | 1 | 3 | 5 |
| | | | | 3 | 4 |
| | | | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 10 | 13 |
| | | | | 3 | 3 |
| | | | | | 1 |
| | | | 1 | 8 | 12 |
| | | | | 3 | 9 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 2 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | 2 | 5 | 3 | 7 |
| | | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Gingivitis ulcerative | 1 | 2 |
| Glossitis | | 1 |
| Glossodynia | 17 | 25 |
| Glucose tolerance impaired | 1 | 1 |
| Goitre | 1 | 1 |
| Gout | 3 | 3 |
| Granulomatous lymphadenitis | 2 | 2 |
| Grip strength | 1 | 1 |
| Grip strength decreased | 2 | 5 |
| Groin pain | 9 | 17 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematemesis | 6 | 12 |
| Haematochezia | 4 | 5 |
| Haematocrit increased | 1 | 1 |
| Haematoma | 1 | 4 |
| Haematuria | 4 | 5 |
| Haemoglobin decreased | 1 | 2 |
| Haemoglobin increased | 1 | 1 |
| Haemoptysis | 6 | 7 |
| Haemorrhage | 10 | 10 |
| Haemorrhage intracranial | | 1 |
| Haemorrhage subcutaneous | 1 | 2 |
| Haemorrhage urinary tract | 1 | 2 |
| Haemorrhagic stroke | | 2 |
| Haemorrhoids | 1 | 1 |
| Hair colour changes | | 1 |
| Hallucination | 26 | 39 |
| Hallucination, auditory | 2 | 2 |
| Hallucination, olfactory | | 1 |
| Hallucinations, mixed | 1 | 1 |
| Hallucination, tactile | | 1 |
| Hallucination, visual | 1 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | 1 | 6 | 16 | 19 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 4 |
| 1 | 1 | | 5 | 9 | 12 |
| | | | | 1 | 1 |
| | | | | 6 | 12 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 3 |
| | | 1 | 2 | 3 | 3 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 6 | 7 |
| | | | | 10 | 10 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 26 | 39 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Halo vision | 1 | 1 |
| Hangover | 6 | 10 |
| Headache | 1,831 | 3,135 |
| Head banging | 1 | 1 |
| Head discomfort | 19 | 29 |
| Head injury | 5 | 11 |
| Heart rate | 1 | 1 |
| Heart rate abnormal | 3 | 6 |
| Heart rate decreased | 9 | 10 |
| Heart rate increased | 66 | 129 |
| Heart rate irregular | 7 | 9 |
| Heat illness | | 1 |
| Heat oedema | 1 | 2 |
| Heat stroke | | 1 |
| Hemiparaesthesia | | 1 |
| Hemiparesis | 1 | 8 |
| Hemiplegia | 2 | 2 |
| Hemiplegic migraine | 2 | 2 |
| Hepatic pain | 2 | 2 |
| Hepatitis | 1 | 2 |
| Herpes ophthalmic | 1 | 1 |
| Herpes simplex | 1 | 2 |
| Herpes virus infection | | 1 |
| Herpes zoster | 51 | 70 |
| Herpes zoster reactivation | | 1 |
| Histamine intolerance | 1 | 1 |
| Hormone level abnormal | 1 | 1 |
| Hot flush | 55 | 96 |
| Hunger | 2 | 3 |
| Hyperacusis | 5 | 8 |
| Hyperaesthesia | 7 | 15 |
| Hyperaesthesia teeth | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 8 |
| 14 | 19 | 250 | 752 | 1581 | 2383 |
| | | 1 | 1 | | |
| 1 | 1 | 2 | 7 | 17 | 22 |
| | | 2 | 5 | 3 | 6 |
| | | 1 | 1 | | |
| | | | 1 | 3 | 5 |
| | | 1 | 1 | 8 | 9 |
| | | 11 | 37 | 55 | 92 |
| | | 1 | 1 | 6 | 8 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 8 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 3 | 12 | 48 | 58 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 7 | 24 | 48 | 72 |
| | | | 1 | 2 | 2 |
| | | 2 | 3 | 3 | 5 |
| | | 3 | 6 | 4 | 9 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Hyperchlorhydria | 3 | 4 |
| Hypergeusia | 1 | 1 |
| Hyperglycaemia | 6 | 9 |
| Hyperhidrosis | 151 | 250 |
| Hyperpyrexia | 1 | 3 |
| Hyperreflexia | 1 | 1 |
| Hypersensitivity | 54 | 102 |
| Hypersomnia | 29 | 41 |
| Hypertension | 52 | 104 |
| Hypertensive crisis | | 1 |
| Hypertonia | 1 | 2 |
| Hypertonic bladder | 1 | 1 |
| Hyperventilation | 3 | 3 |
| Hypoacusis | 5 | 8 |
| Hypoaesthesia | 135 | 226 |
| Hypoaesthesia eye | | 1 |
| Hypoaesthesia oral | 36 | 75 |
| Hypoaesthesia teeth | 1 | 1 |
| Hypoglycaemia | 6 | 13 |
| Hypokalaemic syndrome | 1 | 1 |
| Hypokinesia | 5 | 7 |
| Hypomenorrhoea | 1 | 1 |
| Hyponatraemia | 1 | 2 |
| Hypophagia | 2 | 3 |
| Hypopnoea | 10 | 12 |
| Hyporeflexia | | 2 |
| Hyporesponsive to stimuli | | 1 |
| Hyposmia | 1 | 3 |
| Hyposomnia | 1 | 1 |
| Hypotension | 32 | 64 |
| Hypothermia | 3 | 5 |
| Hypothyroidism | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 7 |
| 1 | 1 | 29 | 67 | 122 | 183 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | 5 | 19 | 49 | 83 |
| | | 7 | 11 | 22 | 30 |
| 1 | 1 | 5 | 26 | 47 | 78 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | 2 | 2 | 1 | 1 |
| | | 2 | 4 | 3 | 4 |
| 1 | 1 | 29 | 72 | 106 | 154 |
| | | | | | 1 |
| | | 8 | 31 | 28 | 44 |
| | | 1 | 1 | | |
| | | | 1 | 6 | 12 |
| | | | | 1 | 1 |
| | | 2 | 3 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | | | 10 | 12 |
| | | | | | 2 |
| | | | | | 1 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 6 | 16 | 26 | 48 |
| | | | | 3 | 5 |
| | | | | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hypotonia | 1 | 2 |
| Hypoxia | 4 | 5 |
| Idiopathic intracranial hypertension | | 1 |
| Illness | 143 | 201 |
| Immune-mediated adverse reaction | 1 | 1 |
| Immune system disorder | 2 | 3 |
| Immune thrombocytopenia | 2 | 2 |
| Impaired driving ability | 1 | 3 |
| Impaired gastric emptying | 1 | 1 |
| Impaired healing | 1 | 1 |
| Impaired work ability | 4 | 4 |
| Impetigo | 1 | 1 |
| Inappropriate schedule of product administration | 5 | 14 |
| Incoherent | | 1 |
| Incomplete course of vaccination | 1 | 1 |
| Incontinence | 3 | 6 |
| Incorrect dose administered | 1 | 2 |
| Incorrect route of product administration | 11 | 29 |
| Increased insulin requirement | 1 | 1 |
| Increased tendency to bruise | 2 | 2 |
| Increased upper airway secretion | 1 | 3 |
| Increased viscosity of upper respiratory secretion | 1 | 2 |
| Indifference | | 1 |
| Induration | 1 | 2 |
| Infantile vomiting | 1 | 1 |
| Infected dermal cyst | 1 | 1 |
| Infected skin ulcer | 1 | 1 |
| Infection | 8 | 12 |
| Infectious mononucleosis | 1 | 1 |
| Infertility | 1 | 1 |
| Inflammation | 18 | 33 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | 4 | 5 |
| | | | | | 1 |
| 1 | 1 | 11 | 30 | 132 | 171 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | 1 | 2 | 2 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 4 | 13 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | 3 | 5 |
| | | 1 | 2 | | |
| | | 10 | 28 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 7 | 11 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 9 | 16 | 24 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Inflammatory marker increased | 1 | 2 |
| Influenza | 118 | 158 |
| Influenza like illness | 197 | 351 |
| Infusion related reaction | 1 | 1 |
| Inguinal mass | | 1 |
| Initial insomnia | 1 | 2 |
| Injected limb mobility decreased | 5 | 6 |
| Injection related reaction | 2 | 4 |
| Injection site erythema | | 7 |
| Injection site joint movement impairment | 1 | 1 |
| Injection site mass | | 2 |
| Injection site pain | 8 | 27 |
| Injection site pruritus | | 3 |
| Injection site rash | 1 | 3 |
| Injection site swelling | | 5 |
| Injection site warmth | 1 | 4 |
| Injury | 1 | 1 |
| Injury associated with device | | 1 |
| Injury corneal | | 1 |
| Inner ear disorder | 2 | 2 |
| Insomnia | 119 | 179 |
| Intentional self-injury | | 1 |
| International normalised ratio decreased | 2 | 2 |
| International normalised ratio increased | 1 | 2 |
| Intestinal perforation | 1 | 1 |
| Intranasal hypoaesthesia | | 1 |
| Intranasal paraesthesia | 1 | 1 |
| Intraocular pressure increased | | 1 |
| Iridocyclitis | 2 | 4 |
| Iritis | 1 | 1 |
| Irregular breathing | 4 | 4 |
| Irritability | 9 | 13 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | 1 |
| | | 15 | 33 | 103 | 125 |
| | | 29 | 94 | 168 | 257 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 5 | 6 |
| | | | 1 | 2 | 3 |
| | | | 7 | | |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | 15 | 8 | 12 |
| | | | 3 | | |
| | | | 2 | 1 | 1 |
| | | | 5 | | |
| | | | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| 1 | 1 | 25 | 53 | 94 | 126 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 2 | 4 |
| | | 1 | 1 | | |
| | | | | 4 | 4 |
| | | 1 | 2 | 8 | 11 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Irritable bowel syndrome | 6 | 11 |
| Ischaemic stroke | 2 | 6 |
| Itching scar | | 1 |
| Jaundice | 1 | 2 |
| Jaw clicking | | 1 |
| Joint effusion | 3 | 4 |
| Joint injury | 1 | 1 |
| Joint range of motion decreased | 25 | 34 |
| Joint stiffness | 14 | 24 |
| Joint swelling | 31 | 46 |
| Joint warmth | | 2 |
| Ketoacidosis | 1 | 1 |
| Kidney infection | 2 | 2 |
| Labile blood pressure | 2 | 2 |
| Labyrinthitis | 5 | 7 |
| Lack of spontaneous speech | 1 | 1 |
| Lacrimation increased | 11 | 21 |
| Lacunar infarction | | 1 |
| Lacunar stroke | | 1 |
| Laryngeal disorder | 1 | 1 |
| Laryngitis | 1 | 1 |
| Left ventricular dysfunction | 1 | 1 |
| Left ventricular failure | 1 | 1 |
| Lethargy | 171 | 293 |
| Leukaemia | | 1 |
| Ligament sprain | 1 | 2 |
| Limb discomfort | 98 | 181 |
| Limb immobilisation | 1 | 1 |
| Limb injury | 3 | 3 |
| Limb mass | 6 | 7 |
| Lip blister | 2 | 4 |
| Lip discolouration | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | 6 | 9 |
| | | | | 2 | 6 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | 4 | 6 | 21 | 28 |
| | | 2 | 3 | 12 | 21 |
| | | 5 | 7 | 26 | 39 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | 1 | 5 | 6 |
| | | 1 | 1 | | |
| | | 1 | 3 | 10 | 18 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 3 | 3 | 29 | 72 | 142 | 221 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 24 | 64 | 74 | 117 |
| | | 1 | 1 | | |
| | | | | 3 | 3 |
| | | 2 | 3 | 4 | 4 |
| | | | | 2 | 4 |
| | | | | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Lip disorder | | 2 |
| Lip dry | 3 | 7 |
| Lip exfoliation | 1 | 1 |
| Lip haemorrhage | 1 | 1 |
| Lip oedema | 1 | 2 |
| Lip pain | 1 | 5 |
| Lip pruritus | | 1 |
| Lip scab | 1 | 1 |
| Lip swelling | 70 | 112 |
| Lip ulceration | 1 | 1 |
| Listless | 1 | 1 |
| Livedo reticularis | 7 | 9 |
| Liver function test abnormal | 1 | 1 |
| Liver function test increased | 1 | 3 |
| Liver injury | 1 | 2 |
| Localised infection | | 1 |
| Localised oedema | 4 | 4 |
| Local reaction | 5 | 11 |
| Locked-in syndrome | | 1 |
| Loss of bladder sensation | 1 | 1 |
| Loss of consciousness | 49 | 72 |
| Loss of control of legs | 2 | 2 |
| Loss of personal independence in daily activities | 22 | 28 |
| Lower limb fracture | 1 | 2 |
| Lower respiratory tract infection | 16 | 21 |
| Lung disorder | 1 | 1 |
| Lymphadenitis | 7 | 9 |
| Lymphadenopathy | 350 | 639 |
| Lymphangitis | 1 | 1 |
| Lymphatic disorder | | 1 |
| Lymph node pain | 78 | 146 |
| Lymph node palpable | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | | |
| | | 1 | 4 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 1 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 5 | 18 | 65 | 94 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 7 | 8 |
| | | | | 1 | 1 |
| | | 1 | 2 | | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 4 | 4 |
| | | | 3 | 5 | 8 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 49 | 72 |
| | | | | 2 | 2 |
| | | 4 | 5 | 18 | 23 |
| | | | | 1 | 2 |
| | | | | 16 | 21 |
| | | | | 1 | 1 |
| | | 2 | 2 | 5 | 7 |
| 2 | 2 | 51 | 190 | 299 | 449 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 11 | 46 | 67 | 100 |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Lymphoedema | 5 | 10 |
| Lymphoma | 1 | 1 |
| Lymphopenia | 1 | 1 |
| Macule | 1 | 1 |
| Maculopathy | | 1 |
| Malaise | 559 | 949 |
| Mallory-Weiss syndrome | 1 | 1 |
| Malnutrition | | 1 |
| Mass | 1 | 3 |
| Mast cell activation syndrome | 1 | 2 |
| Mastication disorder | 1 | 3 |
| Mastitis | 2 | 4 |
| Maternal exposure during pregnancy | 26 | 31 |
| Maternal exposure timing unspecified | 1 | 2 |
| Mean cell volume decreased | 1 | 1 |
| Mechanical urticaria | | 1 |
| Medial tibial stress syndrome | 1 | 1 |
| Melaena | 2 | 3 |
| Melanocytic naevus | 1 | 1 |
| Memory impairment | 10 | 14 |
| Meniere's disease | 3 | 3 |
| Meningitis | 2 | 2 |
| Menopausal symptoms | | 2 |
| Menorrhagia | 11 | 16 |
| Menstrual disorder | 2 | 2 |
| Menstruation delayed | 9 | 10 |
| Menstruation irregular | 3 | 5 |
| Mental disorder | | 1 |
| Mental fatigue | 18 | 25 |
| Mental impairment | 1 | 5 |
| Metamorphopsia | | 2 |
| Metastases to lymph nodes | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 5 | 9 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| 4 | 4 | 94 | 243 | 465 | 706 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 2 | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 3 |
| | | | | 2 | 4 |
| | | 22 | 25 | 4 | 6 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 2 | 4 | 8 | 10 |
| | | | | 3 | 3 |
| | | | | 2 | 2 |
| | | | 2 | | |
| | | | 2 | 11 | 14 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 2 | 8 | 8 |
| | | 1 | 2 | 2 | 3 |
| | | | 1 | | |
| | | 3 | 6 | 15 | 19 |
| | | | | 1 | 5 |
| | | | | | 2 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Metrorrhagia | 1 | 2 |
| Micturition disorder | 2 | 3 |
| Micturition urgency | | 1 |
| Middle ear inflammation | | 1 |
| Middle insomnia | 7 | 13 |
| Migraine | 163 | 271 |
| Migraine with aura | 11 | 17 |
| Miliaria | 1 | 4 |
| Miosis | 1 | 1 |
| Mobility decreased | 39 | 61 |
| Monocytosis | 1 | 1 |
| Monoparesis | 7 | 9 |
| Monoplegia | 9 | 12 |
| Mood altered | 1 | 4 |
| Mood disorder due to a general medical condition | 1 | 1 |
| Mood swings | 4 | 4 |
| Morning sickness | 2 | 3 |
| Motion sickness | 3 | 6 |
| Motor dysfunction | 2 | 2 |
| Mouth breathing | 2 | 2 |
| Mouth cyst | | 1 |
| Mouth injury | 1 | 1 |
| Mouth swelling | 9 | 15 |
| Mouth ulceration | 29 | 42 |
| Movement disorder | 15 | 20 |
| Multiple allergies | 1 | 1 |
| Multiple organ dysfunction syndrome | | 1 |
| Multiple sclerosis | | 2 |
| Multiple sclerosis relapse | 4 | 6 |
| Muscle atrophy | 1 | 1 |
| Muscle contractions involuntary | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 5 | 6 | 8 |
| | | 10 | 50 | 153 | 221 |
| | | 1 | 3 | 10 | 14 |
| | | | | 1 | 4 |
| | | | | 1 | 1 |
| | | 18 | 29 | 21 | 32 |
| | | 1 | 1 | | |
| | | 1 | 2 | 6 | 7 |
| | | | | 9 | 12 |
| | | | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 3 |
| | | | | 2 | 3 |
| | | | 3 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 2 | 9 | 13 |
| | | 6 | 12 | 23 | 30 |
| | | 2 | 3 | 13 | 17 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 2 |
| | | | | 4 | 6 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Muscle fatigue | 34 | 47 |
| Muscle rigidity | 2 | 4 |
| Muscle rupture | 1 | 1 |
| Muscle spasms | 59 | 89 |
| Muscle strain | 2 | 3 |
| Muscle swelling | 2 | 5 |
| Muscle tightness | 6 | 7 |
| Muscle tone disorder | | 1 |
| Muscle twitching | 13 | 25 |
| Muscular weakness | 71 | 115 |
| Musculoskeletal chest pain | 18 | 25 |
| Musculoskeletal discomfort | 11 | 17 |
| Musculoskeletal disorder | 7 | 10 |
| Musculoskeletal pain | 6 | 15 |
| Musculoskeletal stiffness | 79 | 135 |
| Mutism | 2 | 2 |
| Myalgia | 751 | 1,376 |
| Myasthenia gravis | 2 | 2 |
| Mydriasis | 1 | 2 |
| Myelitis | | 1 |
| Myelitis transverse | 6 | 6 |
| Myocardial infarction | 2 | 9 |
| Myocardial ischaemia | 2 | 3 |
| Myocardial oedema | | 1 |
| Myocarditis | 1 | 4 |
| Myoclonus | 2 | 2 |
| Myofascial pain syndrome | 2 | 2 |
| Myositis | | 1 |
| Nail discolouration | 1 | 3 |
| Nasal congestion | 17 | 24 |
| Nasal discharge discolouration | | 1 |
| Nasal discomfort | 6 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 6 | 30 | 41 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | 8 | 20 | 51 | 69 |
| | | | | 2 | 3 |
| | | 1 | 2 | 1 | 3 |
| | | 1 | 1 | 5 | 6 |
| | | | | | 1 |
| | | 4 | 12 | 9 | 13 |
| | | 11 | 28 | 60 | 87 |
| | | 2 | 4 | 16 | 21 |
| | | 2 | 6 | 9 | 11 |
| | | | 1 | 7 | 9 |
| | | 1 | 3 | 5 | 12 |
| | | 10 | 31 | 69 | 104 |
| | | 1 | 1 | 1 | 1 |
| 5 | 8 | 83 | 313 | 668 | 1063 |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 6 | 6 |
| | | | | 2 | 9 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | | | 1 | 4 |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 3 |
| | | 4 | 8 | 13 | 16 |
| | | | 1 | | |
| | | 1 | 2 | 5 | 5 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Nasal obstruction | | 1 |
| Nasal odour | 1 | 2 |
| Nasal oedema | 3 | 3 |
| Nasal pruritus | 1 | 2 |
| Nasopharyngitis | 59 | 92 |
| Nausea | 1,090 | 1,858 |
| Neck mass | 1 | 4 |
| Neck pain | 142 | 248 |
| Needle issue | 1 | 1 |
| Negative thoughts | | 1 |
| Neoplasm malignant | 1 | 1 |
| Nephrotic syndrome | 1 | 1 |
| Nerve compression | 4 | 4 |
| Nerve injury | 2 | 2 |
| Nervousness | 22 | 30 |
| Nervous system disorder | 1 | 1 |
| Neuralgia | 15 | 20 |
| Neurogenic shock | 3 | 5 |
| Neurological symptom | 2 | 2 |
| Neurologic neglect syndrome | 1 | 1 |
| Neuropathy peripheral | 9 | 11 |
| Neuropsychiatric symptoms | 1 | 1 |
| Neutropenia | 4 | 4 |
| Nightmare | 9 | 14 |
| Night sweats | 38 | 60 |
| Nipple pain | 2 | 4 |
| Nipple swelling | | 1 |
| No adverse event | | 1 |
| Nocturia | | 1 |
| Nocturnal dyspnoea | 1 | 1 |
| Nodule | 1 | 3 |
| Non-cardiac chest pain | 4 | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 3 | 3 |
| | | | 1 | 1 | 1 |
| | | 13 | 30 | 46 | 62 |
| 5 | 7 | 132 | 427 | 958 | 1431 |
| | | 1 | 2 | | 2 |
| | | 23 | 71 | 119 | 177 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | 5 | 7 | 17 | 23 |
| | | | | 1 | 1 |
| | | 3 | 4 | 12 | 16 |
| | | | | 3 | 5 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 9 | 11 |
| | | 1 | 1 | | |
| | | | | 4 | 4 |
| | | 2 | 5 | 7 | 9 |
| 2 | 2 | 5 | 17 | 33 | 43 |
| | | | 1 | 2 | 3 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | 1 | 1 | 3 | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Noninfective gingivitis | 1 | 1 |
| Nuchal rigidity | 2 | 2 |
| Numb chin syndrome | 1 | 1 |
| Obstructive airways disorder | | 1 |
| Occipital neuralgia | 1 | 1 |
| Occupational exposure to product | | 1 |
| Ocular discomfort | 4 | 5 |
| Ocular hyperaemia | 16 | 25 |
| Odynophagia | 5 | 6 |
| Oedema | 2 | 5 |
| Oedema mouth | 1 | 3 |
| Oedema peripheral | 9 | 11 |
| Oesophageal pain | 1 | 2 |
| Oesophageal spasm | | 1 |
| Off label use | 224 | 268 |
| Oligomenorrhoea | 1 | 1 |
| Ophthalmic herpes zoster | 2 | 2 |
| Ophthalmoplegia | 1 | 1 |
| Optic nerve disorder | 1 | 1 |
| Optic neuritis | 3 | 4 |
| Oral blood blister | | 2 |
| Oral candidiasis | 2 | 4 |
| Oral discomfort | 9 | 14 |
| Oral disorder | 2 | 2 |
| Oral herpes | 10 | 13 |
| Oral mucosal blistering | 4 | 7 |
| Oral mucosal erythema | | 1 |
| Oral mucosal exfoliation | 1 | 1 |
| Oral pain | 16 | 21 |
| Oral papule | | 1 |
| Oral pruritus | 1 | 1 |
| Oropharyngeal blistering | 4 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 3 | 2 | 2 |
| | | 1 | 3 | 15 | 22 |
| | | 2 | 2 | 3 | 4 |
| | | | 1 | 2 | 4 |
| | | | 1 | 1 | 2 |
| | | 3 | 3 | 6 | 8 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 219 | 260 | 5 | 8 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | | 1 | | 1 |
| | | | 1 | 2 | 3 |
| | | 1 | 2 | 8 | 12 |
| | | 1 | 1 | 1 | 1 |
| | | 3 | 4 | 7 | 9 |
| | | 2 | 4 | 2 | 3 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 2 | 16 | 19 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 7 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Oropharyngeal discomfort | 12 | 17 |
| Oropharyngeal oedema | 1 | 1 |
| Oropharyngeal pain | 173 | 297 |
| Orthostatic hypertension | 1 | 1 |
| Orthostatic hypotension | 1 | 3 |
| Oscillopsia | | 1 |
| Osteoarthritis | 3 | 3 |
| Otitis externa | 1 | 1 |
| Overdose | 2 | 7 |
| Oversensing | 3 | 4 |
| Ovulation pain | 1 | 1 |
| Oxygen saturation decreased | 15 | 29 |
| Pain | 567 | 946 |
| Painful respiration | 7 | 12 |
| Pain in extremity | 777 | 1,300 |
| Pain in jaw | 19 | 33 |
| Pain of skin | 30 | 42 |
| Palatal oedema | 1 | 1 |
| Palatal swelling | 3 | 3 |
| Palatal ulcer | 1 | 1 |
| Pallor | 25 | 50 |
| Palpitations | 127 | 210 |
| Pancreatitis | 1 | 1 |
| Pancytopenia | | 1 |
| Panic attack | 4 | 7 |
| Panic disorder | | 1 |
| Panic reaction | 6 | 6 |
| Papilloedema | 1 | 1 |
| Papule | 1 | 4 |
| Paraesthesia | 193 | 340 |
| Paraesthesia oral | 91 | 200 |
| Paralysis | 8 | 11 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 11 | 15 |
| | | | | 1 | 1 |
| | | 22 | 76 | 151 | 221 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 6 | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | 3 | 4 | 12 | 25 |
| 7 | 7 | 124 | 276 | 443 | 670 |
| | | 1 | 3 | 6 | 9 |
| 13 | 16 | 149 | 384 | 628 | 916 |
| | | 2 | 7 | 17 | 26 |
| | | 4 | 6 | 26 | 36 |
| | | | | 1 | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 5 | 13 | 20 | 37 |
| | | 9 | 35 | 118 | 175 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 4 | 7 |
| | | | | | 1 |
| | | 1 | 1 | 5 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 4 |
| 1 | 1 | 27 | 105 | 166 | 235 |
| 1 | 1 | 19 | 76 | 72 | 124 |
| | | | | 8 | 11 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Paranasal sinus discomfort | 4 | 4 |
| Paranasal sinus inflammation | | 1 |
| Paranoia | | 1 |
| Paresis | 1 | 1 |
| Parkinson's disease | | 1 |
| Parosmia | 10 | 13 |
| Parotid gland enlargement | | 1 |
| Parotitis | 1 | 4 |
| Partial seizures | | 1 |
| Peak expiratory flow rate decreased | 1 | 1 |
| Pelvic pain | 6 | 7 |
| Pemphigoid | 1 | 1 |
| Pemphigus | 1 | 1 |
| Periarthritis | 2 | 4 |
| Pericarditis | 3 | 5 |
| Periorbital haematoma | 1 | 1 |
| Periorbital oedema | 5 | 6 |
| Periorbital swelling | 16 | 20 |
| Peripheral circulatory failure | | 2 |
| Peripheral coldness | 29 | 54 |
| Peripheral ischaemia | | 1 |
| Peripheral sensory neuropathy | 2 | 3 |
| Peripheral swelling | 173 | 275 |
| Peroneal nerve palsy | 3 | 3 |
| Persistent postural-perceptual dizziness | 1 | 1 |
| Petechiae | 5 | 8 |
| Petit mal epilepsy | 4 | 4 |
| Pharyngeal erythema | 1 | 2 |
| Pharyngeal haemorrhage | 1 | 1 |
| Pharyngeal hypoaesthesia | | 2 |
| Pharyngeal inflammation | 1 | 4 |
| Pharyngeal oedema | | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 3 | 3 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 3 | 8 | 10 |
| | | | 1 | | |
| | | | 1 | 1 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 6 | 6 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | 1 | 1 | 4 | 5 |
| | | 2 | 5 | 14 | 15 |
| | | | | | 2 |
| | | 5 | 14 | 24 | 40 |
| | | | | | 1 |
| | | | | 2 | 3 |
| 1 | 1 | 25 | 63 | 148 | 212 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 5 | 7 |
| | | | | 4 | 4 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 1 | 4 |
| | | | | | 3 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Pharyngeal paraesthesia | 9 | 14 |
| Pharyngeal swelling | 32 | 52 |
| Pharyngeal ulceration | 3 | 4 |
| Pharyngitis | | 1 |
| Pharyngitis streptococcal | | 2 |
| Phlebitis | 1 | 1 |
| Phonophobia | | 1 |
| Photophobia | 25 | 53 |
| Photopsia | 9 | 9 |
| Photosensitivity reaction | 8 | 9 |
| pH urine | 1 | 2 |
| pH urine increased | 1 | 1 |
| Physical deconditioning | 1 | 1 |
| Piloerection | 2 | 5 |
| Platelet anisocytosis | 1 | 1 |
| Platelet count decreased | 1 | 1 |
| Pleural effusion | 1 | 2 |
| Pleurisy | 2 | 4 |
| Pleuritic pain | 2 | 5 |
| Plicated tongue | | 1 |
| Pneumonia | 3 | 7 |
| Pneumonia aspiration | | 1 |
| Pneumonia staphylococcal | 1 | 1 |
| Pneumonitis | 2 | 3 |
| Poisoning | | 1 |
| Pollakiuria | 5 | 6 |
| Polymenorrhoea | | 2 |
| Polymerase chain reaction positive | 2 | 2 |
| Polymyalgia rheumatica | 4 | 5 |
| Polymyositis | 1 | 1 |
| Poor peripheral circulation | | 1 |
| Poor quality product administered | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 8 | 12 |
| | | 1 | 9 | 31 | 43 |
| | | 1 | 1 | 2 | 3 |
| | | | | | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 3 | 12 | 22 | 41 |
| | | 1 | 1 | 8 | 8 |
| | | 3 | 3 | 5 | 6 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 4 |
| | | | | 2 | 5 |
| | | | | | 1 |
| | | | | 3 | 7 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | 1 | 1 | 4 | 5 |
| | | | 1 | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Poor quality sleep | 24 | 35 |
| Postictal state | 1 | 1 |
| Post laminectomy syndrome | 1 | 1 |
| Post lumbar puncture syndrome | | 1 |
| Postmenopausal haemorrhage | 1 | 1 |
| Postprandial hypoglycaemia | 1 | 1 |
| Post procedural complication | 1 | 1 |
| Postural orthostatic tachycardia syndrome | 2 | 2 |
| Post viral fatigue syndrome | 1 | 2 |
| Pre-existing condition improved | | 1 |
| Presyncope | 40 | 80 |
| Primary cough headache | 1 | 3 |
| Procedural dizziness | 1 | 1 |
| Procedural nausea | 2 | 3 |
| Proctalgia | 1 | 1 |
| Proctitis ulcerative | | 1 |
| Product administered at inappropriate site | 5 | 7 |
| Product administered to patient of inappropriate age | 26 | 35 |
| Product complaint | 1 | 1 |
| Product dose omission issue | 1 | 1 |
| Productive cough | 17 | 23 |
| Product preparation error | 1 | 1 |
| Product taste abnormal | 1 | 1 |
| Product use issue | 216 | 259 |
| Prophylaxis of nausea and vomiting | 1 | 1 |
| Proteinuria | 1 | 1 |
| Pruritus | 209 | 387 |
| Pseudolymphoma | | 1 |
| Psoriasis | 2 | 3 |
| Psoriatic arthropathy | | 1 |
| Psychiatric symptom | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 8 | 21 | 27 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | | 1 | | |
| 1 | 1 | 9 | 30 | 31 | 50 |
| | | 1 | 1 | | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 4 | 4 | 1 | 3 |
| | | 23 | 31 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 6 | 13 | 17 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 212 | 252 | 4 | 7 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| 1 | 1 | 40 | 128 | 169 | 259 |
| | | | | | 1 |
| 1 | 1 | 2 | 2 | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-------------------------------|--|--|
| Psychogenic seizure | 2 | 2 |
| Psychomotor hyperactivity | 2 | 2 |
| Psychotic disorder | 3 | 3 |
| Psychotic symptom | 1 | 1 |
| Pulmonary congestion | 2 | 2 |
| Pulmonary embolism | 5 | 5 |
| Pulmonary oedema | | 2 |
| Pulmonary pain | 13 | 17 |
| Pulmonary thrombosis | 1 | 2 |
| Pulpitis dental | 1 | 1 |
| Pulse abnormal | 1 | 1 |
| Pulseless electrical activity | 1 | 1 |
| Puncture site discharge | 1 | 1 |
| Pupillary disorder | 1 | 1 |
| Pupillary reflex impaired | | 1 |
| Pupils unequal | | 2 |
| Purpura | 3 | 5 |
| Pustular psoriasis | 1 | 1 |
| Pustule | | 1 |
| Pyelonephritis | | 1 |
| Pyrexia | 1,016 | 1,903 |
| Q fever | 3 | 4 |
| Quadrantanopia | 1 | 1 |
| Radiculopathy | | 1 |
| Rales | 1 | 2 |
| Rash | 187 | 347 |
| Rash erythematous | 73 | 131 |
| Rash macular | 19 | 56 |
| Rash maculo-papular | 5 | 6 |
| Rash morbilliform | 1 | 2 |
| Rash papular | 11 | 25 |
| Rash pruritic | 62 | 109 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | | 2 | 2 |
| | | | | 5 | 5 |
| | | | | | 2 |
| | | 1 | 3 | 12 | 14 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 2 |
| | | | 1 | 3 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| 6 | 9 | 109 | 404 | 907 | 1499 |
| | | | | 3 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 27 | 103 | 160 | 244 |
| | | 10 | 38 | 63 | 93 |
| | | 4 | 27 | 15 | 29 |
| | | | 1 | 5 | 5 |
| | | | | 1 | 2 |
| | | 1 | 9 | 10 | 16 |
| | | 8 | 25 | 54 | 84 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Rash pustular | 1 | 2 |
| Rash vesicular | 7 | 9 |
| Raynaud's phenomenon | 3 | 4 |
| Reaction to excipient | 1 | 1 |
| Reaction to preservatives | 1 | 2 |
| Reaction to previous exposure to any vaccine | 1 | 1 |
| Rectal haemorrhage | 12 | 14 |
| Red blood cell sedimentation rate increased | 1 | 2 |
| Renal failure | 1 | 3 |
| Renal impairment | 1 | 1 |
| Renal pain | 10 | 20 |
| Repetitive speech | 1 | 1 |
| Respiration abnormal | 7 | 9 |
| Respiratory arrest | 1 | 3 |
| Respiratory disorder | 3 | 5 |
| Respiratory distress | 2 | 3 |
| Respiratory failure | 1 | 1 |
| Respiratory rate decreased | 1 | 2 |
| Respiratory rate increased | 9 | 16 |
| Respiratory symptom | | |
| Respiratory tract irritation | 1 | 2 |
| Respiratory tract oedema | 1 | 1 |
| Restless legs syndrome | 4 | 8 |
| Restlessness | 9 | 23 |
| Retching | 9 | 17 |
| Retinal haemorrhage | 2 | 2 |
| Retinal migraine | 2 | 2 |
| Retinal toxicity | 1 | 1 |
| Retinal vein occlusion | 2 | 2 |
| Reversible airways obstruction | 1 | 1 |
| Rhabdomyolysis | | 2 |
| Rheumatoid arthritis | 9 | 11 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | 2 | 3 | 5 | 6 |
| | | 2 | 2 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 12 | 14 |
| | | | | 1 | 2 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | 3 | 8 | 7 | 12 |
| | | | | 1 | 1 |
| | | 1 | 1 | 6 | 8 |
| 1 | 1 | | | 1 | 3 |
| | | | | 3 | 5 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 2 | 3 | 7 | 13 |
| 1 | 1 | | | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 3 | 6 |
| | | | 9 | 9 | 14 |
| | | 1 | 3 | 8 | 14 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 9 | 11 |

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Gender

FEMALE

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|--------------------------------------|------------------------------------|--------------------------------------|
| Rhinalgia | 3 | 3 |
| Rhinitis | 5 | 9 |
| Rhinitis allergic | 1 | 2 |
| Rhinorrhoea | 43 | 66 |
| Right ventricular enlargement | | 1 |
| Right ventricular failure | 1 | 1 |
| Road traffic accident | 1 | 1 |
| Rosacea | 1 | 1 |
| Rotator cuff syndrome | 1 | 1 |
| Sacroiliitis | 1 | 1 |
| Salivary gland pain | | 1 |
| Salivary hypersecretion | 2 | 10 |
| Salt craving | 1 | 1 |
| Sarcoidosis | 1 | 1 |
| Sarcoma | 1 | 1 |
| SARS-CoV-2 ant body test | 1 | 1 |
| SARS-CoV-2 ant body test negative | 6 | 7 |
| SARS-CoV-2 ant body test positive | | 1 |
| SARS-CoV-2 test | 1 | 1 |
| SARS-CoV-2 test negative | 1 | 1 |
| SARS-CoV-2 test positive | 14 | 24 |
| Scab | 1 | 1 |
| Sciatica | 3 | 4 |
| Scleral discolouration | 1 | 1 |
| Scleroderma associated digital ulcer | 1 | 1 |
| Scratch | 3 | 3 |
| Screaming | 1 | 1 |
| Seasonal allergy | 2 | 3 |
| Secretion discharge | 1 | 2 |
| Sedation | 1 | 2 |
| Seizure | 34 | 47 |
| Seizure cluster | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| | | 2 | 4 | 3 | 5 |
| | | | | 1 | 2 |
| 1 | 1 | 5 | 17 | 38 | 49 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 5 | 2 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 4 | 3 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 2 | 4 | 12 | 20 |
| | | 1 | 1 | | |
| | | 1 | 1 | 2 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | | | 34 | 47 |
| | | | | 1 | 1 |

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FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Sensation of blood flow | 1 | 1 |
| Sensation of foreign body | 7 | 10 |
| Sense of a foreshortened future | 1 | 1 |
| Sensitive skin | 14 | 20 |
| Sensory disturbance | 7 | 18 |
| Sensory loss | 4 | 6 |
| Sepsis | 3 | 6 |
| Serositis | | 1 |
| Serum ferritin increased | 1 | 1 |
| Serum sickness | 1 | 1 |
| Shock | 4 | 4 |
| Shoulder injury related to vaccine administration | 1 | 1 |
| Sialoadenitis | 1 | 1 |
| Sinonasal obstruction | | 1 |
| Sinus bradycardia | | 1 |
| Sinus congestion | 4 | 6 |
| Sinus disorder | 1 | 2 |
| Sinus headache | 16 | 26 |
| Sinusitis | 7 | 8 |
| Sinus node dysfunction | 1 | 1 |
| Sinus pain | 12 | 23 |
| Sinus tachycardia | 5 | 12 |
| Sjogren's syndrome | 1 | 2 |
| Skin abrasion | 3 | 4 |
| Skin burning sensation | 11 | 25 |
| Skin discolouration | 8 | 14 |
| Skin disorder | 2 | 3 |
| Skin erosion | 2 | 3 |
| Skin exfoliation | 4 | 8 |
| Skin fissures | 1 | 1 |
| Skin induration | | 1 |
| Skin irritation | 10 | 14 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 7 | 10 |
| | | | | 1 | 1 |
| | | 1 | 3 | 13 | 17 |
| | | 3 | 10 | 4 | 8 |
| | | | 1 | 4 | 5 |
| | | | | 3 | 6 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 2 | 3 | 4 |
| | | | | 1 | 2 |
| | | 2 | 3 | 14 | 23 |
| | | 1 | 1 | 6 | 7 |
| | | | | 1 | 1 |
| | | 1 | 4 | 11 | 19 |
| | | 1 | 5 | 4 | 7 |
| | | | | 1 | 2 |
| | | 1 | 1 | 2 | 3 |
| | | 1 | 3 | 10 | 22 |
| | | 1 | 2 | 7 | 12 |
| | | | 1 | 2 | 2 |
| | | | 1 | 2 | 2 |
| | | 2 | 2 | 2 | 6 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 2 | 10 | 12 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Skin laceration | | 1 |
| Skin laxity | 1 | 1 |
| Skin lesion | 3 | 4 |
| Skin mass | 4 | 6 |
| Skin reaction | 5 | 7 |
| Skin sensitisation | | 2 |
| Skin swelling | 4 | 8 |
| Skin temperature | 1 | 1 |
| Skin tightness | 4 | 10 |
| Skin ulcer | 1 | 2 |
| Skin warm | 14 | 32 |
| Skull fracture | 1 | 1 |
| Sleep apnoea syndrome | 1 | 1 |
| Sleep attacks | | 1 |
| Sleep disorder | 32 | 56 |
| Sleep disorder due to a general medical condition | 1 | 4 |
| Sleep disorder due to general medical condition, insomnia type | 8 | 11 |
| Sleep paralysis | 1 | 1 |
| Sleep terror | | 1 |
| Slow response to stimuli | | 1 |
| Sluggishness | 1 | 1 |
| Small intestinal haemorrhage | 1 | 1 |
| Sneezing | 19 | 36 |
| Snoring | | 1 |
| Social avoidant behaviour | 1 | 1 |
| Social fear | 1 | 1 |
| Soft tissue infection | 1 | 1 |
| Somatic symptom disorder | | 1 |
| Somnolence | 76 | 133 |
| Speech disorder | 8 | 12 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | | 1 | 4 | 5 |
| | | 1 | 2 | 4 | 5 |
| | | | | | 2 |
| | | 1 | 3 | 3 | 5 |
| | | | | 1 | 1 |
| | | 2 | 4 | 2 | 6 |
| | | | | 1 | 2 |
| | | 4 | 11 | 10 | 21 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 11 | 26 | 21 | 30 |
| | | 1 | 2 | | 2 |
| | | 3 | 5 | 5 | 6 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 15 | 15 | 21 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 16 | 36 | 60 | 97 |
| 1 | 1 | 3 | 3 | 5 | 9 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Spinal disorder | | 1 |
| Spinal pain | 3 | 6 |
| Splenomegaly | 1 | 1 |
| Sputum abnormal | 1 | 1 |
| Staring | 1 | 1 |
| Status epilepticus | 4 | 4 |
| Stereotypy | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 1 |
| Stiff leg syndrome | | 1 |
| Stiff tongue | | 1 |
| Stomatitis | 1 | 1 |
| Stress | 2 | 4 |
| Stridor | 3 | 4 |
| Subarachnoid haemorrhage | 2 | 3 |
| Submaxillary gland enlargement | | 1 |
| Sudden death | 1 | 5 |
| Sudden hearing loss | 1 | 2 |
| Suffocation feeling | 1 | 1 |
| Suicide attempt | 1 | 1 |
| Sunburn | 1 | 1 |
| Suprapubic pain | 1 | 1 |
| Supraventricular tachycardia | 4 | 9 |
| Suspected COVID-19 | 87 | 156 |
| Sweating fever | 15 | 24 |
| Swelling | 118 | 183 |
| Swelling face | 81 | 128 |
| Swelling of eyelid | 9 | 17 |
| Swollen joint count increased | 1 | 1 |
| Swollen tongue | 53 | 99 |
| Symphysiolysis | | 1 |
| Symptom recurrence | | 1 |
| Syncope | 150 | 234 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 1 | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| 1 | 1 | 1 | 1 | | |
| | | 1 | 3 | 1 | 1 |
| | | | | 3 | 4 |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | | | 1 | 5 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 4 | 8 |
| | | 17 | 22 | 70 | 134 |
| | | | | 15 | 24 |
| | | 22 | 53 | 96 | 130 |
| | | 11 | 23 | 70 | 105 |
| | | | 3 | 9 | 14 |
| | | | | 1 | 1 |
| | | 7 | 18 | 46 | 81 |
| | | | | | 1 |
| | | | 1 | | |
| 1 | 1 | | | 150 | 234 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Synovial cyst | 2 | 2 |
| Synovitis | 1 | 2 |
| Systemic inflammatory response syndrome | | 1 |
| Systemic lupus erythematosus | 1 | 2 |
| Systolic hypertension | 1 | 1 |
| Tachycardia | 76 | 172 |
| Tachyphrenia | 1 | 1 |
| Tachypnoea | 4 | 7 |
| Taste disorder | 19 | 30 |
| Tearfulness | 2 | 4 |
| Temperature regulation disorder | 1 | 2 |
| Temporal lobe epilepsy | 1 | 1 |
| Temporomandibular joint syndrome | | 2 |
| Tenderness | 15 | 32 |
| Tendonitis | 1 | 1 |
| Tension | | 1 |
| Tension headache | 23 | 44 |
| Terminal insomnia | 1 | 1 |
| Therapeutic product effect increased | 1 | 1 |
| Therapeutic response unexpected | 6 | 7 |
| Thermal burn | 2 | 2 |
| Thermal burns of eye | 1 | 1 |
| Thinking abnormal | 4 | 5 |
| Thirst | 24 | 38 |
| Throat clearing | 2 | 4 |
| Throat irritation | 28 | 40 |
| Throat tightness | 32 | 70 |
| Thrombocytopenia | 4 | 4 |
| Thrombophlebitis | 1 | 1 |
| Thrombosis | 1 | 3 |
| Tinnitus | 53 | 72 |
| Tongue blistering | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 6 | 39 | 70 | 133 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 6 |
| | | 6 | 13 | 13 | 17 |
| | | 2 | 2 | | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 2 | | |
| 1 | 1 | 4 | 16 | 11 | 16 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 6 | 22 | 38 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | 4 | 5 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 5 |
| | | 5 | 12 | 19 | 26 |
| | | | | 2 | 4 |
| | | 3 | 6 | 25 | 34 |
| | | 4 | 13 | 28 | 57 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| 1 | 1 | | | 1 | 3 |
| | | 7 | 15 | 46 | 57 |
| | | 1 | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Tongue coated | 1 | 1 |
| Tongue discolouration | 1 | 1 |
| Tongue discomfort | 3 | 5 |
| Tongue disorder | 6 | 7 |
| Tongue dry | 1 | 1 |
| Tongue eruption | | 1 |
| Tongue injury | 1 | 1 |
| Tongue movement disturbance | 1 | 2 |
| Tongue oedema | 9 | 10 |
| Tongue pruritus | | 1 |
| Tongue spasm | 1 | 1 |
| Tongue ulceration | | 3 |
| Tonic convulsion | 4 | 4 |
| Tonsillar erythema | 1 | 1 |
| Tonsillar hypertrophy | 3 | 7 |
| Tonsillar inflammation | | 2 |
| Tonsillitis | | 6 |
| Tonsillitis bacterial | | 1 |
| Toothache | 4 | 8 |
| Torticollis | | 1 |
| Toxic epidermal necrolysis | 1 | 1 |
| Toxic skin eruption | | 1 |
| Tracheal pain | 1 | 1 |
| Transient global amnesia | 1 | 1 |
| Transient ischaemic attack | 6 | 11 |
| Traumatic haemorrhage | 1 | 1 |
| Tremor | 155 | 251 |
| Trigeminal neuralgia | 1 | 2 |
| Tri-iodothyronine decreased | | 1 |
| Trismus | 2 | 2 |
| Troponin increased | 1 | 3 |
| Tunnel vision | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | 3 | 3 |
| | | | | 6 | 7 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | 1 | 9 | 9 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 2 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 6 |
| | | | 1 | | 1 |
| | | | 1 | | 5 |
| | | | | | 1 |
| | | 1 | 3 | 3 | 5 |
| | | | | | 1 |
| 1 | 1 | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 6 | 11 |
| | | | | 1 | 1 |
| 2 | 2 | 27 | 55 | 128 | 196 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 3 |
| | | | | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Type 1 diabetes mellitus | 2 | 2 |
| Type I hypersensitivity | 1 | 1 |
| Type IV hypersensitivity reaction | 1 | 3 |
| Ulcer | 1 | 1 |
| Ulcerative keratitis | 2 | 2 |
| Ulnar nerve injury | 2 | 2 |
| Underdose | 1 | 3 |
| Unresponsive to stimuli | 5 | 15 |
| Upper-airway cough syndrome | 3 | 4 |
| Upper airway obstruction | 1 | 1 |
| Upper limb fracture | 2 | 3 |
| Upper respiratory tract congestion | | 1 |
| Urinary incontinence | 6 | 8 |
| Urinary retention | 7 | 10 |
| Urinary tract disorder | | 1 |
| Urinary tract infection | 22 | 25 |
| Urinary tract infection bacterial | | 1 |
| Urinary tract pain | 1 | 1 |
| Urine abnormality | 1 | 1 |
| Urine flow decreased | 1 | 1 |
| Urine odour abnormal | 1 | 1 |
| Urine output increased | | 1 |
| Urosepsis | 1 | 1 |
| Urticaria | 107 | 177 |
| Urticaria chronic | 1 | 1 |
| Uterine pain | 1 | 1 |
| Uveitis | 4 | 4 |
| Vaccination complication | 1 | 4 |
| Vaccination failure | 2 | 2 |
| Vaccination site abscess | 2 | 3 |
| Vaccination site bruising | 19 | 33 |
| Vaccination site cellulitis | 8 | 17 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 3 | | |
| | | | | 5 | 15 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | | 1 |
| | | 2 | 2 | 4 | 6 |
| | | | | 7 | 10 |
| | | | | | 1 |
| | | 3 | 3 | 19 | 22 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 9 | 41 | 98 | 136 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 3 |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 2 |
| | 1 | 5 | 10 | 14 | 23 |
| | | 2 | 3 | 6 | 14 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Vaccination site coldness | 1 | 1 |
| Vaccination site discolouration | | 4 |
| Vaccination site discomfort | 11 | 24 |
| Vaccination site dryness | 1 | 1 |
| Vaccination site erythema | 109 | 232 |
| Vaccination site haematoma | 1 | 2 |
| Vaccination site haemorrhage | 7 | 10 |
| Vaccination site hyperaesthesia | 2 | 3 |
| Vaccination site hypersensitivity | 2 | 2 |
| Vaccination site hypoaesthesia | 2 | 9 |
| Vaccination site induration | 9 | 22 |
| Vaccination site infection | 4 | 7 |
| Vaccination site inflammation | 6 | 22 |
| Vaccination site irritation | 3 | 3 |
| Vaccination site joint erythema | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 10 |
| Vaccination site joint pain | 1 | 7 |
| Vaccination site lymphadenopathy | 6 | 7 |
| Vaccination site macule | | 1 |
| Vaccination site mass | 48 | 72 |
| Vaccination site movement impairment | 14 | 31 |
| Vaccination site necrosis | 1 | 1 |
| Vaccination site nodule | 1 | 1 |
| Vaccination site oedema | 1 | 3 |
| Vaccination site pain | 470 | 992 |
| Vaccination site papule | 1 | 1 |
| Vaccination site paraesthesia | 9 | 17 |
| Vaccination site pruritus | 35 | 76 |
| Vaccination site rash | 20 | 46 |
| Vaccination site reaction | 12 | 23 |
| Vaccination site scab | 1 | 1 |
| Vaccination site scar | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 2 | | 2 |
| | | 3 | 12 | 8 | 12 |
| | | | | 1 | 1 |
| | | 24 | 92 | 85 | 140 |
| | | | | 1 | 2 |
| | | | 1 | 7 | 9 |
| | | | 1 | 2 | 2 |
| | | | 2 | 2 | 7 |
| | | 3 | 12 | 6 | 10 |
| | | | 1 | 4 | 6 |
| | | 2 | 10 | 4 | 12 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 4 | | 6 |
| | | | 2 | 1 | 5 |
| | | 1 | 1 | 5 | 6 |
| | | | 1 | | |
| | | 8 | 20 | 40 | 52 |
| 1 | 1 | 5 | 12 | 9 | 19 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| 3 | 7 | 85 | 334 | 385 | 658 |
| | | | | 1 | 1 |
| | | 3 | 7 | 6 | 10 |
| | | 9 | 33 | 26 | 43 |
| | | 4 | 17 | 16 | 29 |
| | | 4 | 9 | 8 | 14 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Vaccination site swelling | 124 | 256 |
| Vaccination site urticaria | 2 | 6 |
| Vaccination site vesicles | 1 | 4 |
| Vaccination site warmth | 65 | 138 |
| Vaginal disorder | 1 | 1 |
| Vaginal haemorrhage | 9 | 13 |
| Varicose vein | 1 | 2 |
| Vascular headache | 2 | 2 |
| Vascular pain | 1 | 1 |
| Vasculitic rash | 2 | 3 |
| Vasculitis | 4 | 5 |
| Vasodilatation | 2 | 4 |
| Vein discolouration | | 1 |
| Vein disorder | 1 | 2 |
| Vein rupture | | 1 |
| Venous haemorrhage | 1 | 1 |
| Ventricular arrhythmia | 1 | 1 |
| Ventricular extrasystoles | 1 | 2 |
| Ventricular fibrillation | 1 | 2 |
| Vertigo | 70 | 110 |
| Vertigo labyrinthine | 2 | 2 |
| Vertigo positional | 5 | 6 |
| Vestibular migraine | 1 | 2 |
| Viral infection | 3 | 3 |
| Viral labyrinthitis | 1 | 1 |
| Viral pharyngitis | 3 | 4 |
| Viral rash | 1 | 4 |
| Viral test | 1 | 1 |
| Viral tonsillitis | | 1 |
| Vision blurred | 46 | 92 |
| Visual acuity reduced | | 1 |
| Visual brightness | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 20 | 82 | 104 | 174 |
| | | | 2 | 2 | 4 |
| | | | | 1 | 4 |
| | | 15 | 53 | 50 | 85 |
| | | 1 | 1 | | |
| | | 1 | 1 | 8 | 12 |
| | | 1 | 2 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 2 |
| | | | | 4 | 5 |
| | | | | 2 | 4 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| 1 | 1 | 4 | 15 | 66 | 95 |
| | | | | 2 | 2 |
| | | | | 5 | 6 |
| | | 1 | 1 | | 1 |
| | | 1 | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 3 | 4 |
| | | 1 | 2 | | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 7 | 28 | 39 | 64 |
| | | | 1 | | |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Visual field defect | 2 | 4 |
| Visual impairment | 18 | 33 |
| Vital capacity | 1 | 1 |
| Vlth nerve paralysis | 2 | 2 |
| Vitreous floaters | 3 | 4 |
| Vocal cord disorder | | 1 |
| Vomiting | 322 | 538 |
| Vomiting projectile | 5 | 9 |
| Vomiting psychogenic | | 1 |
| Vulval abscess | 1 | 1 |
| Vulvovaginal candidiasis | 3 | 5 |
| Vulvovaginal pruritus | | 1 |
| Weight decreased | 10 | 11 |
| Weight loss diet | | 1 |
| Wheezing | 38 | 68 |
| White blood cell count decreased | 2 | 3 |
| White blood cell count increased | 4 | 4 |
| Wound | 2 | 2 |
| Wound complication | 1 | 1 |
| Writer's cramp | | 1 |
| Wrong product administered | | 1 |
| Wrong technique in product usage process | 1 | 1 |
| Yawning | 2 | 2 |
| Yellow skin | 1 | 2 |
| | 4 | 11 |
| | 24,791 | 42,040 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|-----|-------------|-------|---------|-------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 2 | 3 |
| | | 5 | 8 | 13 | 25 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 2 | 2 | 2 |
| | | | | | 1 |
| 2 | 3 | 47 | 129 | 275 | 409 |
| | | | 1 | 5 | 8 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 4 |
| | | | 1 | | |
| | | 2 | 3 | 8 | 8 |
| | | | | | 1 |
| | | 6 | 16 | 32 | 52 |
| | | | | 2 | 3 |
| | | 1 | 1 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | 4 | 11 | | |
| 145 | 175 | 3964 | 10595 | 20827 | 31445 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Abdominal adhesions | | 1 |
| Abdominal discomfort | 15 | 19 |
| Abdominal distension | 2 | 3 |
| Abdominal pain | 21 | 32 |
| Abdominal pain lower | 3 | 5 |
| Abdominal pain upper | 37 | 45 |
| Abdominal rigidity | 1 | 1 |
| Abnormal dreams | 3 | 7 |
| Abnormal weight gain | 2 | 2 |
| Acidosis | | 1 |
| Acne | 2 | 2 |
| Acute cardiac event | | 1 |
| Acute kidney injury | 1 | 4 |
| Acute myocardial infarction | 3 | 5 |
| Acute pulmonary oedema | | 1 |
| Acute respiratory failure | | 1 |
| Adverse drug reaction | 1 | 2 |
| Ageusia | 6 | 12 |
| Aggression | 2 | 2 |
| Agitation | 2 | 6 |
| Alanine aminotransferase increased | | 1 |
| Alcohol interaction | 1 | 1 |
| Alexia | 1 | 1 |
| Allergic cough | | 1 |
| Allergic oedema | | 1 |
| Allergic sinusitis | 1 | 1 |
| Allergy to vaccine | 1 | 3 |
| Alopecia | | 1 |
| Altered state of consciousness | | 1 |
| Amnesia | 3 | 3 |
| Anal incontinence | 4 | 5 |
| Anaphylactic reaction | 17 | 24 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 1 | 2 | 14 | 17 |
| | | | 1 | 2 | 2 |
| | | 2 | 3 | 19 | 29 |
| | | 1 | 1 | 2 | 4 |
| | | 6 | 9 | 31 | 36 |
| | | | | 1 | 1 |
| | | | 2 | 3 | 5 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | 2 | 6 | 10 |
| | | | | 2 | 2 |
| | | | 2 | 2 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | 3 | 4 |
| | | | | 17 | 24 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Anaphylactic shock | 1 | 2 |
| Anaphylactoid reaction | 1 | 1 |
| Anaphylactoid shock | 2 | 2 |
| Anger | 1 | 1 |
| Angina pectoris | 3 | 5 |
| Angioedema | 3 | 9 |
| Ankylosing spondylitis | 1 | 2 |
| Anosmia | 9 | 13 |
| Antibody test abnormal | 1 | 1 |
| Anxiety | 12 | 18 |
| Aortic aneurysm | 1 | 1 |
| Aortic aneurysm rupture | | 1 |
| Apathy | 3 | 4 |
| Aphasia | 2 | 4 |
| Aphonia | 1 | 1 |
| Apthous ulcer | | 1 |
| Apparent death | 1 | 1 |
| Appendicitis | 2 | 2 |
| Arrhythmia | 3 | 4 |
| Arrhythmia supraventricular | 2 | 2 |
| Arterial occlusive disease | 1 | 1 |
| Arterial rupture | 1 | 1 |
| Arthralgia | 168 | 274 |
| Arthritis | 5 | 8 |
| Arthritis bacterial | 1 | 1 |
| Arthritis reactive | 2 | 3 |
| Arthropathy | 1 | 2 |
| Aspartate aminotransferase increased | | 1 |
| Aspiration | 1 | 2 |
| Asthenia | 58 | 90 |
| Asthenopia | 1 | 2 |
| Asthma | 7 | 9 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 3 | 5 |
| | | | | 3 | 9 |
| | | | | 1 | 2 |
| | | 1 | 2 | 8 | 11 |
| | | 1 | 1 | | |
| | | 1 | 3 | 11 | 15 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | 2 | 3 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 3 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| 4 | 4 | 15 | 55 | 153 | 219 |
| | | | 1 | 5 | 7 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | 8 | 22 | 50 | 68 |
| | | | | 1 | 2 |
| | | | 2 | 7 | 7 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Asymptomatic COVID-19 | | 1 |
| Atrial fibrillation | 11 | 19 |
| Atrial flutter | 1 | 1 |
| Atrial tachycardia | 1 | 1 |
| Aura | | 1 |
| Auricular swelling | 2 | 2 |
| Axillary mass | 2 | 4 |
| Axillary pain | 5 | 16 |
| Axonal neuropathy | 1 | 1 |
| Back pain | 55 | 74 |
| Bacterial infection | 1 | 1 |
| Balance disorder | 16 | 26 |
| Bedridden | 2 | 4 |
| Behaviour disorder | 1 | 1 |
| Bile duct stone | | 1 |
| Biliary sepsis | | 1 |
| Bite | | 1 |
| Bladder disorder | 1 | 1 |
| Bladder pain | | 1 |
| Blepharospasm | 1 | 1 |
| Blindness | 2 | 4 |
| Blindness transient | 1 | 1 |
| Blister | 6 | 7 |
| Blood creatine phosphokinase increased | | 2 |
| Blood electrolytes increased | | 1 |
| Blood glucose | 1 | 1 |
| Blood glucose decreased | 1 | 2 |
| Blood glucose increased | 2 | 4 |
| Blood growth hormone | | 1 |
| Blood lactic acid increased | | 1 |
| Blood pH increased | 1 | 1 |
| Blood pressure decreased | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 11 | 19 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | | 2 | 2 | 2 |
| | | 3 | 11 | 2 | 5 |
| | | | | 1 | 1 |
| | | 8 | 18 | 47 | 56 |
| | | | | 1 | 1 |
| | 1 | 3 | 5 | 13 | 21 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | 1 | 6 | 6 |
| | | | 1 | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | | 1 | 2 | 3 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 3 | 4 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Blood pressure diastolic decreased | 1 | 1 |
| Blood pressure increased | 14 | 18 |
| Blood pressure systolic increased | | 1 |
| Blood sodium decreased | | 1 |
| Blood test abnormal | | 1 |
| Blood urea increased | | 1 |
| Blood urine present | 1 | 1 |
| Blood viscosity increased | 1 | 1 |
| Body temperature abnormal | 1 | 4 |
| Body temperature decreased | | 2 |
| Body temperature fluctuation | 3 | 5 |
| Body temperature increased | 14 | 20 |
| Bone pain | 7 | 15 |
| Bradycardia | 3 | 6 |
| Bradyphrenia | 2 | 2 |
| Brain stem stroke | 1 | 1 |
| Breath odour | 1 | 1 |
| Breath sounds abnormal | 1 | 1 |
| Bronchiectasis | 1 | 1 |
| Bundle branch block right | 2 | 3 |
| Burning sensation | 1 | 4 |
| Bursitis | 1 | 1 |
| Cardiac arrest | 12 | 24 |
| Cardiac failure | 2 | 2 |
| Cardiac flutter | 4 | 4 |
| Cardio-respiratory arrest | | 1 |
| Catarrh | 1 | 1 |
| Catatonia | 1 | 1 |
| Cellulitis | 2 | 2 |
| Central vision loss | | 1 |
| Cerebellar infarction | | 2 |
| Cerebral disorder | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 2 | 4 | 12 | 14 |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 3 |
| | | | | | 2 |
| | | 1 | 2 | 2 | 3 |
| | | 5 | 9 | 9 | 11 |
| | | 1 | 4 | 6 | 11 |
| | | | | 3 | 6 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | 1 | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 12 | 24 |
| | | | | 2 | 2 |
| 1 | 1 | | | 4 | 4 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Cerebral haemorrhage | 1 | 1 |
| Cerebral infarction | 2 | 3 |
| Cerebrovascular accident | 9 | 18 |
| Cervicobrachial syndrome | 1 | 1 |
| Chest discomfort | 18 | 26 |
| Chest pain | 50 | 69 |
| Chills | 215 | 383 |
| Choking | | 1 |
| Chorea | 1 | 1 |
| Chromaturia | | 2 |
| Chronic obstructive pulmonary disease | 1 | 1 |
| Circulatory collapse | 4 | 12 |
| Circumstance or information capable of leading to medication error | | 1 |
| Clonic convulsion | 1 | 1 |
| Coagulation time prolonged | 1 | 1 |
| Cognitive disorder | 2 | 3 |
| Cold sweat | 15 | 26 |
| Colitis ulcerative | 1 | 2 |
| Coma scale abnormal | | 3 |
| Communication disorder | 1 | 1 |
| Condition aggravated | 14 | 17 |
| Confusional state | 34 | 52 |
| Conjunctival haemorrhage | 2 | 3 |
| Constipation | 4 | 6 |
| Contusion | 6 | 9 |
| Coordination abnormal | 7 | 7 |
| Corneal reflex decreased | 1 | 1 |
| Coronary artery disease | 1 | 2 |
| Coronavirus test positive | 1 | 1 |
| Costochondritis | 1 | 1 |
| Cough | 40 | 70 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 9 | 18 |
| | | | | 1 | 1 |
| | | 1 | 4 | 17 | 22 |
| 1 | 1 | 5 | 12 | 45 | 57 |
| 1 | 1 | 24 | 83 | 191 | 300 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 4 | 12 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | 2 | 7 | 13 | 19 |
| | | | | 1 | 2 |
| | | | | | 3 |
| | | 1 | 1 | | |
| | | 3 | 3 | 11 | 14 |
| | | 5 | 10 | 29 | 42 |
| | | | | 2 | 3 |
| | | | | 4 | 6 |
| | | | 1 | 6 | 8 |
| | | | | 7 | 7 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 8 | 22 | 32 | 48 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| COVID-19 | 42 | 93 |
| COVID-19 pneumonia | 2 | 3 |
| C-reactive protein increased | 4 | 5 |
| Creutzfeldt-Jakob disease | 1 | 1 |
| Crohn's disease | 2 | 2 |
| Crying | 2 | 2 |
| Crystal arthropathy | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 |
| Cyanosis | | 1 |
| Cystitis | 1 | 2 |
| Deafness | 5 | 7 |
| Deafness neurosensory | 1 | 1 |
| Deafness unilateral | 2 | 2 |
| Death | 15 | 40 |
| Decreased appetite | 42 | 71 |
| Deep vein thrombosis | 1 | 2 |
| Dehydration | 6 | 10 |
| Delirium | 11 | 20 |
| Delusion | 1 | 1 |
| Dementia | 2 | 3 |
| Dementia with Lewy bodies | 1 | 1 |
| Depressed level of consciousness | 3 | 4 |
| Depressed mood | 2 | 2 |
| Depression | 4 | 6 |
| Dermatitis allergic | 2 | 5 |
| Dermatitis bullous | 1 | 2 |
| Dermatitis exfoliative | 1 | 1 |
| Diabetes mellitus | 1 | 1 |
| Diabetes mellitus inadequate control | | 1 |
| Diabetic ketoacidosis | 1 | 1 |
| Diarrhoea | 111 | 163 |
| Diplopia | 5 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 4 | 39 | 89 |
| | | | | 2 | 3 |
| | | 2 | 3 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 5 | 7 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 15 | 40 |
| 1 | 1 | 6 | 14 | 36 | 57 |
| | | | | 1 | 2 |
| | | | 2 | 6 | 8 |
| | | | | 11 | 20 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 3 | 4 |
| | | | | 2 | 2 |
| | | | | 4 | 6 |
| | | | 2 | 2 | 3 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 7 | 19 | 104 | 144 |
| | | | 1 | 5 | 5 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Discomfort | 6 | 9 |
| Disease progression | 1 | 1 |
| Disease recurrence | 17 | 19 |
| Disorientation | 7 | 10 |
| Disseminated varicella zoster virus infection | 1 | 1 |
| Dissociation | 1 | 1 |
| Dissociative disorder | 1 | 1 |
| Disturbance in attention | 7 | 11 |
| Dizziness | 131 | 209 |
| Dizziness exertional | 2 | 2 |
| Dizziness postural | 7 | 13 |
| Dreamy state | 1 | 1 |
| Drooling | 1 | 1 |
| Drug eruption | 1 | 1 |
| Drug hypersensitivity | 1 | 1 |
| Drug ineffective | 53 | 116 |
| Dry eye | 2 | 3 |
| Dry mouth | 9 | 14 |
| Dry skin | | 2 |
| Dry throat | 2 | 2 |
| Dysarthria | 6 | 10 |
| Dysentery | 1 | 1 |
| Dysgeusia | 13 | 23 |
| Dyskinesia | 2 | 3 |
| Dyspepsia | 4 | 4 |
| Dysphagia | 6 | 8 |
| Dysphonia | 3 | 4 |
| Dyspnoea | 76 | 123 |
| Dyspnoea exertional | 3 | 6 |
| Dysstasia | | 4 |
| Dystonia | | 1 |
| Dysuria | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 6 | 3 | 3 |
| | | | | 1 | 1 |
| | | 1 | 1 | 16 | 18 |
| | | | 1 | 7 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | 6 | 9 |
| | | 8 | 41 | 123 | 168 |
| | | | | 2 | 2 |
| | | | | 7 | 13 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 53 | 116 |
| | | | | 2 | 3 |
| | | 3 | 4 | 6 | 10 |
| | | | 2 | | |
| | | | | 2 | 2 |
| | | | 1 | 6 | 9 |
| | | | | 1 | 1 |
| | | 6 | 15 | 7 | 8 |
| | | | 1 | 2 | 2 |
| | | | | 4 | 4 |
| | | | | 6 | 8 |
| | | | | 3 | 4 |
| | | 4 | 18 | 72 | 105 |
| | | 2 | 3 | 1 | 3 |
| | | | 2 | | 2 |
| | | | | | 1 |
| | | 2 | 2 | 2 | 3 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Ear congestion | | 1 |
| Ear discomfort | 2 | 2 |
| Ear disorder | | 1 |
| Ear infection | 1 | 2 |
| Ear pain | 9 | 13 |
| Ear swelling | 2 | 2 |
| Eating disorder | 4 | 4 |
| Eating disorder symptom | 1 | 1 |
| Eczema | 2 | 2 |
| Eczema nummular | 1 | 1 |
| Electrocardiogram abnormal | 1 | 1 |
| Electrocardiogram ST segment abnormal | | 1 |
| Embolism | 1 | 1 |
| Emotional disorder | 1 | 1 |
| Emotional distress | 2 | 3 |
| Encephalitis | 2 | 2 |
| Enlarged uvula | 1 | 1 |
| Enteritis | | 1 |
| Enuresis | | 1 |
| Epididymitis | 1 | 1 |
| Epiglottic oedema | 1 | 1 |
| Epilepsy | 4 | 6 |
| Epistaxis | 10 | 14 |
| Erectile dysfunction | 4 | 5 |
| Eructation | | 2 |
| Erythema | 10 | 18 |
| Essential tremor | 1 | 1 |
| Expired product administered | | 1 |
| Exposure via breast milk | 1 | 1 |
| Extrasystoles | 3 | 4 |
| Eye disorder | 1 | 1 |
| Eye infection | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 4 | 8 | 9 |
| | | | | 2 | 2 |
| | | 3 | 3 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 6 |
| | | | 1 | 10 | 13 |
| | | | | 4 | 5 |
| | | | | | 2 |
| | | 1 | 6 | 9 | 12 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eye irritation | 1 | 2 |
| Eyelid function disorder | | 1 |
| Eyelid ptosis | 1 | 1 |
| Eye movement disorder | 1 | 1 |
| Eye pain | 23 | 35 |
| Eye pruritus | 2 | 6 |
| Eye swelling | 4 | 8 |
| Face oedema | 2 | 2 |
| Facial asymmetry | 1 | 1 |
| Facial discomfort | 1 | 2 |
| Facial neuralgia | 1 | 1 |
| Facial pain | 3 | 4 |
| Facial paralysis | 20 | 31 |
| Facial paresis | 4 | 5 |
| Facial spasm | 2 | 3 |
| Faeces discoloured | 2 | 3 |
| Faeces pale | 1 | 2 |
| Fall | 13 | 24 |
| Fatigue | 382 | 594 |
| Fear of falling | 1 | 1 |
| Feeding disorder | 2 | 3 |
| Feeling abnormal | 22 | 38 |
| Feeling cold | 41 | 61 |
| Feeling drunk | | 1 |
| Feeling hot | 23 | 42 |
| Feeling of body temperature change | 3 | 9 |
| Feeling of despair | 1 | 1 |
| Fibromyalgia | 1 | 1 |
| Fixed eruption | | 1 |
| Flank pain | 1 | 2 |
| Flashback | 1 | 1 |
| Flatulence | 8 | 9 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 4 | 9 | 19 | 26 |
| | | | 1 | 2 | 5 |
| | | | | 4 | 8 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 3 |
| | | | | 20 | 31 |
| | | 2 | 3 | 2 | 2 |
| | | | 1 | 2 | 2 |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 2 | | |
| | | | 2 | 13 | 22 |
| 9 | 10 | 54 | 141 | 328 | 453 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| 2 | 3 | 3 | 7 | 19 | 31 |
| | | 6 | 18 | 35 | 43 |
| | | | | | 1 |
| | | 6 | 17 | 17 | 25 |
| | | 1 | 2 | 2 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 7 | 8 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Fluid retention | 2 | 2 |
| Flushing | 6 | 13 |
| Foreign body sensation in eyes | | 1 |
| Formication | | 1 |
| Frequent bowel movements | 2 | 3 |
| Furuncle | 2 | 3 |
| Gait disturbance | 19 | 25 |
| Gait inability | 8 | 14 |
| Gastric disorder | 2 | 2 |
| Gastric haemorrhage | 2 | 2 |
| Gastric varices haemorrhage | 1 | 1 |
| Gastritis | 2 | 2 |
| Gastroenteritis | 4 | 6 |
| Gastroenteritis viral | | 1 |
| Gastrointestinal pain | 3 | 4 |
| Gastroesophageal reflux disease | 3 | 3 |
| Generalised tonic-clonic seizure | 1 | 1 |
| Genital herpes | | 1 |
| Genital pain | 1 | 1 |
| Genitourinary symptom | 1 | 1 |
| Giant cell arteritis | 1 | 1 |
| Gingival blister | | 1 |
| Gingival pain | 2 | 2 |
| Gingival swelling | 1 | 1 |
| Glassy eyes | | 1 |
| Glaucoma | 1 | 1 |
| Gliososis | 1 | 1 |
| Glossodynia | 4 | 5 |
| Gonorrhoea | 1 | 1 |
| Gout | 7 | 9 |
| Groin pain | 2 | 2 |
| Guillain-Barre syndrome | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | 1 | 1 |
| | | | 5 | 6 | 8 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | | 1 | 2 | 2 |
| | | 3 | 5 | 16 | 20 |
| | | 1 | 1 | 7 | 13 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 4 | 5 |
| | | | | | 1 |
| | | | | 3 | 4 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 3 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 7 | 9 |
| | | | | 2 | 2 |
| | | | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Haematemesis | | 4 |
| Haematochezia | 1 | 1 |
| Haematoma | 2 | 2 |
| Haemoglobin decreased | 1 | 2 |
| Haemoptysis | 2 | 3 |
| Haemorrhage | 4 | 4 |
| Haemorrhage intracranial | | 1 |
| Haemorrhage urinary tract | 1 | 1 |
| Haemorrhoids | 1 | 1 |
| Hallucination | 2 | 8 |
| Hallucinations, mixed | 1 | 1 |
| Hallucination, visual | | 3 |
| Hand-eye coordination impaired | | 1 |
| Hangover | | 1 |
| Headache | 401 | 670 |
| Head discomfort | 1 | 3 |
| Head injury | 5 | 7 |
| Heart rate abnormal | 3 | 3 |
| Heart rate decreased | 3 | 5 |
| Heart rate increased | 14 | 22 |
| Heart rate irregular | 2 | 3 |
| Hemiparesis | 1 | 4 |
| Hepatic artery embolism | | 1 |
| Hepatic enzyme increased | | 1 |
| Hepatic pain | 1 | 2 |
| Herpes simplex | 1 | 1 |
| Herpes virus infection | 2 | 2 |
| Herpes zoster | 21 | 25 |
| Herpes zoster oticus | | 1 |
| Herpes zoster reactivation | 1 | 1 |
| Hiccups | 1 | 1 |
| Hordeolum | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 4 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 3 |
| 1 | 1 | | | 4 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 8 |
| | | | | 1 | 1 |
| | | | | | 3 |
| | | | | | 1 |
| | | | 1 | | |
| 3 | 3 | 41 | 151 | 360 | 519 |
| | | 1 | 1 | | 2 |
| | | | 1 | 5 | 6 |
| | | | | 3 | 3 |
| | | 1 | 1 | 2 | 4 |
| | | | 3 | 14 | 19 |
| | | | | 2 | 3 |
| | | | | 1 | 4 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 2 | 20 | 23 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------------|------------------------------------|--------------------------------------|
| Hot flush | 7 | 16 |
| Hyperacusis | 2 | 2 |
| Hyperaesthesia | 3 | 5 |
| Hyperglycaemia | 1 | 6 |
| Hyperhidrosis | 66 | 96 |
| Hyperkalaemia | 1 | 1 |
| Hypersensitivity | 9 | 16 |
| Hypersensitivity pneumonitis | | 1 |
| Hypersomnia | 7 | 9 |
| Hypertension | 12 | 19 |
| Hypertonic bladder | | 1 |
| Hyperventilation | 2 | 3 |
| Hypoacusis | 1 | 1 |
| Hypoaesthesia | 21 | 31 |
| Hypoaesthesia oral | | 3 |
| Hypoglycaemia | 7 | 8 |
| Hypokinesia | | 1 |
| Hyponatraemia | | 1 |
| Hypophagia | | 1 |
| Hypopnoea | 3 | 3 |
| Hyporeflexia | 1 | 1 |
| Hyposmia | | 2 |
| Hypotension | 11 | 20 |
| Hypothermia | 2 | 7 |
| Hypoxia | 2 | 5 |
| Illrd nerve paralysis | 2 | 2 |
| Illness | 32 | 40 |
| Immobile | 2 | 3 |
| Immune-mediated adverse reaction | | 1 |
| Immune system disorder | 2 | 2 |
| Immune thrombocytopenia | 1 | 2 |
| Impaired driving ability | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 5 | 6 | 11 |
| | | | | 2 | 2 |
| | | 2 | 4 | 1 | 1 |
| | | | | 1 | 6 |
| 1 | 1 | 12 | 26 | 54 | 70 |
| | | | | 1 | 1 |
| | | 1 | 4 | 8 | 12 |
| | | | | | 1 |
| | | 3 | 4 | 4 | 5 |
| | | | | 12 | 19 |
| | | | 1 | | |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 2 | 5 | 19 | 26 |
| | | | 1 | | 2 |
| | | | 1 | 7 | 7 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | 1 |
| | | 1 | 4 | 10 | 16 |
| | | | | 2 | 7 |
| | | | | 2 | 5 |
| | | | | 2 | 2 |
| | | 5 | 8 | 27 | 32 |
| | | | | 2 | 3 |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 2 |
| | | 1 | 1 | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Impaired work ability | 2 | 2 |
| Inappropriate schedule of product administration | 2 | 6 |
| Incision site pain | | 1 |
| Incoherent | 1 | 2 |
| Incontinence | 4 | 4 |
| Incorrect route of product administration | 2 | 4 |
| Increased bronchial secretion | 1 | 1 |
| Increased upper airway secretion | | 1 |
| Increased viscosity of upper respiratory secretion | | 1 |
| Indifference | 1 | 1 |
| Infarction | | 1 |
| Infection | 3 | 6 |
| Inflammation | 1 | 2 |
| Inflammatory marker increased | 1 | 1 |
| Influenza | 28 | 37 |
| Influenza like illness | 55 | 99 |
| Infusion related reaction | 1 | 1 |
| Initial insomnia | 2 | 3 |
| Injection related reaction | 4 | 4 |
| Injection site pain | | 4 |
| Insomnia | 38 | 65 |
| Internal haemorrhage | 1 | 1 |
| International normalised ratio decreased | 1 | 1 |
| International normalised ratio increased | 7 | 10 |
| Intestinal ischaemia | 1 | 1 |
| Intestinal obstruction | 1 | 1 |
| Intestinal pseudo-obstruction | 1 | 1 |
| Iridocyclitis | 1 | 1 |
| Irritability | 6 | 6 |
| Ischaemic stroke | 1 | 4 |
| Joint dislocation | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | 2 | 6 | | |
| | | | | | 1 |
| | | 1 | 1 | | 1 |
| | | 1 | 1 | 3 | 3 |
| | | 2 | 4 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 3 | 6 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 3 | 6 | 25 | 31 |
| | | 10 | 30 | 45 | 69 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | | | 4 | 4 |
| | | | 3 | | 1 |
| | | 9 | 24 | 29 | 41 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 7 | 10 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 3 | 3 | 3 |
| | | | | 1 | 4 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Joint effusion | 1 | 3 |
| Joint injury | 2 | 2 |
| Joint lock | | 1 |
| Joint noise | | 1 |
| Joint range of motion decreased | 6 | 9 |
| Joint stiffness | 7 | 10 |
| Joint swelling | 13 | 17 |
| Ketoacidosis | 1 | 1 |
| Labyrinthitis | 1 | 2 |
| Lack of spontaneous speech | 1 | 1 |
| Lacrimation increased | 2 | 5 |
| Lacunar infarction | | 1 |
| Laziness | 1 | 1 |
| Lethargy | 42 | 80 |
| Limb discomfort | 21 | 32 |
| Limb immobilisation | | 1 |
| Limb mass | 1 | 1 |
| Lip disorder | 1 | 1 |
| Lip dry | 1 | 1 |
| Lip erythema | 1 | 1 |
| Lip exfoliation | 1 | 1 |
| Lip swelling | 9 | 11 |
| Listless | 2 | 2 |
| Liver function test abnormal | 1 | 1 |
| Liver function test increased | 1 | 1 |
| Localised infection | 1 | 2 |
| Localised oedema | 1 | 1 |
| Local reaction | 2 | 3 |
| Logorrhoea | 1 | 1 |
| Long thoracic nerve palsy | 1 | 1 |
| Loss of consciousness | 19 | 28 |
| Loss of personal independence in daily activities | 5 | 11 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| 1 | 1 | 1 | 3 | 5 | 6 |
| | | 1 | 3 | 6 | 7 |
| | | 4 | 8 | 9 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 2 | 2 | 3 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 5 | 19 | 37 | 61 |
| 1 | 1 | 7 | 16 | 14 | 16 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | 7 | 7 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 19 | 28 |
| | | 2 | 3 | 3 | 8 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Lower respiratory tract infection | 5 | 12 |
| Lung consolidation | | 1 |
| Lymphadenitis | 2 | 3 |
| Lymphadenopathy | 43 | 80 |
| Lymph node pain | 8 | 14 |
| Lymphoedema | 1 | 2 |
| Malaise | 126 | 217 |
| Mass | 1 | 1 |
| Medication overuse headache | | 1 |
| Melaena | | 1 |
| Memory impairment | 4 | 5 |
| Meniere's disease | 1 | 1 |
| Mental disorder | 1 | 1 |
| Metabolic acidosis | 1 | 1 |
| Metastases to lymph nodes | 1 | 1 |
| Micturition urgency | 2 | 2 |
| Middle insomnia | 4 | 5 |
| Migraine | 18 | 31 |
| Migraine with aura | 2 | 3 |
| Miliaria | 1 | 2 |
| Moaning | 1 | 1 |
| Mobility decreased | 8 | 13 |
| Mononeuropathy | | 1 |
| Monoparesis | 1 | 1 |
| Monoplegia | | 2 |
| Mood swings | 1 | 1 |
| Motion sickness | 1 | 2 |
| Motor dysfunction | 1 | 1 |
| Mouth swelling | | 1 |
| Mouth ulceration | 3 | 6 |
| Movement disorder | 3 | 6 |
| Mucous stools | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 5 | 12 |
| | | | | | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 4 | 19 | 39 | 61 |
| | | 1 | 5 | 7 | 9 |
| | | | | 1 | 2 |
| 1 | 1 | 18 | 53 | 108 | 164 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 4 | 5 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 3 | 3 | 1 | 2 |
| | | | 2 | 18 | 29 |
| | | | 1 | 2 | 2 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 3 | 8 | 10 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 2 | 5 | 1 | 1 |
| | | | 1 | 3 | 5 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Multiple injuries | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 2 |
| Multiple sclerosis relapse | 1 | 1 |
| Muscle contractions involuntary | 2 | 3 |
| Muscle disorder | 1 | 1 |
| Muscle fatigue | 4 | 6 |
| Muscle rigidity | 2 | 4 |
| Muscle spasms | 11 | 15 |
| Muscle tightness | 3 | 4 |
| Muscle twitching | 5 | 7 |
| Muscular weakness | 28 | 44 |
| Musculoskeletal chest pain | 1 | 2 |
| Musculoskeletal discomfort | 1 | 2 |
| Musculoskeletal pain | | 2 |
| Musculoskeletal stiffness | 25 | 38 |
| Myalgia | 206 | 394 |
| Myelitis transverse | 1 | 1 |
| Myocardial infarction | 10 | 18 |
| Myocarditis | | 1 |
| Myoclonus | | 1 |
| Myofascial pain syndrome | 1 | 2 |
| Narcolepsy | | 1 |
| Nasal congestion | 7 | 11 |
| Nasal discomfort | | 2 |
| Nasal dryness | | 1 |
| Nasal oedema | | 1 |
| Nasal pruritus | 1 | 1 |
| Nasopharyngitis | 12 | 17 |
| Nausea | 153 | 262 |
| Neck pain | 32 | 46 |
| Necrotising fasciitis | 1 | 1 |
| Nephritis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 4 | 5 |
| | | | | 2 | 4 |
| | | | 1 | 11 | 14 |
| | | | 1 | 3 | 3 |
| | | | | 5 | 7 |
| | | 5 | 8 | 23 | 36 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | | 1 | | 1 |
| 2 | 2 | 3 | 8 | 22 | 30 |
| 1 | 1 | 21 | 86 | 185 | 308 |
| | | | | 1 | 1 |
| | | | | 10 | 18 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | 3 | 5 | 4 | 6 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 5 | 9 | 12 |
| 2 | 3 | 18 | 63 | 135 | 199 |
| | | 5 | 9 | 27 | 37 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Nephrotic syndrome | | 1 |
| Nerve degeneration | 1 | 1 |
| Nervousness | 8 | 10 |
| Nervous system disorder | 2 | 2 |
| Neuralgia | 9 | 10 |
| Neurogenic shock | 2 | 4 |
| Neurological symptom | 1 | 1 |
| Neurologic neglect syndrome | 1 | 1 |
| Neuromyopathy | 1 | 1 |
| Neuropathy peripheral | 4 | 4 |
| Neutropenia | 2 | 2 |
| Nightmare | 5 | 8 |
| Night sweats | 14 | 29 |
| Nipple pain | 1 | 2 |
| Nipple swelling | | 1 |
| No adverse event | | 1 |
| Obsessive-compulsive symptom | | 1 |
| Occupational exposure to SARS-CoV-2 | | 2 |
| Ocular discomfort | 1 | 1 |
| Ocular hyperaemia | 3 | 4 |
| Oesophageal stenosis | 1 | 1 |
| Off label use | 48 | 56 |
| Oliguria | 1 | 1 |
| Optic neuropathy | 1 | 1 |
| Oral discomfort | 1 | 1 |
| Oral disorder | 1 | 1 |
| Oral herpes | 6 | 9 |
| Oral mucosa erosion | | 1 |
| Oral mucosal eruption | | 1 |
| Oral pain | 4 | 4 |
| Oral pruritus | 2 | 2 |
| Orchitis | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 2 | 3 | 6 | 7 |
| | | | | 2 | 2 |
| | | 2 | 2 | 7 | 8 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | 1 | 3 | 4 | 5 |
| 1 | 1 | 3 | 9 | 11 | 20 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | 48 | 56 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 3 | 5 | 6 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Oropharyngeal pain | 32 | 49 |
| Oropharyngeal spasm | 1 | 1 |
| Orthopnoea | 1 | 2 |
| Orthostatic hypotension | 2 | 2 |
| Osteoporosis | 1 | 1 |
| Overdose | 1 | 1 |
| Oxygen saturation decreased | 6 | 8 |
| Pain | 119 | 183 |
| Painful respiration | 2 | 2 |
| Pain in extremity | 154 | 244 |
| Pain in jaw | 7 | 9 |
| Pain of skin | 3 | 4 |
| Pallor | 3 | 9 |
| Palpitations | 21 | 28 |
| Pancreatitis necrotising | 1 | 1 |
| Panic attack | 2 | 2 |
| Panic reaction | 2 | 2 |
| Paraesthesia | 30 | 46 |
| Paraesthesia oral | 7 | 12 |
| Paralysis | 2 | 5 |
| Paranoia | 1 | 1 |
| Paraparesis | 1 | 1 |
| Parkinsonism | 2 | 2 |
| Parkinson's disease | 1 | 1 |
| Parosmia | 6 | 8 |
| Pelvic discomfort | 1 | 1 |
| Pemphigoid | 2 | 2 |
| Penile swelling | | 1 |
| Periarthritis | 1 | 1 |
| Pericarditis | 1 | 1 |
| Periorbital cellulitis | 1 | 1 |
| Periorbital oedema | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 12 | 31 | 37 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 6 | 8 |
| 2 | 2 | 22 | 57 | 97 | 126 |
| | | 1 | 1 | 1 | 1 |
| 4 | 4 | 33 | 73 | 121 | 171 |
| | | 1 | 3 | 6 | 6 |
| | | | | 3 | 4 |
| | | | 3 | 3 | 6 |
| | | 3 | 7 | 18 | 21 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | 1 | 1 |
| | | 4 | 13 | 26 | 33 |
| | | 2 | 5 | 5 | 7 |
| | | | | 2 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 6 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Periorbital swelling | 1 | 2 |
| Peripheral coldness | 9 | 11 |
| Peripheral swelling | 26 | 38 |
| Peroneal nerve palsy | | 1 |
| Personality change | 1 | 1 |
| Petechiae | 2 | 4 |
| Petit mal epilepsy | | 2 |
| Pharyngeal hypoesthesia | 1 | 1 |
| Pharyngeal inflammation | 1 | 2 |
| Pharyngeal oedema | | 1 |
| Pharyngeal paraesthesia | | 1 |
| Pharyngeal swelling | 9 | 9 |
| Pharyngeal ulceration | 1 | 1 |
| Pharyngitis | 1 | 1 |
| Photophobia | 5 | 7 |
| Photopsia | 2 | 3 |
| Photosensitivity reaction | 3 | 3 |
| Plantar fasciitis | 1 | 1 |
| Plasma cell myeloma | 1 | 1 |
| Platelet count decreased | 1 | 1 |
| Pleuritic pain | | 1 |
| Pneumonia | 7 | 11 |
| Pneumonia aspiration | | 2 |
| Pneumonitis | 4 | 4 |
| Pollakiuria | 1 | 2 |
| Polymyalgia rheumatica | 1 | 1 |
| Polyuria | | 1 |
| Poor quality sleep | 4 | 5 |
| Posterior reversible encephalopathy syndrome | | 1 |
| Postoperative ileus | | 1 |
| Post procedural complication | 1 | 1 |
| Posture abnormal | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | 8 | 9 |
| | | 6 | 10 | 20 | 28 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 9 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 5 | 7 |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 7 | 11 |
| | | | | | 2 |
| | | | | 4 | 4 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 3 | 3 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Post viral fatigue syndrome | | 1 |
| Pre-existing condition improved | | 1 |
| Presyncope | 12 | 21 |
| Primary headache associated with sexual activity | | 1 |
| Product administered to patient of inappropriate age | 6 | 7 |
| Productive cough | 8 | 10 |
| Product quality issue | 1 | 1 |
| Product use issue | 48 | 55 |
| Prostatomegaly | 1 | 2 |
| Pruritus | 29 | 49 |
| Psoriasis | 1 | 1 |
| Psoriatic arthropathy | 1 | 1 |
| Psychiatric symptom | 1 | 1 |
| Psychotic behaviour | | 1 |
| Psychotic disorder | 1 | 1 |
| Pulmonary artery thrombosis | 1 | 1 |
| Pulmonary congestion | 1 | 1 |
| Pulmonary embolism | 6 | 8 |
| Pulmonary infarction | 1 | 2 |
| Pulmonary pain | 1 | 1 |
| Pulmonary thrombosis | 2 | 2 |
| Pulse abnormal | | 1 |
| Pulseless electrical activity | | 1 |
| Puncture site bruise | 1 | 1 |
| Purpura | 1 | 2 |
| Pustule | 1 | 1 |
| Pyrexia | 293 | 572 |
| Q fever | 1 | 1 |
| Radial pulse abnormal | 1 | 1 |
| Rash | 48 | 67 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | | |
| | | 3 | 6 | 9 | 15 |
| | | | | | 1 |
| | | 6 | 7 | | |
| | | 3 | 3 | 5 | 7 |
| | | 1 | 1 | | |
| | | 48 | 55 | | |
| | | 1 | 2 | | |
| | | 2 | 14 | 27 | 35 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 6 | 8 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| 1 | 1 | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 25 | 115 | 268 | 457 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 16 | 44 | 51 |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|----------------------------|--|--|
| Rash erythematous | 11 | 17 |
| Rash macular | 4 | 8 |
| Rash maculo-papular | 1 | 3 |
| Rash morbilliform | 1 | 1 |
| Rash papular | 1 | 2 |
| Rash pruritic | 11 | 15 |
| Rash vesicular | 2 | 4 |
| Raynaud's phenomenon | 1 | 1 |
| Reaction to preservatives | 1 | 1 |
| Rectal discharge | 1 | 1 |
| Rectal haemorrhage | 2 | 2 |
| Red man syndrome | 1 | 1 |
| Regurgitation | | 1 |
| Renal pain | 5 | 6 |
| Respiration abnormal | 1 | 3 |
| Respiratory arrest | 1 | 3 |
| Respiratory disorder | 2 | 4 |
| Respiratory distress | 1 | 1 |
| Respiratory rate increased | 4 | 4 |
| Respiratory symptom | 1 | 1 |
| Respiratory tract oedema | 1 | 2 |
| Restless legs syndrome | 2 | 2 |
| Restlessness | 5 | 9 |
| Retching | 6 | 8 |
| Retinal migraine | 1 | 2 |
| Rhabdomyolysis | 1 | 2 |
| Rhinitis | 2 | 3 |
| Rhinorrhoea | 10 | 13 |
| Road traffic accident | 1 | 1 |
| Sacroiliitis | | 1 |
| Salivary duct obstruction | 1 | 1 |
| Salivary hypersecretion | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 1 | 1 | 3 | 6 | 8 | 11 |
| | | 2 | 6 | 2 | 2 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | 10 | 13 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | 5 | 5 |
| | | | 1 | 1 | 2 |
| | | 1 | 1 | | 2 |
| | | | 1 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 2 |
| | | | 1 | 5 | 8 |
| | | 1 | 3 | 5 | 5 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | 1 | 2 | 2 |
| | | | 3 | 10 | 10 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Sarcoidosis | 1 | 1 |
| SARS-CoV-2 ant body test negative | 5 | 6 |
| SARS-CoV-2 test false positive | | 1 |
| SARS-CoV-2 test positive | 3 | 6 |
| Sciatica | | 1 |
| Scrotal erythema | | 1 |
| Scrotal exfoliation | | 1 |
| Scrotal pain | 1 | 3 |
| Scrotal swelling | | 1 |
| Second primary malignancy | 1 | 1 |
| Sedation | 1 | 1 |
| Seizure | 17 | 23 |
| Sensation of blood flow | 1 | 1 |
| Sense of a foreshortened future | 1 | 1 |
| Sensitive skin | 1 | 2 |
| Sensitivity to weather change | 1 | 1 |
| Sensory disturbance | 1 | 1 |
| Sensory loss | 1 | 1 |
| Sepsis | 3 | 5 |
| Serotonin syndrome | | 1 |
| Serum sickness-like reaction | 1 | 1 |
| Sinus congestion | 1 | 2 |
| Sinus headache | 1 | 2 |
| Sinus tachycardia | 2 | 3 |
| Skin abrasion | 1 | 1 |
| Skin burning sensation | 1 | 2 |
| Skin cancer | | 1 |
| Skin discolouration | 5 | 7 |
| Skin disorder | 1 | 1 |
| Skin erosion | 1 | 2 |
| Skin exfoliation | 1 | 4 |
| Skin irritation | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | 5 | 6 | | |
| | | | 1 | | |
| | | | | 3 | 6 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 17 | 23 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | 2 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | 1 | 3 | 4 | 4 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 3 |
| | | 1 | 1 | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Skin laceration | 1 | 1 |
| Skin lesion | 1 | 2 |
| Skin mass | | 1 |
| Skin swelling | 1 | 1 |
| Skin temperature | 1 | 1 |
| Skin tightness | | 1 |
| Skin warm | 3 | 7 |
| Skin weeping | | 1 |
| Sleep attacks | | 1 |
| Sleep deficit | | 1 |
| Sleep disorder | 8 | 17 |
| Sleep disorder due to a general medical condition | 1 | 2 |
| Sleep paralysis | 1 | 1 |
| Slow response to stimuli | 1 | 1 |
| Slow speech | 1 | 1 |
| Small intestinal obstruction | | 1 |
| Sneezing | 9 | 12 |
| Somnolence | 17 | 31 |
| Speech disorder | 3 | 3 |
| Spinal pain | 2 | 3 |
| Sputum abnormal | 1 | 1 |
| Sputum purulent | | 1 |
| Stevens-Johnson syndrome | | 1 |
| Stoma site discharge | | 1 |
| Stoma site extravasation | | 1 |
| Stoma site haemorrhage | | 1 |
| Stress | 2 | 2 |
| Stridor | 2 | 2 |
| Subcutaneous abscess | 1 | 1 |
| Sudden death | 6 | 9 |
| Sudden hearing loss | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 2 | 3 | 5 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 3 | 7 | 5 | 10 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 2 | 9 | 10 |
| | | 3 | 11 | 14 | 20 |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |
| | | | | 6 | 9 |
| | | | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Suicidal ideation | 2 | 2 |
| Superficial injury of eye | | 1 |
| Superficial vein prominence | | 1 |
| Supraventricular tachycardia | | 1 |
| Suspected COVID-19 | 29 | 41 |
| Sweating fever | 6 | 8 |
| Swelling | 14 | 19 |
| Swelling face | 13 | 18 |
| Swelling of eyelid | 1 | 1 |
| Swollen tongue | 5 | 10 |
| Syncope | 31 | 44 |
| Synovial cyst | | 1 |
| Synovial rupture | | 1 |
| Synovitis | 1 | 1 |
| Systolic hypertension | 1 | 1 |
| Tachycardia | 15 | 30 |
| Tachypnoea | | 3 |
| Taste disorder | 4 | 7 |
| Temperature intolerance | 1 | 1 |
| Temperature regulation disorder | 1 | 2 |
| Tenderness | 2 | 5 |
| Tendon injury | 1 | 2 |
| Tendonitis | 1 | 2 |
| Tendon pain | 1 | 1 |
| Tension headache | 6 | 9 |
| Testicular pain | 1 | 1 |
| Testicular torsion | 1 | 1 |
| Therapeutic response unexpected | | 2 |
| Thermal burn | 1 | 1 |
| Thirst | 4 | 6 |
| Throat irritation | 2 | 4 |
| Throat tightness | 7 | 10 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|---|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | 5 | 5 | 24 | 36 |
| | | | | 6 | 8 |
| 1 | 1 | 2 | 6 | 12 | 13 |
| | | 4 | 4 | 9 | 14 |
| | | 1 | 4 | 4 | 6 |
| | | | | 31 | 44 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 4 | 14 | 26 |
| | | | 1 | | 2 |
| | | 1 | 3 | 3 | 4 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| 1 | 1 | | 1 | 2 | 4 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 5 | 7 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | 4 | 5 |
| | | | 1 | 2 | 3 |
| | | 1 | 2 | 6 | 8 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Thrombocytopenia | 2 | 6 |
| Thrombocytosis | | 1 |
| Thrombosis | 2 | 4 |
| Thunderclap headache | | 1 |
| Tinnitus | 10 | 16 |
| Tongue biting | 1 | 1 |
| Tongue discomfort | | 1 |
| Tongue disorder | 1 | 1 |
| Tongue dry | | 1 |
| Tongue erythema | 1 | 2 |
| Tongue pruritus | 2 | 2 |
| Tongue ulceration | 1 | 1 |
| Tonic convulsion | 2 | 2 |
| Tonsillar hypertrophy | 1 | 1 |
| Tonsillar ulcer | 1 | 1 |
| Tonsillitis | 1 | 1 |
| Tonsillitis bacterial | 1 | 1 |
| Toothache | 1 | 3 |
| Toxic epidermal necrolysis | | 1 |
| Transient ischaemic attack | 8 | 9 |
| Treatment noncompliance | 1 | 1 |
| Tremor | 41 | 61 |
| Trigeminal neuralgia | 2 | 2 |
| Trismus | | 1 |
| Troponin increased | 1 | 1 |
| Tunnel vision | 1 | 2 |
| Type IV hypersensitivity reaction | 1 | 1 |
| Ulnar nerve injury | 1 | 1 |
| Unresponsive to stimuli | 1 | 7 |
| Upper gastrointestinal haemorrhage | | 2 |
| Upper limb fracture | 1 | 1 |
| Upper respiratory tract congestion | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 6 |
| | | | | | 1 |
| | | | | 2 | 4 |
| | | | | | 1 |
| | | | 4 | 10 | 12 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 2 |
| | | | | | 1 |
| | | | | 8 | 9 |
| | | | | 1 | 1 |
| | | 5 | 10 | 36 | 51 |
| | | 1 | 1 | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 7 |
| | | | | | 2 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Urinary incontinence | 6 | 9 |
| Urinary retention | 4 | 6 |
| Urinary tract infection | 3 | 4 |
| Urine output decreased | | 1 |
| Urine output increased | 1 | 1 |
| Urosepsis | | 1 |
| Urticaria | 11 | 26 |
| Urticaria papular | 1 | 1 |
| Uveitis | 1 | 1 |
| Vaccination complication | 3 | 4 |
| Vaccination site bruising | 3 | 9 |
| Vaccination site discolouration | | 2 |
| Vaccination site discomfort | 1 | 4 |
| Vaccination site erythema | 6 | 17 |
| Vaccination site haemorrhage | | 1 |
| Vaccination site hypoaesthesia | 2 | 4 |
| Vaccination site infection | 1 | 2 |
| Vaccination site inflammation | 1 | 2 |
| Vaccination site joint movement impairment | 1 | 2 |
| Vaccination site joint pain | | 2 |
| Vaccination site mass | 1 | 4 |
| Vaccination site movement impairment | 4 | 5 |
| Vaccination site oedema | 1 | 2 |
| Vaccination site pain | 103 | 239 |
| Vaccination site paraesthesia | | 1 |
| Vaccination site pruritus | 3 | 5 |
| Vaccination site reaction | 2 | 5 |
| Vaccination site swelling | 11 | 31 |
| Vaccination site ulcer | | 1 |
| Vaccination site vesicles | 2 | 2 |
| Vaccination site warmth | 3 | 9 |
| Vascular dementia | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 6 | 8 |
| | | | | 4 | 6 |
| | | | | 3 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 2 | 13 | 9 | 13 |
| | | | | 1 | 1 |
| | | | 1 | 3 | 3 |
| | | 1 | 4 | 2 | 5 |
| | | | | | 2 |
| | | | 1 | 1 | 3 |
| | | | 4 | 6 | 13 |
| | | | | | 1 |
| | | | 2 | 2 | 2 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | | 1 | | 1 |
| | | | 2 | 1 | 2 |
| | | 3 | 3 | 1 | 2 |
| | | | | 1 | 2 |
| | | 23 | 95 | 80 | 144 |
| | | | 1 | | |
| | | | 2 | 3 | 3 |
| | | 1 | 2 | 1 | 3 |
| | | 1 | 13 | 10 | 18 |
| | | | | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | | 2 | 3 | 7 |
| | | | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Vasculitis | 1 | 1 |
| Vena cava embolism | | 1 |
| Vena cava thrombosis | | 1 |
| Ventricular extrasystoles | 2 | 4 |
| Ventricular fibrillation | | 3 |
| Vertigo | 13 | 22 |
| Vertigo positional | 2 | 3 |
| Vestibular neuritis | 1 | 3 |
| Viral labyrinthitis | | 1 |
| Viral rash | 1 | 1 |
| Viral upper respiratory tract infection | | 1 |
| Virologic failure | 1 | 1 |
| Vision blurred | 14 | 24 |
| Visual acuity reduced | 1 | 1 |
| Visual impairment | 7 | 10 |
| Vitreous detachment | 1 | 1 |
| Vitreous floaters | | 1 |
| Vomiting | 59 | 98 |
| Vomiting projectile | 2 | 2 |
| Weight bearing difficulty | 2 | 2 |
| Weight decreased | 4 | 4 |
| Weight increased | 2 | 2 |
| Wheezing | 12 | 15 |
| Wound | 1 | 1 |
| Yawning | 1 | 1 |
| | | 1 |
| | 5,975 | 9,842 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 2 | 1 | 2 |
| | | | | | 3 |
| | | 1 | 2 | 12 | 20 |
| | | | | 2 | 3 |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 2 | 6 | 12 | 18 |
| | | | | 1 | 1 |
| | | 1 | 1 | 6 | 9 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 3 | 17 | 56 | 81 |
| | | | | 2 | 2 |
| | | | | 2 | 2 |
| | | 1 | 1 | 3 | 3 |
| | | | | 2 | 2 |
| | | | 2 | 12 | 13 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 43 | 47 | 825 | 2230 |
| | | | | 5150 | 7612 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 2 | 2 | | | 2 | 2 |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 6 | 6 | | | 6 | 6 |
| Abdominal pain upper | 8 | 10 | | 2 | 8 | 8 |
| Accidental overdose | 2 | 2 | 2 | 2 | | |
| Adnexa uteri pain | 1 | 1 | | | 1 | 1 |
| Ageusia | 2 | 3 | | | 2 | 3 |
| Agitation | 1 | 2 | | | 1 | 2 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Anosmia | 2 | 2 | | | 2 | 2 |
| Anxiety | 2 | 2 | 1 | 1 | 1 | 1 |
| Arthralgia | 27 | 38 | 7 | 13 | 20 | 25 |
| Arthritis | | 1 | | | | 1 |
| Arthropathy | 1 | 1 | 1 | 1 | | |
| Asthenia | 8 | 12 | 3 | 4 | 5 | 8 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | | 1 | | | | 1 |
| Autoimmune uveitis | 1 | 1 | | | 1 | 1 |
| Axillary mass | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Back pain | 9 | 12 | 1 | 4 | 8 | 8 |
| Balance disorder | 2 | 4 | | 1 | 2 | 3 |
| Bladder disorder | 1 | 1 | | | 1 | 1 |
| Blepharitis | 1 | 1 | | | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood lactic acid increased | 1 | 1 | | | 1 | 1 |
| Blood potassium decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 3 | 3 | 1 | 1 | 2 | 2 |
| Body temperature decreased | 3 | 3 | 1 | 1 | 2 | 2 |

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Gender

UNKNOWN

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Body temperature increased | | 3 |
| Bone pain | 1 | 2 |
| Bronchospasm | | 1 |
| Burning sensation | | 1 |
| Cellulitis | 1 | 2 |
| Chest discomfort | 3 | 4 |
| Chest pain | 4 | 8 |
| Chills | 36 | 53 |
| Circumstance or information capable of leading to medication error | 1 | 2 |
| Cluster headache | 1 | 1 |
| Cold sweat | 3 | 4 |
| Condition aggravated | 1 | 2 |
| Confusional state | 1 | 1 |
| Conjunctivitis | 1 | 1 |
| Conjunctivitis bacterial | 1 | 1 |
| Constipation | 2 | 2 |
| Contusion | 1 | 3 |
| Coordination abnormal | 1 | 1 |
| Coronavirus infection | | 1 |
| Cough | 2 | 6 |
| COVID-19 | 9 | 67 |
| Death | 3 | 3 |
| Death neonatal | 1 | 1 |
| Decreased appetite | 6 | 8 |
| Delirium | 1 | 1 |
| Dermatitis | 1 | 1 |
| Diarrhoea | 14 | 22 |
| Discomfort | | 1 |
| Disturbance in attention | 1 | 2 |
| Dizziness | 25 | 36 |
| Dizziness postural | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | 2 |
| 1 | 2 | | |
| | | | 1 |
| | | | 1 |
| | | 1 | 2 |
| | | 3 | 4 |
| | 1 | 4 | 7 |
| 8 | 17 | 28 | 36 |
| 1 | 2 | | |
| | | 1 | 1 |
| 1 | 1 | 2 | 3 |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 2 |
| | 1 | 1 | 2 |
| | | 1 | 1 |
| | 2 | 2 | 4 |
| 1 | 1 | 8 | 66 |
| | | 3 | 3 |
| | | 1 | 1 |
| 3 | 4 | 3 | 4 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 5 | 12 | 17 |
| | | | 1 |
| | 1 | 1 | 1 |
| 4 | 8 | 21 | 28 |
| | 1 | | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Drug eruption | | 1 |
| Drug ineffective | 12 | 73 |
| Dry mouth | 1 | 4 |
| Dysarthria | 1 | 1 |
| Dysgeusia | 3 | 7 |
| Dyspepsia | 1 | 1 |
| Dyspnoea | 6 | 9 |
| Ear haemorrhage | 1 | 1 |
| Ear infection | | 1 |
| Ear pain | 1 | 5 |
| Epistaxis | 1 | 2 |
| Eructation | 1 | 1 |
| Erythema | 4 | 5 |
| Exfoliative rash | 1 | 1 |
| Exposure via breast milk | 6 | 9 |
| Eye haemorrhage | 1 | 1 |
| Eye irritation | 1 | 2 |
| Eye pain | 2 | 3 |
| Facial pain | | 2 |
| Facial paralysis | 3 | 3 |
| Fall | | 2 |
| Fatigue | 81 | 112 |
| Feeding disorder | 1 | 2 |
| Feeling abnormal | 2 | 3 |
| Feeling cold | 6 | 6 |
| Feeling hot | 2 | 5 |
| Flatulence | 1 | 1 |
| Flushing | 1 | 1 |
| Foreign body sensation in eyes | 1 | 1 |
| Functional gastrointestinal disorder | 1 | 1 |
| Gait disturbance | 1 | 1 |
| Gait inability | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 12 | 73 |
| | 2 | 1 | 2 |
| | | 1 | 1 |
| | 4 | 3 | 3 |
| | | 1 | 1 |
| | | 6 | 9 |
| | | 1 | 1 |
| | | | 1 |
| | 3 | 1 | 2 |
| | | 1 | 2 |
| | | 1 | 1 |
| 3 | 3 | 1 | 2 |
| | | 1 | 1 |
| 5 | 8 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 2 |
| | | 2 | 3 |
| | 1 | | 1 |
| | | 3 | 3 |
| | 1 | | 1 |
| 13 | 30 | 68 | 82 |
| 1 | 1 | | 1 |
| 1 | 2 | 1 | 1 |
| 1 | 1 | 5 | 5 |
| 1 | 4 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Gastrointestinal pain | 1 | 2 |
| Genital pain | 1 | 1 |
| Gingival pain | 1 | 1 |
| Glossodynia | 1 | 1 |
| Haematochezia | 1 | 1 |
| Haemorrhage | | 1 |
| Haemorrhoids | 1 | 1 |
| Hallucination | 1 | 1 |
| Headache | 79 | 120 |
| Head discomfort | 4 | 4 |
| Head injury | | 1 |
| Heart rate decreased | | 1 |
| Heart rate increased | 4 | 5 |
| Heart rate irregular | 1 | 1 |
| Herpes zoster | 4 | 4 |
| Hot flush | 3 | 5 |
| Hypercapnia | 1 | 1 |
| Hyperhidrosis | 3 | 6 |
| Hypersensitivity | 2 | 6 |
| Hypersomnia | 2 | 2 |
| Hypertension | 1 | 1 |
| Hypoaesthesia | 6 | 9 |
| Hypoaesthesia oral | 1 | 2 |
| Hypotension | 2 | 3 |
| Hypothermia | 1 | 1 |
| Illness | 7 | 7 |
| Immobile | 1 | 1 |
| Incorrect route of product administration | 1 | 1 |
| Increased tendency to bruise | 1 | 1 |
| Inflammation | 1 | 1 |
| Influenza | 5 | 9 |
| Influenza like illness | 8 | 13 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 15 | 34 | 64 | 86 |
| 3 | 3 | 1 | 1 |
| | 1 | | |
| | | | 1 |
| 1 | 1 | 3 | 4 |
| | | 1 | 1 |
| | | 4 | 4 |
| 1 | 3 | 2 | 2 |
| | | 1 | 1 |
| 1 | 1 | 2 | 5 |
| 1 | 3 | 1 | 3 |
| | | 2 | 2 |
| | | 1 | 1 |
| 3 | 4 | 3 | 5 |
| 1 | 1 | | 1 |
| 1 | 1 | 1 | 2 |
| | | 1 | 1 |
| 3 | 3 | 4 | 4 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | 5 | 8 |
| 1 | 5 | 7 | 8 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Injection site pain | | 4 | | 4 | | |
| Insomnia | 9 | 11 | 1 | 2 | 8 | 9 |
| Irritability | 1 | 1 | | | 1 | 1 |
| Joint range of motion decreased | 1 | 1 | 1 | 1 | | |
| Joint swelling | 1 | 2 | | | 1 | 2 |
| Labyrinthitis | | 1 | | | | 1 |
| Lacrimation increased | 1 | 3 | | | 1 | 3 |
| Lethargy | 6 | 11 | 1 | 4 | 5 | 7 |
| Limb discomfort | 3 | 4 | 1 | 2 | 2 | 2 |
| Limb mass | 1 | 1 | 1 | 1 | | |
| Lip oedema | 1 | 1 | | | 1 | 1 |
| Lip swelling | | 2 | | | | 2 |
| Liquid product physical issue | | 2 | | 2 | | |
| Localised infection | 1 | 1 | 1 | 1 | | |
| Local reaction | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | | 1 | | | | 1 |
| Loss of personal independence in daily activities | 1 | 1 | | | 1 | 1 |
| Lymphadenitis | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 16 | 25 | 3 | 9 | 13 | 16 |
| Lymph node pain | 1 | 2 | | 1 | 1 | 1 |
| Lymphoma | 2 | 2 | | | 2 | 2 |
| Malaise | 17 | 27 | 2 | 7 | 15 | 20 |
| Maternal exposure during pregnancy | 2 | 2 | | | 2 | 2 |
| Medication error | 1 | 1 | 1 | 1 | | |
| Melaena | 1 | 1 | | | 1 | 1 |
| Menorrhagia | 1 | 1 | | | 1 | 1 |
| Metastases to lymph nodes | 3 | 3 | | | 3 | 3 |
| Metrorrhagia | 1 | 1 | | | 1 | 1 |
| Migraine | 9 | 11 | 2 | 4 | 7 | 7 |
| Mobility decreased | 2 | 3 | 2 | 2 | | 1 |
| Motion sickness | 1 | 1 | | | 1 | 1 |
| Mouth ulceration | 2 | 2 | 1 | 1 | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------|------------------------------------|--------------------------------------|
| Muscle fatigue | 2 | 2 |
| Muscle spasms | 2 | 2 |
| Muscle strain | | 1 |
| Muscle twitching | 1 | 1 |
| Muscular weakness | 3 | 8 |
| Musculoskeletal chest pain | | 1 |
| Musculoskeletal discomfort | 1 | 1 |
| Musculoskeletal stiffness | 4 | 7 |
| Myalgia | 43 | 59 |
| Myelosuppression | 1 | 1 |
| Nasal congestion | 1 | 2 |
| Nasal disorder | 1 | 1 |
| Nasopharyngitis | 2 | 3 |
| Nausea | 40 | 67 |
| Neck pain | 3 | 12 |
| Nervousness | 3 | 3 |
| Neurogenic shock | 1 | 1 |
| Night sweats | | 1 |
| No adverse event | 4 | 5 |
| Ocular hyperaemia | 1 | 2 |
| Off label use | 6 | 7 |
| Oral pain | 1 | 2 |
| Oral pruritus | | 1 |
| Oropharyngeal pain | 9 | 15 |
| Osteoarthritis | | 1 |
| Overdose | | 2 |
| Oxygen saturation decreased | | 2 |
| Pain | 18 | 32 |
| Pain in extremity | 28 | 47 |
| Pain in jaw | 2 | 3 |
| Pain of skin | 1 | 3 |
| Pallor | | 2 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 2 | 2 |
| | | 2 | 2 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | 2 | 7 |
| | | | 1 |
| | | 1 | 1 |
| 2 | 2 | 2 | 5 |
| 10 | 20 | 33 | 39 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| | 1 | 2 | 2 |
| 6 | 18 | 34 | 49 |
| | 6 | 3 | 6 |
| | | 3 | 3 |
| | | 1 | 1 |
| | | | 1 |
| 4 | 5 | | |
| | | 1 | 2 |
| 6 | 7 | | |
| | | 1 | 2 |
| | 1 | | |
| | 5 | 9 | 10 |
| | 1 | | |
| | 2 | | |
| | | | 2 |
| 2 | 10 | 16 | 22 |
| 10 | 22 | 18 | 25 |
| | 1 | 2 | 2 |
| | 1 | 1 | 2 |
| | 1 | | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Palpitations | 8 | 11 |
| Papule | | 1 |
| Paraesthesia | 6 | 11 |
| Paraesthesia oral | 3 | 4 |
| Paralysis | 1 | 1 |
| Peau d'orange | | 1 |
| Pelvic pain | 1 | 1 |
| Periorbital swelling | 1 | 1 |
| Peripheral coldness | 2 | 4 |
| Peripheral swelling | 5 | 10 |
| Pharyngeal hypoaesthesia | | 1 |
| Pharyngeal swelling | 1 | 3 |
| Photophobia | 2 | 2 |
| Poor quality product administered | 1 | 10 |
| Premature baby | 2 | 2 |
| Presyncope | 3 | 4 |
| Product administered to patient of inappropriate age | 1 | 1 |
| Productive cough | 1 | 1 |
| Product label confusion | | 1 |
| Product packaging quantity issue | | 4 |
| Product preparation error | | 3 |
| Product preparation issue | | 2 |
| Product quality issue | 1 | 1 |
| Product temperature excursion issue | | 3 |
| Product use issue | 6 | 6 |
| Pruritus | 12 | 18 |
| Pulmonary embolism | 1 | 1 |
| Pulmonary pain | 1 | 1 |
| Pyrexia | 53 | 82 |
| Rash | 6 | 9 |
| Rash erythematous | | 3 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 2 | 7 | 9 |
| | 1 | | |
| 1 | 2 | 5 | 9 |
| 2 | 3 | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 3 | 1 | 1 |
| | 1 | 5 | 9 |
| | | | 1 |
| | 1 | 1 | 2 |
| 1 | 1 | 1 | 1 |
| 1 | 10 | | |
| | | 2 | 2 |
| 1 | 1 | 2 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | 4 | | |
| | 3 | | |
| | 2 | | |
| 1 | 1 | | |
| | 3 | | |
| 6 | 6 | | |
| 4 | 8 | 8 | 10 |
| | | 1 | 1 |
| 1 | 1 | | |
| 9 | 29 | 44 | 53 |
| | 2 | 6 | 7 |
| | 3 | | |

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Gender

UNKNOWN

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|-----------------------------------|--|--|
| Rash macular | 1 | 2 |
| Rash papular | 1 | 1 |
| Rash pruritic | 1 | 1 |
| Renal pain | 2 | 2 |
| Retching | 1 | 3 |
| Rhinitis allergic | 1 | 1 |
| Rhinorrhoea | 3 | 3 |
| SARS-CoV-2 ant body test negative | 3 | 3 |
| SARS-CoV-2 test positive | | 2 |
| Sinus headache | 2 | 2 |
| Sinusitis | 1 | 1 |
| Sinus pain | | 1 |
| Sinus tachycardia | 1 | 1 |
| Skin exfoliation | 1 | 1 |
| Skin lesion | 1 | 1 |
| Skin warm | 4 | 5 |
| Sleep disorder | | 1 |
| Sneezing | 2 | 2 |
| Somnolence | 3 | 3 |
| Spinal pain | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 1 |
| Stomatitis | 1 | 1 |
| Sudden visual loss | 1 | 1 |
| Suspected COVID-19 | 7 | 8 |
| Swelling | 5 | 7 |
| Swelling face | 3 | 5 |
| Swelling of eyelid | 1 | 1 |
| Swollen tongue | 1 | 1 |
| Syncope | 5 | 8 |
| Tachycardia | 3 | 4 |
| Taste disorder | | 1 |
| Tension headache | 1 | 1 |

| Spontaneous | | | |
|-------------|---|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | | 1 | 3 |
| 1 | 1 | | |
| | | 3 | 3 |
| | | | 2 |
| 2 | 2 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 4 | 5 |
| | 1 | | |
| | | 2 | 2 |
| 2 | 2 | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 1 | 1 | 6 | 7 |
| 3 | 5 | 2 | 2 |
| | | 3 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 5 | 8 |
| 1 | 1 | 2 | 3 |
| | 1 | | |
| | | 1 | 1 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thirst | 1 | 1 | | | 1 | 1 |
| Throat irritation | | 2 | | 2 | | |
| Throat tightness | 2 | 3 | 1 | 1 | 1 | 2 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Tinnitus | | 2 | | | | 2 |
| Tongue discomfort | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Tonsillar disorder | 1 | 1 | 1 | 1 | | |
| Tonsillar hypertrophy | 1 | 1 | | | 1 | 1 |
| Tremor | 6 | 8 | | | 6 | 8 |
| Underdose | | 3 | | 3 | | |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 2 | 3 | | | 2 | 3 |
| Urticaria | 2 | 4 | 1 | 2 | 1 | 2 |
| Urticaria thermal | 1 | 1 | 1 | 1 | | |
| Vaccination site bruising | | 2 | | | | 2 |
| Vaccination site cellulitis | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site discomfort | | 1 | | 1 | | |
| Vaccination site erythema | 3 | 7 | 2 | 6 | 1 | 1 |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 3 | | 1 | 1 | 2 |
| Vaccination site movement impairment | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site necrosis | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 19 | 35 | 5 | 14 | 14 | 21 |
| Vaccination site paraesthesia | | 1 | | | | 1 |
| Vaccination site pruritus | 3 | 4 | 1 | 2 | 2 | 2 |
| Vaccination site swelling | 4 | 10 | 1 | 7 | 3 | 3 |
| Vaccination site warmth | 1 | 5 | 1 | 4 | | 1 |
| Vasoconstriction | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 3 | | | 1 | 3 |
| Viral infection | | 1 | | 1 | | |
| Vision blurred | 3 | 5 | | | 3 | 5 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|-----|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vlth nerve paralysis | 1 | 1 | | | 1 | 1 |
| Vomiting | 8 | 15 | 1 | 2 | 7 | 13 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| Wound secretion | 1 | 1 | | | 1 | 1 |
| | 1 | 2 | 1 | 2 | | |
| | 1,018 | 1,690 | 223 | 519 | 795 | 1171 |

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Country Where Event Occurred
UNITED STATES

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 26 | 77 | | | 26 | 77 | | |
| Abdominal distension | 6 | 16 | | | 6 | 16 | | |
| Abdominal pain | 20 | 84 | | | 17 | 77 | 3 | 7 |
| Abdominal pain lower | 1 | 7 | | | 1 | 4 | | 3 |
| Abdominal pain upper | 41 | 102 | | | 38 | 94 | 3 | 8 |
| Abdominal rigidity | 1 | 3 | | | 1 | 2 | | 1 |
| Abdominal symptom | 1 | 1 | | | 1 | 1 | | |
| Abdominal wall haematoma | 1 | 1 | | | | | 1 | 1 |
| Abdominal wall haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Abnormal behaviour | 3 | 4 | | | 3 | 3 | | 1 |
| Abnormal dreams | 3 | 12 | | | 3 | 12 | | |
| Abnormal faeces | 1 | 1 | | | 1 | 1 | | |
| Abnormal sensation in eye | | 3 | | | | 3 | | |
| Abnormal withdrawal bleeding | 1 | 1 | | | 1 | 1 | | |
| Abortion spontaneous | 7 | 12 | | | | | 7 | 12 |
| Acarodermatitis | 1 | 2 | | | | 1 | 1 | 1 |
| Accidental exposure to product | 11 | 22 | | | 11 | 21 | | 1 |
| Accidental overdose | 2 | 13 | | | 2 | 12 | | 1 |
| Accidental underdose | 1 | 1 | | | 1 | 1 | | |
| Acetonaemia | | 1 | | | | 1 | | |
| Acne | 3 | 7 | | | 3 | 7 | | |
| Activated partial thromboplastin time prolonged | 1 | 1 | | | 1 | 1 | | |
| Acute disseminated encephalomyelitis | | 1 | | | | | | 1 |
| Acute hepatic failure | | 1 | | | | | | 1 |
| Acute kidney injury | | 2 | | | | | | 2 |
| Acute myeloid leukaemia | 2 | 2 | | | | | 2 | 2 |
| Acute myocardial infarction | | 1 | | | | | | 1 |
| Acute pulmonary oedema | 1 | 1 | | | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Adnexa uteri pain | | 1 | | | | 1 | | |
| Adrenal disorder | 1 | 1 | | | | | 1 | 1 |
| Adrenocortical insufficiency acute | 1 | 1 | | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Ageusia | 26 | 79 |
| Aggression | | 1 |
| Agitation | 2 | 6 |
| Alanine aminotransferase increased | 2 | 3 |
| Allergy to arthropod sting | 1 | 1 |
| Allergy to vaccine | 13 | 37 |
| Allodynia | | 1 |
| Alopecia | | 2 |
| Altered state of consciousness | 2 | 3 |
| Amnesia | 6 | 11 |
| Amyloidosis | 1 | 1 |
| Anaesthesia | | 1 |
| Anal haemorrhage | 1 | 1 |
| Anal incontinence | 1 | 2 |
| Anal skin tags | 1 | 1 |
| Anaphylactic reaction | 34 | 110 |
| Anaphylactic shock | 3 | 5 |
| Anaphylactoid reaction | | 3 |
| Aneurysm | 1 | 1 |
| Anger | 1 | 3 |
| Angina pectoris | 4 | 4 |
| Angioedema | 3 | 14 |
| Angiopathy | 2 | 2 |
| Animal bite | | 1 |
| Anion gap abnormal | 1 | 1 |
| Anorectal discomfort | 1 | 1 |
| Anosmia | 20 | 70 |
| Antibody test abnormal | 1 | 1 |
| Anxiety | 40 | 100 |
| Apathy | 3 | 3 |
| Aphasia | 4 | 9 |
| Aphonia | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 22 | 69 | 4 | 10 |
| | | | 1 | | |
| | | 2 | 6 | | |
| | | 2 | 2 | | 1 |
| | | 1 | 1 | | |
| | | 11 | 26 | 2 | 11 |
| | | | 1 | | |
| | | | 2 | | |
| | | | | 2 | 3 |
| | | 5 | 8 | 1 | 3 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | 1 | 3 | 33 | 107 |
| | | | 1 | 3 | 4 |
| | | | | | 3 |
| | | | | 1 | 1 |
| | | 1 | 3 | | |
| | | | | 4 | 4 |
| | | | | 3 | 14 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 16 | 59 | 4 | 11 |
| | | 1 | 1 | | |
| | | 36 | 91 | 4 | 9 |
| | | 3 | 3 | | |
| | | 2 | 4 | 2 | 5 |
| | | | | 1 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------------|------------------------------------|--------------------------------------|
| Appendicitis | 2 | 6 |
| Appetite disorder | 1 | 2 |
| Aptyalism | 1 | 2 |
| Arrhythmia | 2 | 6 |
| Arthralgia | 247 | 755 |
| Arthritis | 7 | 21 |
| Arthropathy | 5 | 9 |
| Arthropod bite | 1 | 4 |
| Aspartate aminotransferase increased | 1 | 2 |
| Aspiration | 1 | 1 |
| Asthenia | 137 | 389 |
| Asthenopia | 4 | 11 |
| Asthma | 7 | 19 |
| Asymptomatic COVID-19 | 3 | 7 |
| Ataxia | 1 | 1 |
| Atelectasis | 1 | 1 |
| Atrial fibrillation | 16 | 20 |
| Aura | | 1 |
| Auricular swelling | | 1 |
| Autoimmune disorder | 3 | 6 |
| Autoimmune thyroiditis | 2 | 3 |
| Autonomic nervous system imbalance | 1 | 2 |
| Axillary mass | 1 | 9 |
| Axillary pain | 31 | 72 |
| Back disorder | 2 | 2 |
| Back injury | 1 | 2 |
| Back pain | 83 | 219 |
| Bacterial infection | | 1 |
| Balance disorder | 17 | 39 |
| Basal ganglia stroke | 2 | 2 |
| Bedridden | | 5 |
| Bladder discomfort | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 2 | 6 |
| | | 1 | 2 | | |
| | | 1 | 2 | | |
| | | | | 2 | 6 |
| | | 241 | 725 | 6 | 30 |
| | | 7 | 21 | | |
| | | 4 | 8 | 1 | 1 |
| | | 1 | 4 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 118 | 347 | 19 | 42 |
| | | 4 | 10 | | 1 |
| | | 6 | 17 | 1 | 2 |
| | | | | 3 | 7 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 16 | 20 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 3 | 6 |
| | | | | 2 | 3 |
| | | 1 | 1 | | 1 |
| | | 1 | 7 | | 2 |
| | | 31 | 71 | | 1 |
| | | 2 | 2 | | |
| | | 1 | 2 | | |
| | | 72 | 199 | 11 | 20 |
| | | | | | 1 |
| | | 16 | 35 | 1 | 4 |
| | | | | 2 | 2 |
| | | | 4 | | 1 |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Bladder disorder | 1 | 1 |
| Blepharitis | 1 | 1 |
| Blepharospasm | 1 | 4 |
| Blindness | 6 | 8 |
| Blindness transient | 1 | 2 |
| Blindness unilateral | 1 | 1 |
| Blister | 6 | 19 |
| Blood albumin decreased | | 1 |
| Blood bilirubin increased | 1 | 1 |
| Blood blister | 1 | 1 |
| Blood calcium decreased | | 1 |
| Blood chloride decreased | | 1 |
| Blood chloride increased | | 1 |
| Blood cholesterol increased | 1 | 1 |
| Blood count abnormal | 1 | 2 |
| Blood creatine increased | | 1 |
| Blood creatinine increased | 2 | 2 |
| Blood disorder | | 1 |
| Blood glucose abnormal | 1 | 3 |
| Blood glucose decreased | 5 | 7 |
| Blood glucose increased | 3 | 8 |
| Blood iron decreased | 1 | 2 |
| Blood lactic acid increased | 1 | 1 |
| Blood potassium decreased | | 4 |
| Blood potassium increased | 1 | 1 |
| Blood pressure abnormal | 2 | 5 |
| Blood pressure decreased | 12 | 22 |
| Blood pressure diastolic decreased | | 1 |
| Blood pressure diastolic increased | | 1 |
| Blood pressure fluctuation | 2 | 5 |
| Blood pressure increased | 54 | 141 |
| Blood pressure systolic increased | 1 | 8 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 4 | | |
| | | | | 6 | 8 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 2 | 15 | 4 | 4 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | 5 | 7 | | |
| | | 2 | 7 | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 3 | | 1 |
| | | 1 | 1 | | |
| | | 2 | 5 | | |
| | | 10 | 17 | 2 | 5 |
| | | | 1 | | |
| | | | | | 1 |
| | | 2 | 4 | | 1 |
| | | 32 | 84 | 22 | 57 |
| | | | 2 | 1 | 6 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Blood sodium decreased | | 1 |
| Blood test abnormal | 1 | 1 |
| Blood testosterone decreased | | 1 |
| Blood thyroid stimulating hormone increased | | 2 |
| Blood triglycerides increased | | 1 |
| Blood urine present | 2 | 5 |
| Body height decreased | 6 | 11 |
| Body temperature abnormal | 5 | 11 |
| Body temperature decreased | 1 | 4 |
| Body temperature fluctuation | 1 | 2 |
| Body temperature increased | 17 | 51 |
| Bone pain | 13 | 45 |
| Bone swelling | 1 | 5 |
| Booster dose missed | | 2 |
| Bowel movement irregularity | 1 | 3 |
| Brachial plexopathy | | 2 |
| Bradykinesia | | 1 |
| Bradyphrenia | 1 | 2 |
| Brain injury | | 2 |
| Brain oedema | | 1 |
| Brain stem haemorrhage | 1 | 1 |
| Brain stem syndrome | 1 | 1 |
| Breast cancer | 1 | 1 |
| Breast discharge | 4 | 4 |
| Breast discomfort | 1 | 3 |
| Breast mass | 1 | 2 |
| Breast milk discolouration | | 1 |
| Breast pain | 9 | 18 |
| Breast swelling | 1 | 4 |
| Breast tenderness | 2 | 5 |
| Breath odour | 1 | 1 |
| Bronchiectasis | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | 2 | 5 | | |
| | | 6 | 11 | | |
| | | 5 | 11 | | |
| | | 1 | 3 | | 1 |
| | | 1 | 2 | | |
| | | 16 | 50 | 1 | 1 |
| | | 11 | 38 | 2 | 7 |
| | | 1 | 5 | | |
| | | | 2 | | |
| | | 1 | 3 | | |
| | | | 1 | | 1 |
| | | | | 1 | 2 |
| | | | | | 2 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 4 | 4 | | |
| | | 1 | 3 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 9 | 18 | | |
| | | 1 | 4 | | |
| | | 2 | 4 | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Bronchitis | 2 | 4 |
| Bronchospasm | 1 | 6 |
| Bruxism | 1 | 1 |
| Burning sensation | 46 | 94 |
| Burn oral cavity | | 1 |
| Bursitis | | 1 |
| Butterfly rash | 1 | 1 |
| Candida infection | 1 | 1 |
| Capillary nail refill test abnormal | | 1 |
| Cardiac arrest | 1 | 3 |
| Cardiac discomfort | | 1 |
| Cardiac disorder | 4 | 9 |
| Cardiac failure | 1 | 1 |
| Cardiac failure congestive | 1 | 2 |
| Cardiac fibrillation | 1 | 1 |
| Cardiac flutter | 3 | 7 |
| Cardiac neoplasm unspecified | | 1 |
| Cardiac valve sclerosis | | 1 |
| Cardio-respiratory arrest | | 1 |
| Cardiovascular disorder | 1 | 1 |
| Carpal tunnel syndrome | 1 | 1 |
| Cartilage injury | | 1 |
| Cataract | 2 | 2 |
| Cellulitis | 7 | 12 |
| Central nervous system lesion | 1 | 2 |
| Cerebral disorder | | 2 |
| Cerebral haemorrhage | 1 | 3 |
| Cerebral infarction | 1 | 1 |
| Cerebral thrombosis | 1 | 1 |
| Cerebrovascular accident | 24 | 32 |
| Chalazion | | 1 |
| Chapped lips | 1 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | 1 | 2 |
| | | | 4 | 1 | 2 |
| | | 1 | 1 | | |
| | | 40 | 82 | 6 | 12 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | 2 | 6 | 2 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 3 | 7 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 7 | 12 |
| | | | 1 | 1 | 1 |
| | | | 2 | | |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 24 | 32 |
| | | | 1 | | |
| | | 1 | 3 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Cheilitis | 1 | 2 |
| Chest discomfort | 61 | 192 |
| Chest pain | 60 | 161 |
| Chest X-ray abnormal | 1 | 1 |
| Chills | 501 | 1,665 |
| Choking | 1 | 3 |
| Choking sensation | 1 | 3 |
| Cholecystitis | | 1 |
| Chondritis | 1 | 1 |
| Chromaturia | 1 | 6 |
| Chronic obstructive pulmonary disease | 2 | 3 |
| Ciliary muscle spasm | 1 | 1 |
| Circulatory collapse | | 3 |
| Circumoral swelling | | 1 |
| Circumstance or information capable of leading to medication error | 16 | 61 |
| Cluster headache | 1 | 2 |
| Coccidioidomycosis | 1 | 1 |
| Cognitive disorder | 4 | 7 |
| Cold sweat | 10 | 33 |
| Colitis | 1 | 1 |
| Colitis ulcerative | | 1 |
| Colon cancer | 1 | 1 |
| Communication disorder | | 1 |
| Condition aggravated | 35 | 72 |
| Confusional state | 19 | 38 |
| Conjunctival haemorrhage | | 1 |
| Conjunctivitis | 3 | 6 |
| Conjunctivitis allergic | | 2 |
| Conjunctivitis viral | | 1 |
| Constipation | 3 | 6 |
| Contraindicated product administered | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | 43 | 134 | 18 | 58 |
| | | 47 | 118 | 13 | 43 |
| | | | | 1 | 1 |
| | | 471 | 1588 | 30 | 77 |
| | | | | 1 | 3 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 6 | | |
| | | | 1 | 2 | 2 |
| | | 1 | 1 | | |
| | | | | | 3 |
| | | | 1 | | |
| | | 16 | 61 | | |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | 3 | 5 | 1 | 2 |
| | | 10 | 29 | | 4 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 23 | 53 | 12 | 19 |
| | | 15 | 32 | 4 | 6 |
| | | | | | 1 |
| | | 3 | 6 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | 3 | 6 | | |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Contraindication to vaccination | 1 | 1 |
| Contrast media allergy | | 1 |
| Contusion | 17 | 33 |
| Corneal oedema | | 1 |
| Corneal reflex decreased | 1 | 1 |
| Coronavirus test positive | | 1 |
| Costochondritis | 1 | 2 |
| Costovertebral angle tenderness | | 1 |
| Cough | 86 | 274 |
| COVID-19 | 144 | 428 |
| COVID-19 immunisation | | 1 |
| COVID-19 pneumonia | 3 | 5 |
| Cranial nerve disorder | 1 | 1 |
| C-reactive protein increased | 2 | 7 |
| Crohn's disease | 3 | 3 |
| Crying | 7 | 20 |
| Crystal urine | | 1 |
| Culture urine positive | | 1 |
| Cyanosis | 2 | 8 |
| Cyst | | 2 |
| Cystitis | 4 | 4 |
| Daydreaming | 1 | 1 |
| Deafness | 13 | 19 |
| Deafness neurosensory | 2 | 3 |
| Deafness unilateral | 3 | 7 |
| Death | 10 | 22 |
| Decreased appetite | 45 | 120 |
| Decreased interest | 1 | 1 |
| Deep vein thrombosis | 1 | 5 |
| Defaecation urgency | | 1 |
| Dehydration | 11 | 29 |
| Delirium | 4 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 17 | 33 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | 1 |
| | | | 1 | | |
| | | 78 | 235 | 8 | 39 |
| 2 | 2 | 11 | 38 | 133 | 390 |
| | | | 1 | | |
| | | | | 3 | 5 |
| | | | | 1 | 1 |
| | | 1 | 5 | 1 | 2 |
| | | | | 3 | 3 |
| | | 7 | 19 | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 5 | 1 | 3 |
| | | | 2 | | |
| | | 3 | 3 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 12 | 18 |
| | | | | 2 | 3 |
| | | | | 3 | 7 |
| | | | | 10 | 22 |
| | | 43 | 112 | 2 | 8 |
| | | 1 | 1 | | |
| | | | | 1 | 5 |
| | | | 1 | | |
| | | 8 | 22 | 3 | 7 |
| | | | | 4 | 5 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Delusional perception | | 3 |
| Dementia | 5 | 5 |
| Demyelinating polyneuropathy | | 1 |
| Dental paraesthesia | | 2 |
| Dental restoration failure | | 1 |
| Depersonalisation/derealisation disorder | | 1 |
| Depressed level of consciousness | 1 | 4 |
| Depressed mood | 4 | 12 |
| Depression | 2 | 5 |
| Dermatitis | 2 | 5 |
| Dermatitis acneiform | 1 | 1 |
| Dermatitis allergic | | 3 |
| Dermatitis contact | | 4 |
| Dermatitis diaper | 1 | 1 |
| Dermatitis exfoliative | | 1 |
| Device breakage | | 1 |
| Diabetes mellitus | 2 | 4 |
| Diabetes mellitus inadequate control | 4 | 4 |
| Diabetic foot infection | 1 | 1 |
| Diaphragmatic paralysis | 1 | 1 |
| Diarrhoea | 134 | 416 |
| Diarrhoea haemorrhagic | 3 | 4 |
| Diastolic hypotension | | 1 |
| Diet refusal | | 1 |
| Dilatation ventricular | | 1 |
| Diplopia | 2 | 4 |
| Discomfort | 23 | 60 |
| Disease progression | | 1 |
| Disease recurrence | 20 | 42 |
| Disorientation | 10 | 14 |
| Dissociation | 1 | 3 |
| Disturbance in attention | 10 | 27 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 2 | | 1 |
| | | | | 5 | 5 |
| | | | | | 1 |
| | | | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 4 |
| | | 3 | 10 | 1 | 2 |
| | | 2 | 3 | | 2 |
| | | 2 | 5 | | |
| | | 1 | 1 | | |
| | | | 3 | | |
| | | | 4 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 2 | 4 |
| | | | | 4 | 4 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 127 | 397 | 7 | 19 |
| | | | | 3 | 4 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 1 | 2 | 1 | 2 |
| | | 21 | 54 | 2 | 6 |
| | | | 1 | | |
| | | 15 | 35 | 5 | 7 |
| | | 6 | 9 | 4 | 5 |
| | | 1 | 2 | | 1 |
| | | 8 | 22 | 2 | 5 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------|------------------------------------|--------------------------------------|
| Diverticulitis | 4 | 4 |
| Diverticulum intestinal | 1 | 1 |
| Dizziness | 309 | 955 |
| Dizziness exertional | | 1 |
| Dizziness postural | 8 | 16 |
| Drooling | | 1 |
| Drug eruption | | 2 |
| Drug hypersensitivity | 6 | 16 |
| Drug ineffective | 155 | 541 |
| Drug interaction | 2 | 7 |
| Drug intolerance | 1 | 1 |
| Dry eye | 4 | 8 |
| Dry mouth | 16 | 45 |
| Dry skin | 7 | 10 |
| Dry throat | 4 | 21 |
| Duodenogastric reflux | 1 | 1 |
| Dysaesthesia | 3 | 5 |
| Dysarthria | 9 | 14 |
| Dyschromatopsia | 1 | 1 |
| Dysentery | 1 | 1 |
| Dysgeusia | 39 | 133 |
| Dyskinesia | 2 | 6 |
| Dysmenorrhoea | 1 | 5 |
| Dyspepsia | 10 | 21 |
| Dysphagia | 36 | 69 |
| Dysphemia | 2 | 2 |
| Dysphonia | 14 | 38 |
| Dyspnoea | 146 | 391 |
| Dyspnoea exertional | 2 | 11 |
| Dysstasia | 12 | 19 |
| Dystonia | | 1 |
| Dysuria | 4 | 7 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 4 | 4 |
| | | | | 1 | 1 |
| | | 268 | 830 | 41 | 125 |
| | | | 1 | | |
| | | 7 | 14 | 1 | 2 |
| | | | 1 | | |
| | | | 2 | | |
| | | 3 | 12 | 3 | 4 |
| 2 | 2 | 1 | 14 | 154 | 527 |
| | | 2 | 6 | | 1 |
| | | 1 | 1 | | |
| | | 4 | 8 | | |
| | | 15 | 40 | 1 | 5 |
| | | 7 | 10 | | |
| | | 4 | 17 | | 4 |
| | | 1 | 1 | | |
| | | 2 | 4 | 1 | 1 |
| | | 3 | 7 | 6 | 7 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 37 | 128 | 2 | 5 |
| | | 1 | 3 | 1 | 3 |
| | | 1 | 5 | | |
| | | 10 | 21 | | |
| | | 26 | 43 | 10 | 26 |
| | | 1 | 1 | 1 | 1 |
| | | 11 | 24 | 3 | 14 |
| | | 95 | 252 | 51 | 139 |
| | | 2 | 9 | | 2 |
| | | 6 | 10 | 6 | 9 |
| | | | | | 1 |
| | | 3 | 6 | 1 | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Ear congestion | | 2 |
| Ear discomfort | 9 | 28 |
| Ear disorder | 5 | 7 |
| Ear haemorrhage | 1 | 1 |
| Ear infection | 3 | 5 |
| Ear neoplasm | | 1 |
| Ear pain | 19 | 67 |
| Ear pruritus | 2 | 6 |
| Ear swelling | 3 | 9 |
| Eating disorder | 6 | 16 |
| Eczema | 1 | 3 |
| Ejection fraction decreased | 1 | 1 |
| Electrocardiogram abnormal | 2 | 4 |
| Electrocardiogram QT prolonged | | 1 |
| Electrocardiogram T wave peaked | 1 | 1 |
| Emotional disorder | | 5 |
| Emotional distress | 1 | 2 |
| Enanthema | | 1 |
| Encephalitis | 1 | 1 |
| Encephalopathy | | 1 |
| Endodontic procedure | 1 | 1 |
| Energy increased | | 2 |
| Enlarged uvula | 1 | 5 |
| Eosinophil count increased | | 2 |
| Eosinophilia | | 1 |
| Epicondylitis | | 2 |
| Epinephrine increased | | 1 |
| Episcleritis | | 2 |
| Epistaxis | 9 | 27 |
| Eructation | 3 | 3 |
| Erythema | 78 | 215 |
| Erythema of eyelid | 2 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | 1 |
| | | 9 | 28 | | |
| | | 1 | 3 | 4 | 4 |
| | | 1 | 1 | | |
| | | 2 | 4 | 1 | 1 |
| | | | 1 | | |
| | | 16 | 62 | 3 | 5 |
| | | 2 | 6 | | |
| | | 2 | 8 | 1 | 1 |
| | | 5 | 13 | 1 | 3 |
| | | 1 | 3 | | |
| | | | | 1 | 1 |
| | | 1 | 3 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 5 | | |
| | | 1 | 1 | | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 1 | 2 | | 3 |
| | | | | | 2 |
| | | | 1 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | 6 | 23 | 3 | 4 |
| | | 3 | 3 | | |
| | | 66 | 182 | 12 | 33 |
| | | | 4 | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Escherichia infection | | 1 |
| Euphoric mood | 1 | 1 |
| Eustachian tube disorder | 1 | 1 |
| Excessive cerumen production | 1 | 1 |
| Exercise lack of | | 1 |
| Expired product administered | 1 | 2 |
| Exposure during pregnancy | 8 | 22 |
| Exposure to SARS-CoV-2 | 7 | 36 |
| Exposure via breast milk | | 5 |
| Exposure via eye contact | | 1 |
| Exposure via skin contact | 10 | 19 |
| Extensive swelling of vaccinated limb | | 1 |
| External ear pain | | 1 |
| Extraocular muscle paresis | 1 | 1 |
| Extrasystoles | 1 | 3 |
| Extremity contracture | | 1 |
| Eye allergy | | 1 |
| Eye contusion | | 3 |
| Eye discharge | 4 | 7 |
| Eye disorder | 2 | 13 |
| Eye haemorrhage | 3 | 7 |
| Eye infection | 2 | 3 |
| Eye inflammation | | 5 |
| Eye irritation | 6 | 21 |
| Eyelid disorder | 1 | 3 |
| Eyelid function disorder | | 1 |
| Eyelid irritation | 1 | 2 |
| Eyelid oedema | | 1 |
| Eyelid pain | 3 | 4 |
| Eyelid ptosis | 2 | 4 |
| Eyelid sensory disorder | | 1 |
| Eyelids pruritus | | 4 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 8 | 21 | | 1 |
| | | 7 | 30 | | 6 |
| | | | 5 | | |
| | | | 1 | | |
| | | 10 | 18 | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | | 3 | | |
| | | 4 | 7 | | |
| | | 2 | 11 | | 2 |
| | | | | 3 | 7 |
| | | 2 | 3 | | |
| | | | 3 | | 2 |
| | | 6 | 20 | | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 2 | 3 | 1 | 1 |
| | | | 1 | 2 | 3 |
| | | | 1 | | |
| | | | 3 | | 1 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Eye movement disorder | 1 | 4 |
| Eye oedema | 2 | 5 |
| Eye pain | 14 | 55 |
| Eye paraesthesia | | 1 |
| Eye pruritus | 18 | 33 |
| Eye swelling | 26 | 64 |
| Face injury | 1 | 4 |
| Face oedema | | 2 |
| Facial discomfort | 2 | 5 |
| Facial nerve disorder | 1 | 2 |
| Facial neuralgia | 1 | 1 |
| Facial pain | 7 | 27 |
| Facial paralysis | 41 | 82 |
| Facial paresis | 1 | 6 |
| Facial spasm | 1 | 1 |
| Faeces discoloured | 2 | 4 |
| Faeces soft | 1 | 1 |
| Fall | 22 | 41 |
| Fatigue | 581 | 1,738 |
| Fear | 5 | 14 |
| Febrile convulsion | | 1 |
| Feeding disorder | 5 | 12 |
| Feeling abnormal | 131 | 329 |
| Feeling cold | 50 | 125 |
| Feeling drunk | 2 | 5 |
| Feeling hot | 79 | 236 |
| Feeling jittery | 5 | 14 |
| Feeling of body temperature change | 11 | 30 |
| Fibrin D dimer increased | 1 | 3 |
| Fibromyalgia | 1 | 1 |
| Fine motor skill dysfunction | 1 | 4 |
| Flank pain | 7 | 10 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 3 | | 1 |
| | | 2 | 5 | | |
| | | 12 | 48 | 2 | 7 |
| | | | | | 1 |
| | | 17 | 28 | 1 | 5 |
| | | 16 | 51 | 10 | 13 |
| | | 1 | 3 | | 1 |
| | | | 1 | | 1 |
| | | 2 | 5 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 7 | 25 | | 2 |
| | | | | 41 | 82 |
| | | | 2 | 1 | 4 |
| | | | | 1 | 1 |
| | | 2 | 4 | | |
| | | 1 | 1 | | |
| | | 16 | 30 | 6 | 11 |
| | | 551 | 1673 | 30 | 65 |
| | | 5 | 13 | | 1 |
| | | | | | 1 |
| | | 5 | 10 | | 2 |
| | | 116 | 299 | 15 | 30 |
| | | 45 | 115 | 5 | 10 |
| | | 2 | 5 | | |
| | | 70 | 208 | 9 | 28 |
| | | 4 | 11 | 1 | 3 |
| | | 11 | 29 | | 1 |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | 1 | 4 | | |
| | | 6 | 9 | 1 | 1 |

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FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Flatulence | 4 | 11 |
| Fluid imbalance | | 1 |
| Fluid retention | 1 | 1 |
| Flushing | 39 | 184 |
| Foetal death | 1 | 1 |
| Folliculitis | 2 | 2 |
| Food allergy | | 1 |
| Food aversion | | 1 |
| Food poisoning | | 1 |
| Foot deformity | 2 | 2 |
| Foreign body aspiration | | 1 |
| Foreign body in throat | 1 | 1 |
| Formication | 2 | 4 |
| Freezing phenomenon | | 1 |
| Frequent bowel movements | 1 | 5 |
| Frostbite | | 1 |
| Frustration tolerance decreased | 1 | 3 |
| Fungal infection | 1 | 4 |
| Furuncle | | 1 |
| Gait disturbance | 40 | 78 |
| Gait inability | 14 | 23 |
| Gal bladder disorder | 1 | 3 |
| Gal bladder polyp | | 1 |
| Gastric disorder | 3 | 3 |
| Gastric pH decreased | | 1 |
| Gastric ulcer | 1 | 1 |
| Gastritis | | 1 |
| Gastritis bacterial | 1 | 1 |
| Gastroenteritis viral | 1 | 2 |
| Gastrointestinal disorder | 4 | 16 |
| Gastrointestinal haemorrhage | 2 | 2 |
| Gastrointestinal infection | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 10 | 1 | 1 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 33 | 140 | 6 | 44 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 2 | 4 | | |
| | | | 1 | | |
| | | 1 | 5 | | |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | 33 | 64 | 7 | 14 |
| | | 6 | 13 | 8 | 10 |
| | | 1 | 2 | | 1 |
| | | | 1 | | |
| | | 3 | 3 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | 1 |
| | | 4 | 15 | | 1 |
| | | | | 2 | 2 |
| | | 1 | 1 | | |

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|---|------------------------------------|--------------------------------------|
| Gastrointestinal motility disorder | 1 | 2 |
| Gastrointestinal pain | 2 | 8 |
| Gastrointestinal sounds abnormal | 1 | 3 |
| Gastrointestinal stoma complication | 1 | 1 |
| Gastrointestinal viral infection | | 1 |
| Gastrooesophageal reflux disease | 8 | 10 |
| Gastrooesophageal sphincter insufficiency | | 1 |
| General physical health deterioration | | 2 |
| Genital herpes | 1 | 1 |
| Genital lesion | 1 | 1 |
| Genital ulceration | 1 | 1 |
| Giant cell arteritis | | 1 |
| Gingival bleeding | | 3 |
| Gingival blister | 1 | 2 |
| Gingival discomfort | | 1 |
| Gingival disorder | | 1 |
| Gingival erythema | 1 | 3 |
| Gingival pain | 1 | 5 |
| Gingival recession | | 1 |
| Gingival swelling | 2 | 6 |
| Gingivitis | 1 | 1 |
| Glare | | 1 |
| Glassy eyes | 1 | 2 |
| Glaucoma | 1 | 2 |
| Glomerular filtration rate decreased | | 1 |
| Glossitis | | 3 |
| Glossodynia | 7 | 13 |
| Gout | 1 | 1 |
| Grip strength decreased | | 2 |
| Groin pain | 1 | 2 |
| Grunting | | 2 |
| Guillain-Barre syndrome | 4 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 2 | | |
| | | 2 | 8 | | |
| | | 1 | 3 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 8 | 10 | | |
| | | | | | 1 |
| | | | | | 2 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 3 | | |
| | | | 1 | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | 1 | 4 | | 1 |
| | | | 1 | | |
| | | 2 | 6 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 1 |
| | | | | 1 | 2 |
| | | | 1 | | |
| | | | 3 | | |
| | | 6 | 12 | 1 | 1 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 1 | 2 | | |
| | | | 1 | | 1 |
| | | | | 4 | 6 |

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|---------------------------------|------------------------------------|--------------------------------------|
| Haematochezia | 4 | 10 |
| Haematocrit decreased | | 2 |
| Haematocrit increased | | 1 |
| Haematuria | 1 | 1 |
| Haemoglobin decreased | 2 | 5 |
| Haemoglobin increased | | 1 |
| Haemoptysis | 3 | 8 |
| Haemorrhage | 7 | 11 |
| Haemorrhagic varicella syndrome | 1 | 1 |
| Haemorrhoids | | 1 |
| Hallucination | 9 | 10 |
| Hallucination, auditory | | 2 |
| Hallucination, visual | 4 | 6 |
| Hand-eye coordination impaired | | 1 |
| Hangover | 2 | 5 |
| Headache | 687 | 2,342 |
| Head discomfort | 19 | 50 |
| Head injury | 2 | 6 |
| Heart rate abnormal | 4 | 7 |
| Heart rate decreased | 5 | 8 |
| Heart rate increased | 92 | 297 |
| Heart rate irregular | 7 | 13 |
| Helicobacter infection | 1 | 1 |
| Hemiparesis | 1 | 2 |
| Hemiplegia | 2 | 3 |
| Hepatic cirrhosis | 1 | 1 |
| Hepatic pain | 1 | 2 |
| Herpes simplex | 2 | 4 |
| Herpes simplex reactivation | 2 | 2 |
| Herpes virus infection | 2 | 7 |
| Herpes zoster | 23 | 52 |
| Hidradenitis | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 4 | 10 |
| | | | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 1 | 3 | 1 | 2 |
| | | | 1 | | |
| | | 2 | 5 | 1 | 3 |
| | | | 1 | 7 | 10 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 9 | 10 |
| | | | | | 2 |
| | | | | 4 | 6 |
| | | | | | 1 |
| | | 2 | 5 | | |
| | | 643 | 2214 | 44 | 128 |
| | | 16 | 44 | 3 | 6 |
| | | | 3 | 2 | 3 |
| | | 3 | 6 | 1 | 1 |
| | | 3 | 5 | 2 | 3 |
| | | 73 | 230 | 19 | 67 |
| | | 6 | 11 | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 2 | 3 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 2 | 4 | | |
| | | 2 | 2 | | |
| | | 2 | 7 | | |
| | | 17 | 45 | 6 | 7 |
| | | | 2 | | |

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|---------------------------|------------------------------------|--------------------------------------|
| Histamine level increased | | 1 |
| Hordeolum | 1 | 4 |
| Hormone level abnormal | 2 | 2 |
| Hot flush | 20 | 74 |
| Hunger | | 4 |
| Hydrophobia | | 1 |
| Hyperacusis | | 4 |
| Hyperaemia | | 1 |
| Hyperaesthesia | 2 | 15 |
| Hyperaesthesia teeth | | 2 |
| Hyperglycaemia | | 2 |
| Hyperhidrosis | 77 | 220 |
| Hyperlipidaemia | 1 | 1 |
| Hyperpyrexia | 1 | 2 |
| Hyperreflexia | 1 | 1 |
| Hypersensitivity | 32 | 102 |
| Hypersomnia | 10 | 35 |
| Hypertension | 47 | 107 |
| Hypertensive crisis | 1 | 2 |
| Hypertensive emergency | | 3 |
| Hypertonia | | 1 |
| Hyperventilation | 3 | 10 |
| Hypoacusis | 7 | 15 |
| Hypoaesthesia | 114 | 339 |
| Hypoaesthesia eye | 2 | 3 |
| Hypoaesthesia oral | 30 | 105 |
| Hypoaesthesia teeth | 1 | 1 |
| Hypocalcaemia | | 1 |
| Hypogeusia | 3 | 6 |
| Hypoglycaemia | | 3 |
| Hypokalaemia | 1 | 2 |
| Hypokinesia | 3 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 3 | 1 | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 16 | 64 | 4 | 10 |
| | | | 4 | | |
| | | | 1 | | |
| | | | 4 | | |
| | | | 1 | | |
| | | 2 | 14 | | 1 |
| | | | 2 | | |
| | | | 1 | | 1 |
| | | 70 | 201 | 7 | 19 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | 1 | 1 | | |
| | | 22 | 71 | 10 | 31 |
| | | 10 | 33 | | 2 |
| | | 26 | 63 | 21 | 44 |
| | | | | 1 | 2 |
| | | | | | 3 |
| | | | 1 | | |
| | | 3 | 7 | | 3 |
| | | 4 | 12 | 3 | 3 |
| | | 98 | 283 | 16 | 56 |
| | | 2 | 3 | | |
| | | 24 | 83 | 6 | 22 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 3 | 6 | | |
| | | | 3 | | |
| | | | | 1 | 2 |
| | | 3 | 6 | | |

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|--|------------------------------------|--------------------------------------|
| Hypomagnesaemia | | 1 |
| Hypophagia | | 1 |
| Hypopnoea | 2 | 4 |
| Hyporeflexia | 1 | 1 |
| Hyporesponsive to stimuli | 1 | 1 |
| Hyposmia | | 4 |
| Hypotension | 13 | 27 |
| Hypothermia | 2 | 3 |
| Hypothyroidism | 1 | 3 |
| Hypotonia | | 1 |
| Idiosyncratic drug reaction | | 1 |
| Ill-defined disorder | | 1 |
| Illness | 39 | 109 |
| Illness anxiety disorder | | 1 |
| Immune-mediated arthritis | | 1 |
| Immune system disorder | 2 | 6 |
| Immune thrombocytopenia | 6 | 6 |
| Immunodeficiency | 2 | 4 |
| Immunosuppression | 1 | 1 |
| Impaired driving ability | 5 | 8 |
| Impaired work ability | 2 | 8 |
| Impulsive behaviour | | 1 |
| Inappropriate schedule of product administration | 104 | 311 |
| Incoherent | 1 | 2 |
| Incomplete course of vaccination | 1 | 6 |
| Incontinence | | 1 |
| Incorrect dosage administered | 4 | 4 |
| Incorrect dose administered | 2 | 9 |
| Incorrect route of product administration | 12 | 54 |
| Increased appetite | | 1 |
| Increased tendency to bruise | 1 | 1 |
| Increased upper airway secretion | 1 | 5 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | | 1 |
| | | 2 | 3 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 4 | | |
| | | 8 | 18 | 5 | 9 |
| | | | | 2 | 3 |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 38 | 104 | 1 | 5 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 4 | 1 | 2 |
| | | | | 6 | 6 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | 5 | 8 | | |
| | | 2 | 8 | | |
| | | | 1 | | |
| | | 104 | 311 | | |
| | | | | 1 | 2 |
| | | 1 | 6 | | |
| | | | 1 | | |
| | | 4 | 4 | | |
| | | 1 | 7 | 1 | 2 |
| | | 12 | 52 | | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 3 | 1 | 2 |

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|--|------------------------------------|--------------------------------------|
| Increased viscosity of bronchial secretion | 1 | 1 |
| Increased viscosity of upper respiratory secretion | 1 | 1 |
| Induration | 1 | 3 |
| Infant irritability | | 1 |
| Infection | 2 | 5 |
| Infection parasitic | | 1 |
| Infertility | 1 | 1 |
| Inflammation | 9 | 22 |
| Inflammatory pain | | 1 |
| Influenza | 12 | 38 |
| Influenza B virus test positive | | 1 |
| Influenza like illness | 29 | 127 |
| Initial insomnia | 1 | 2 |
| Injected limb mobility decreased | 1 | 3 |
| Injection site bruising | | 2 |
| Injection site erythema | 2 | 10 |
| Injection site extravasation | 1 | 2 |
| Injection site haemorrhage | | 1 |
| Injection site indentation | 1 | 1 |
| Injection site joint pain | | 1 |
| Injection site mass | | 2 |
| Injection site pain | 4 | 31 |
| Injection site pruritus | | 1 |
| Injection site rash | 1 | 4 |
| Injection site reaction | | 1 |
| Injection site swelling | | 7 |
| Injection site urticaria | | 1 |
| Injection site warmth | 2 | 3 |
| Insomnia | 55 | 140 |
| Intentional overdose | 1 | 1 |
| Intercepted medication error | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 1 | 3 | 1 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 9 | 20 | | 2 |
| | | | 1 | | |
| | | 12 | 37 | | 1 |
| | | | 1 | | |
| | | 29 | 126 | | 1 |
| | | 1 | 2 | | |
| | | 1 | 3 | | |
| | | | 2 | | |
| | | 2 | 10 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 2 | | |
| | | 3 | 29 | 1 | 2 |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | | 1 | | |
| | | | 7 | | |
| | | | 1 | | |
| | | 2 | 3 | | |
| | | 53 | 135 | 2 | 5 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |

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|--|------------------------------------|--------------------------------------|
| Internal haemorrhage | 1 | 1 |
| International normalised ratio increased | | 1 |
| Intervertebral disc protrusion | 1 | 1 |
| Intestinal ischaemia | 1 | 1 |
| Intestinal obstruction | 1 | 2 |
| Intestinal perforation | 1 | 1 |
| Intracranial aneurysm | 1 | 1 |
| Intracranial pressure increased | | 1 |
| Intranasal paraesthesia | 1 | 3 |
| Intraocular pressure increased | 1 | 2 |
| Irregular sleep wake rhythm disorder | 1 | 2 |
| Irritability | 4 | 11 |
| Irritability postvaccinal | | 1 |
| Irritable bowel syndrome | | 1 |
| Ischaemic stroke | 2 | 2 |
| Jaundice | | 1 |
| Jaw disorder | 2 | 2 |
| Joint dislocation | 2 | 4 |
| Joint effusion | 1 | 2 |
| Joint injury | | 1 |
| Joint instability | | 2 |
| Joint noise | | 1 |
| Joint range of motion decreased | 11 | 32 |
| Joint stiffness | 5 | 16 |
| Joint swelling | 15 | 41 |
| Joint warmth | 1 | 1 |
| Kidney infection | 3 | 4 |
| Labile hypertension | | 1 |
| Laboratory test abnormal | | 1 |
| Labyrinthitis | | 1 |
| Lacrimation decreased | 1 | 1 |
| Lacrimation increased | 10 | 20 |

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|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 1 | 3 | | |
| | | | 1 | 1 | 1 |
| | | 1 | 2 | | |
| | | 4 | 10 | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | | | 2 | 4 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | | | | 2 |
| | | | 1 | | |
| | | 11 | 29 | | 3 |
| | | 4 | 14 | 1 | 2 |
| | | 15 | 39 | | 2 |
| | | 1 | 1 | | |
| | | | | 3 | 4 |
| | | | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 9 | 19 | 1 | 1 |

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|-------------------------------|------------------------------------|--------------------------------------|
| Laryngeal oedema | | 2 |
| Laryngeal pain | | 1 |
| Laryngitis | 1 | 3 |
| Laryngospasm | | 3 |
| Laziness | | 2 |
| Lethargy | 29 | 73 |
| Leukocytosis | | 1 |
| Ligament injury | | 2 |
| Ligament sprain | | 1 |
| Limb discomfort | 16 | 74 |
| Limb injury | 4 | 8 |
| Limb mass | 2 | 3 |
| Lip blister | 3 | 6 |
| Lip discolouration | 1 | 1 |
| Lip disorder | 2 | 4 |
| Lip dry | | 1 |
| Lip erythema | | 3 |
| Lip exfoliation | | 1 |
| Lipids increased | | 1 |
| Lip infection | | 1 |
| Lip injury | | 2 |
| Lip oedema | | 3 |
| Lip pain | 1 | 2 |
| Lip pruritus | 4 | 8 |
| Lip swelling | 23 | 77 |
| Liquid product physical issue | 1 | 1 |
| Livedo reticularis | 1 | 4 |
| Liver disorder | 1 | 1 |
| Liver injury | | 1 |
| Liver tenderness | 1 | 1 |
| Localised infection | 1 | 2 |
| Localised oedema | | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 2 |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | | | | 3 |
| | | | 2 | | |
| | | 26 | 69 | 3 | 4 |
| | | | 1 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | 15 | 66 | 1 | 8 |
| | | 4 | 8 | | |
| | | 2 | 3 | | |
| | | 1 | 4 | 2 | 2 |
| | | | | 1 | 1 |
| | | 2 | 4 | | |
| | | | 1 | | |
| | | | 3 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | | 2 | | 1 |
| | | 1 | 2 | | |
| | | 1 | 5 | 3 | 3 |
| | | 15 | 50 | 8 | 27 |
| | | 1 | 1 | | |
| | | | 1 | 1 | 3 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 1 | 2 | | |
| | | | 2 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Local reaction | | 1 |
| Loss of consciousness | 44 | 75 |
| Loss of personal independence in daily activities | 11 | 32 |
| Loss of proprioception | | 1 |
| Lower respiratory tract congestion | | 1 |
| Lower respiratory tract infection | 1 | 2 |
| Lung carcinoma cell type unspecified stage I | 1 | 1 |
| Lung disorder | 3 | 5 |
| Lymphadenitis | 2 | 8 |
| Lymphadenopathy | 156 | 494 |
| Lymph gland infection | 1 | 2 |
| Lymph node pain | 35 | 109 |
| Lymph node palpable | | 1 |
| Lymphocyte count abnormal | 1 | 1 |
| Lymphocyte count decreased | | 1 |
| Lymphocytosis | 1 | 1 |
| Lymphoedema | 2 | 9 |
| Lymphoma | 2 | 2 |
| Macroglossia | 1 | 1 |
| Macule | | 1 |
| Major depression | 1 | 1 |
| Malaise | 180 | 546 |
| Malignant hypertension | 1 | 1 |
| Mania | 1 | 2 |
| Mass | 5 | 10 |
| Mastitis | | 1 |
| Mastoid disorder | 1 | 1 |
| Maternal exposure during pregnancy | 11 | 86 |
| Maternal exposure timing unspecified | 1 | 3 |
| May-Thurner syndrome | 1 | 1 |
| Mean cell volume increased | | 1 |
| Mechanical urticaria | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 1 | 1 | 43 | 74 |
| | | 8 | 26 | 3 | 6 |
| | | | 1 | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 3 | 2 | 2 |
| | | 2 | 8 | | |
| | | 150 | 466 | 6 | 28 |
| | | 1 | 2 | | |
| | | 34 | 104 | 1 | 5 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 2 | 9 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 171 | 517 | 9 | 29 |
| | | | | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | 5 | 10 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 11 | 85 | | 1 |
| | | 1 | 3 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------|------------------------------------|--------------------------------------|
| Memory impairment | 9 | 20 |
| Meningeal disorder | 1 | 1 |
| Meningism | | 1 |
| Meningitis viral | | 1 |
| Menopausal symptoms | 1 | 1 |
| Menorrhagia | 5 | 8 |
| Menstrual disorder | 4 | 12 |
| Menstruation delayed | 2 | 2 |
| Menstruation irregular | 1 | 11 |
| Mental disorder | 3 | 10 |
| Mental impairment | 13 | 26 |
| Mental status changes | 1 | 2 |
| Metastases to meninges | | 1 |
| Metrorrhagia | 2 | 6 |
| Microembolism | | 1 |
| Micturition disorder | 1 | 1 |
| Micturition urgency | 2 | 3 |
| Middle insomnia | 6 | 19 |
| Migraine | 44 | 136 |
| Migraine with aura | 4 | 6 |
| Miliaria | 3 | 3 |
| Mixed connective tissue disease | | 1 |
| Mobility decreased | 12 | 31 |
| Mononeuropathy | | 1 |
| Monoplegia | 3 | 3 |
| Mood swings | 1 | 1 |
| Motion sickness | | 2 |
| Motor dysfunction | 1 | 3 |
| Mouth haemorrhage | 3 | 3 |
| Mouth injury | 1 | 1 |
| Mouth swelling | 6 | 13 |
| Mouth ulceration | 1 | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 6 | 13 | 3 | 7 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | 5 | 8 | | |
| | | 4 | 12 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 11 | | |
| | | 3 | 9 | | 1 |
| | | | | 13 | 26 |
| | | 1 | 1 | | 1 |
| | | | | | 1 |
| | | 2 | 6 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 5 | 17 | 1 | 2 |
| | | 41 | 126 | 3 | 10 |
| | | 4 | 6 | | |
| | | 3 | 3 | | |
| | | | | | 1 |
| | | 7 | 24 | 5 | 7 |
| | | | | | 1 |
| | | | | 3 | 3 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 1 | 1 | | 2 |
| | | 2 | 2 | 1 | 1 |
| | | 1 | 1 | | |
| | | 3 | 7 | 3 | 6 |
| | | 1 | 3 | | |

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|--------------------------------------|------------------------------------|--------------------------------------|
| Movement disorder | 17 | 33 |
| Mucosal disorder | 1 | 2 |
| Mucosa vesicle | 1 | 1 |
| Mucous stools | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Muscle atrophy | | 1 |
| Muscle contractions involuntary | 1 | 2 |
| Muscle discomfort | 1 | 5 |
| Muscle disorder | 1 | 3 |
| Muscle fatigue | 4 | 8 |
| Muscle rigidity | 1 | 1 |
| Muscle rupture | 1 | 1 |
| Muscle spasms | 33 | 99 |
| Muscle spasticity | 1 | 1 |
| Muscle strain | 2 | 4 |
| Muscle swelling | 1 | 2 |
| Muscle tightness | 11 | 46 |
| Muscle twitching | 11 | 25 |
| Muscular weakness | 34 | 87 |
| Musculoskeletal chest pain | 6 | 20 |
| Musculoskeletal discomfort | 5 | 22 |
| Musculoskeletal disorder | 2 | 6 |
| Musculoskeletal pain | 2 | 8 |
| Musculoskeletal stiffness | 39 | 103 |
| Mutism | | 1 |
| Myalgia | 248 | 848 |
| Mydriasis | | 1 |
| Myelitis transverse | 1 | 2 |
| Myocardial infarction | 10 | 16 |
| Myocardial necrosis marker increased | 1 | 3 |
| Myocarditis | 1 | 2 |
| Myopia | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 14 | 29 | 3 | 4 |
| | | | 1 | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | 1 |
| | | 1 | 5 | | |
| | | 1 | 3 | | |
| | | 4 | 8 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 31 | 91 | 2 | 8 |
| | | 1 | 1 | | |
| | | 1 | 3 | 1 | 1 |
| | | | 1 | 1 | 1 |
| | | 10 | 43 | 1 | 3 |
| | | 10 | 23 | 1 | 2 |
| | | 27 | 70 | 7 | 17 |
| | | 6 | 20 | | |
| | | 5 | 21 | | 1 |
| | | 1 | 4 | 1 | 2 |
| | | 2 | 7 | | 1 |
| | | 35 | 97 | 4 | 6 |
| | | | | | 1 |
| | | 233 | 807 | 15 | 41 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | | | 10 | 16 |
| | | | | 1 | 3 |
| | | | | 1 | 2 |
| | | | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|----------------------------|------------------------------------|--------------------------------------|
| Myositis | | 1 |
| Narcolepsy | 1 | 1 |
| Nasal congestion | 32 | 128 |
| Nasal crusting | 1 | 1 |
| Nasal discomfort | 3 | 7 |
| Nasal disorder | 1 | 2 |
| Nasal dryness | 1 | 1 |
| Nasal injury | | 2 |
| Nasal oedema | 5 | 11 |
| Nasal pruritus | 1 | 1 |
| Nasopharyngitis | 27 | 76 |
| Nausea | 369 | 1,228 |
| Near death experience | 3 | 3 |
| Neck injury | | 1 |
| Neck mass | 4 | 6 |
| Neck pain | 72 | 215 |
| Needle issue | | 1 |
| Neoplasm malignant | 1 | 1 |
| Neoplasm skin | 1 | 2 |
| Nephrolithiasis | 2 | 3 |
| Nephropathy | 1 | 1 |
| Nerve compression | 1 | 6 |
| Nerve injury | 3 | 5 |
| Nervousness | 26 | 54 |
| Nervous system disorder | 4 | 5 |
| Neuralgia | 12 | 34 |
| Neuralgic amyotrophy | 3 | 3 |
| Neurological symptom | 3 | 3 |
| Neuropathy peripheral | 7 | 16 |
| Neutropenia | 1 | 1 |
| Neutrophil count decreased | 2 | 3 |
| Neutrophil count increased | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | 30 | 116 | 2 | 12 |
| | | 1 | 1 | | |
| | | 3 | 5 | | 2 |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 2 | 6 | 3 | 5 |
| | | 1 | 1 | | |
| | | 27 | 74 | | 2 |
| | | 345 | 1144 | 24 | 84 |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | 4 | 6 | | |
| | | 60 | 197 | 12 | 18 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | 1 | 6 | | |
| | | 2 | 4 | 1 | 1 |
| | | 26 | 53 | | 1 |
| | | 4 | 4 | | 1 |
| | | 10 | 31 | 2 | 3 |
| | | 2 | 2 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | | 7 | 16 |
| | | | | 1 | 1 |
| | | 1 | 2 | 1 | 1 |
| | | 1 | 1 | | 1 |

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|-------------------------------------|------------------------------------|--------------------------------------|
| Nightmare | 6 | 11 |
| Night sweats | 20 | 51 |
| Nipple pain | 1 | 3 |
| Nipple swelling | | 1 |
| No adverse event | 6 | 6 |
| Nodule | 1 | 1 |
| Noninfective encephalitis | 2 | 2 |
| Noninfective gingivitis | 1 | 2 |
| Normocytic anaemia | 1 | 1 |
| Nuchal rigidity | 1 | 3 |
| Nystagmus | | 2 |
| Obstructive airways disorder | | 4 |
| Occipital neuralgia | 1 | 1 |
| Occupational exposure to product | 2 | 2 |
| Occupational exposure to SARS-CoV-2 | 1 | 6 |
| Ocular discomfort | 5 | 13 |
| Ocular hyperaemia | 9 | 29 |
| Odynophagia | 5 | 9 |
| Oedema | 1 | 6 |
| Oedema mouth | 1 | 1 |
| Oedema peripheral | 1 | 8 |
| Oesophageal pain | 1 | 1 |
| Off label use | 104 | 325 |
| Oligodipsia | | 1 |
| Ophthalmic herpes simplex | 1 | 1 |
| Optic neuritis | | 1 |
| Oral blood blister | 1 | 1 |
| Oral candidiasis | | 2 |
| Oral discomfort | 6 | 13 |
| Oral disorder | 3 | 10 |
| Oral herpes | 7 | 19 |
| Oral mucosal blistering | | 3 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 6 | 11 | | |
| | | 20 | 49 | | 2 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | 6 | 6 | | |
| | | 1 | 1 | | |
| | | | | 2 | 2 |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | 2 | 1 | 1 |
| | | | 1 | | 1 |
| | | | 1 | | 3 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | 5 | 1 | 1 |
| | | 4 | 9 | 1 | 4 |
| | | 7 | 26 | 2 | 3 |
| | | 3 | 7 | 2 | 2 |
| | | | 4 | 1 | 2 |
| | | | | 1 | 1 |
| | | 1 | 7 | | 1 |
| | | 1 | 1 | | |
| | | 100 | 320 | 4 | 5 |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | 6 | 12 | | 1 |
| | | 3 | 9 | | 1 |
| | | 7 | 18 | | 1 |
| | | | 3 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Oral mucosal eruption | | 5 |
| Oral mucosal erythema | | 3 |
| Oral mucosal exfoliation | 1 | 1 |
| Oral pain | 3 | 10 |
| Oral pruritus | 4 | 11 |
| Oral viral infection | | 1 |
| Oropharyngeal blistering | | 1 |
| Oropharyngeal discomfort | 5 | 20 |
| Oropharyngeal pain | 64 | 235 |
| Oropharyngeal spasm | 1 | 2 |
| Orthopnoea | | 1 |
| Orthostatic heart rate response increased | | 1 |
| Orthostatic hypotension | 1 | 2 |
| Osteoarthritis | 1 | 2 |
| Osteochondritis | | 1 |
| Overdose | 18 | 37 |
| Overweight | 1 | 2 |
| Oxygen saturation abnormal | 2 | 2 |
| Oxygen saturation decreased | 7 | 19 |
| Pain | 412 | 1,408 |
| Painful respiration | 4 | 7 |
| Pain in extremity | 386 | 1,134 |
| Pain in jaw | 11 | 38 |
| Pain of skin | 9 | 21 |
| Palatal disorder | 1 | 2 |
| Palatal swelling | | 3 |
| Pallor | 13 | 29 |
| Palmar erythema | | 4 |
| Palpitations | 63 | 197 |
| Pancreatitis | 1 | 2 |
| Pancreatitis acute | 1 | 2 |
| Pancytopenia | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 5 | | |
| | | | 2 | | 1 |
| | | 1 | 1 | | |
| | | 3 | 9 | | 1 |
| | | 1 | 8 | 3 | 3 |
| | | | 1 | | |
| | | | 1 | | |
| | | 5 | 14 | | 6 |
| | | 60 | 218 | 4 | 17 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | | | 1 | 2 |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 17 | 35 | 1 | 2 |
| | | 1 | 2 | | |
| | | 2 | 2 | | |
| | | 3 | 9 | 4 | 10 |
| | | 388 | 1341 | 24 | 67 |
| | | 2 | 5 | 2 | 2 |
| | | 369 | 1102 | 17 | 32 |
| | | 9 | 34 | 2 | 4 |
| | | 8 | 19 | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | | 2 | | 1 |
| | | 8 | 20 | 5 | 9 |
| | | | 3 | | 1 |
| | | 51 | 148 | 12 | 49 |
| | | | | 1 | 2 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |

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|--------------------------------|------------------------------------|--------------------------------------|
| Panic attack | 3 | 7 |
| Panic disorder | 1 | 1 |
| Panic reaction | 3 | 8 |
| Papule | | 2 |
| Paraesthesia | 120 | 395 |
| Paraesthesia ear | | 1 |
| Paraesthesia mucosal | | 1 |
| Paraesthesia oral | 42 | 152 |
| Paralysis | 4 | 8 |
| Paranasal sinus discomfort | 4 | 15 |
| Paranasal sinus hypersecretion | 2 | 3 |
| Paranoia | | 2 |
| Parosmia | 10 | 25 |
| Pelvic pain | 1 | 3 |
| Periarthritis | | 3 |
| Pericardial effusion | 2 | 3 |
| Pericarditis | 1 | 2 |
| Periorbital cellulitis | 1 | 1 |
| Periorbital discomfort | | 1 |
| Periorbital pain | 1 | 1 |
| Periorbital swelling | 7 | 16 |
| Peripheral coldness | 12 | 39 |
| Peripheral nerve injury | 1 | 1 |
| Peripheral swelling | 62 | 180 |
| Peripheral vascular disorder | 1 | 2 |
| Personality change | 1 | 1 |
| Pertussis | | 1 |
| Petechiae | 7 | 16 |
| Pharyngeal disorder | 1 | 4 |
| Pharyngeal enanthema | 1 | 1 |
| Pharyngeal erythema | 1 | 5 |
| Pharyngeal hypoaesthesia | 3 | 10 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 5 | | 2 |
| | | 1 | 1 | | |
| | | 3 | 7 | | 1 |
| | | | 2 | | |
| | | 104 | 344 | 16 | 51 |
| | | | 1 | | |
| | | | 1 | | |
| | | 29 | 119 | 13 | 33 |
| | | | | 4 | 8 |
| | | 4 | 15 | | |
| | | 2 | 3 | | |
| | | | 2 | | |
| | | 10 | 24 | | 1 |
| | | 1 | 3 | | |
| | | | 2 | | 1 |
| | | | | 2 | 3 |
| | | | | 1 | 2 |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | 6 | 14 | 1 | 2 |
| | | 11 | 37 | 1 | 2 |
| | | | | 1 | 1 |
| | | 57 | 170 | 5 | 10 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 5 | 12 | 2 | 4 |
| | | 1 | 4 | | |
| | | 1 | 1 | | |
| | | 1 | 5 | | |
| | | 3 | 7 | | 3 |

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|-------------------------------|------------------------------------|--------------------------------------|
| Pharyngeal inflammation | | 1 |
| Pharyngeal mass | 3 | 3 |
| Pharyngeal oedema | 2 | 4 |
| Pharyngeal paraesthesia | 3 | 19 |
| Pharyngeal swelling | 29 | 80 |
| Pharyngitis | 2 | 3 |
| Pharyngitis streptococcal | 2 | 3 |
| Phlebitis | | 1 |
| Photophobia | 5 | 25 |
| Photopsia | 2 | 4 |
| Photosensitivity reaction | 3 | 11 |
| Phrenic nerve injury | 1 | 1 |
| Physical deconditioning | | 1 |
| Physical examination abnormal | 1 | 1 |
| Pigmentation disorder | 1 | 1 |
| Piloerection | | 5 |
| Pityriasis | 1 | 1 |
| Platelet count abnormal | 1 | 1 |
| Platelet count decreased | 7 | 8 |
| Platelet count increased | 1 | 5 |
| Pleural effusion | | 2 |
| Pleurisy | 2 | 2 |
| Pleuritic pain | 1 | 3 |
| Plicated tongue | | 1 |
| Pneumonia | 10 | 17 |
| Pneumonia aspiration | 2 | 2 |
| Pneumonitis | | 1 |
| PO2 decreased | | 2 |
| Pollakiuria | 5 | 9 |
| Polychondritis | 1 | 1 |
| Polydipsia | | 2 |
| Polymenorrhoea | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 2 | 2 | 1 | 1 |
| | | | | 2 | 4 |
| | | 3 | 13 | | 6 |
| | | 18 | 46 | 11 | 34 |
| | | 1 | 2 | 1 | 1 |
| | | 2 | 3 | | |
| | | | 1 | | |
| | | 5 | 24 | | 1 |
| | | 2 | 4 | | |
| | | 3 | 11 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 4 | | 1 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 3 | 3 | 4 | 5 |
| | | 1 | 3 | | 2 |
| | | | | | 2 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | | | 10 | 17 |
| | | | | 2 | 2 |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | 5 | 9 | | |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | 1 | 1 | | |

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|--|------------------------------------|--------------------------------------|
| Polymyalgia rheumatica | 1 | 2 |
| Polyneuropathy | | 1 |
| Polyuria | | 1 |
| Poor peripheral circulation | | 2 |
| Poor quality product administered | 9 | 16 |
| Poor quality sleep | 5 | 19 |
| Post herpetic neuralgia | 1 | 1 |
| Postictal state | | 1 |
| Post-traumatic neuralgia | 1 | 1 |
| Post-traumatic stress disorder | | 2 |
| Postural orthostatic tachycardia syndrome | 2 | 3 |
| Posture abnormal | | 1 |
| Pre-existing condition improved | | 1 |
| Premature rupture of membranes | | 1 |
| Premenstrual syndrome | 2 | 2 |
| Pressure of speech | 1 | 1 |
| Presyncope | 32 | 74 |
| Procedural pain | | 2 |
| Procedural site reaction | 1 | 1 |
| Proctalga | 1 | 1 |
| Product administered at inappropriate site | 6 | 32 |
| Product administered to patient of inappropriate age | 3 | 5 |
| Product administration error | 3 | 7 |
| Product colour issue | 1 | 1 |
| Product communication issue | 1 | 1 |
| Product confusion | | 1 |
| Product container issue | 1 | 1 |
| Product dose omission issue | | 1 |
| Product formulation issue | | 1 |
| Productive cough | 5 | 15 |
| Product leakage | 2 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | 1 |
| | | 9 | 16 | | |
| | | 5 | 19 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | | 1 | 2 | 2 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | 25 | 57 | 7 | 17 |
| | | | 1 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 6 | 31 | | 1 |
| | | 3 | 5 | | |
| | | 2 | 6 | 1 | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 5 | 14 | | 1 |
| | | 2 | 6 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Product lot number issue | 1 | 1 |
| Product preparation error | 5 | 20 |
| Product preparation issue | 8 | 15 |
| Product prescribing error | 1 | 5 |
| Product quality issue | 1 | 3 |
| Product storage error | 2 | 2 |
| Product supply issue | 1 | 2 |
| Product temperature excursion issue | 1 | 4 |
| Product use issue | 94 | 308 |
| Prothrombin time prolonged | 1 | 1 |
| Pruritus | 129 | 405 |
| Pruritus genital | | 1 |
| Psoriasis | | 1 |
| Psychiatric symptom | | 1 |
| Psychomotor hyperactivity | | 1 |
| Pulmonary congestion | 2 | 4 |
| Pulmonary embolism | | 1 |
| Pulmonary oedema | 2 | 3 |
| Pulmonary pain | 4 | 7 |
| Pulmonary thrombosis | 2 | 2 |
| Pulse abnormal | 3 | 12 |
| Pulse absent | 1 | 1 |
| Pupillary disorder | | 1 |
| Purpura | 1 | 2 |
| Pustule | 1 | 2 |
| Pyrexia | 478 | 1,650 |
| Radiculitis brachial | | 1 |
| Rash | 131 | 373 |
| Rash erythematous | 28 | 69 |
| Rash macular | 14 | 49 |
| Rash maculo-papular | 2 | 7 |
| Rash morbilliform | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | 5 | 19 | | 1 |
| | | 7 | 13 | 1 | 2 |
| | | 1 | 5 | | |
| | | 1 | 3 | | |
| | | 2 | 2 | | |
| | | 1 | 2 | | |
| | | 1 | 4 | | |
| | | 90 | 302 | 4 | 6 |
| | | | | 1 | 1 |
| | | 112 | 359 | 17 | 46 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | | 2 | 4 |
| | | | | | 1 |
| | | | | 2 | 3 |
| | | 4 | 6 | | 1 |
| | | | | 2 | 2 |
| | | 1 | 7 | 2 | 5 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 1 | 2 | | |
| | | 446 | 1556 | 32 | 94 |
| | | | | | 1 |
| | | 107 | 311 | 24 | 62 |
| | | 25 | 57 | 3 | 12 |
| | | 11 | 42 | 3 | 7 |
| | | 2 | 7 | | |
| | | 1 | 1 | 1 | 1 |

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Gender

FEMALE

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|---|------------------------------------|--------------------------------------|
| Rash papular | 8 | 27 |
| Rash pruritic | 16 | 57 |
| Rash pustular | | 1 |
| Rash vesicular | 3 | 10 |
| Raynaud's phenomenon | 1 | 2 |
| Reaction to excipient | 1 | 4 |
| Rectal discharge | 1 | 1 |
| Rectal haemorrhage | 2 | 3 |
| Rectal tenesmus | 1 | 1 |
| Red blood cell count decreased | | 2 |
| Red blood cell sedimentation rate abnormal | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 2 |
| Red ear syndrome | 1 | 1 |
| Reduced facial expression | 1 | 2 |
| Renal disorder | 3 | 3 |
| Renal failure | 1 | 1 |
| Renal impairment | | 1 |
| Renal pain | 5 | 11 |
| Respiration abnormal | 1 | 2 |
| Respiratory arrest | 2 | 3 |
| Respiratory disorder | 5 | 7 |
| Respiratory distress | 4 | 13 |
| Respiratory failure | | 2 |
| Respiratory rate decreased | | 1 |
| Respiratory rate increased | 6 | 11 |
| Respiratory symptom | | 1 |
| Respiratory tract congestion | 5 | 14 |
| Respiratory tract infection | 1 | 2 |
| Respiratory tract oedema | | 1 |
| Restless legs syndrome | | 2 |
| Restlessness | 6 | 17 |
| Retching | 4 | 13 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 7 | 26 | 1 | 1 |
| | | 15 | 53 | 1 | 4 |
| | | | 1 | | |
| | | 2 | 8 | 1 | 2 |
| | | 1 | 2 | | |
| | | | 2 | 1 | 2 |
| | | 1 | 1 | | |
| | | | | 2 | 3 |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | 1 | 1 |
| | | 2 | 2 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | 4 | 10 | 1 | 1 |
| | | 1 | 2 | | |
| | | | | 2 | 3 |
| | | 2 | 3 | 3 | 4 |
| | | 1 | 2 | 3 | 11 |
| | | | 1 | | 1 |
| | | | | | 1 |
| | | 4 | 6 | 2 | 5 |
| | | | | | 1 |
| | | 5 | 14 | | |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | 2 | | |
| | | 5 | 14 | 1 | 3 |
| | | 3 | 11 | 1 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-----------------------------------|------------------------------------|--------------------------------------|
| Retinal tear | 1 | 1 |
| Retinitis | 1 | 1 |
| Rheumatoid arthritis | 5 | 7 |
| Rhinalgia | 1 | 4 |
| Rhinitis | 1 | 2 |
| Rhinitis allergic | | 1 |
| Rhinorrhoea | 41 | 123 |
| Rhinovirus infection | | 1 |
| Right ventricular dysfunction | | 1 |
| Rosacea | 1 | 2 |
| Rotator cuff syndrome | 1 | 1 |
| Rubber sensitivity | | 1 |
| Ruptured cerebral aneurysm | 1 | 1 |
| Saliva discolouration | 1 | 1 |
| Salivary gland pain | | 1 |
| Salivary hypersecretion | 1 | 3 |
| SARS-CoV-2 ant body test negative | 8 | 13 |
| SARS-CoV-2 ant body test positive | 2 | 4 |
| SARS-CoV-2 test positive | 20 | 140 |
| Scab | 1 | 2 |
| Scar | 1 | 2 |
| Sciatica | | 2 |
| Scleritis | | 1 |
| Scratch | 2 | 6 |
| Screaming | 1 | 3 |
| Seasonal allergy | 1 | 4 |
| Secretion discharge | 1 | 2 |
| Sedation | | 2 |
| Seizure | 7 | 14 |
| Seizure like phenomena | | 1 |
| Sensation of blood flow | 2 | 2 |
| Sensation of foreign body | 8 | 29 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | 5 | 7 |
| | | 1 | 4 | | |
| | | 1 | 2 | | |
| | | | 1 | | |
| | | 41 | 117 | | 6 |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 3 | | |
| | | 6 | 11 | 2 | 2 |
| | | 2 | 4 | | |
| | | 5 | 19 | 15 | 121 |
| | | 1 | 2 | | |
| | | | 1 | 1 | 1 |
| | | | 2 | | |
| | | | | | 1 |
| | | 2 | 4 | | 2 |
| | | 1 | 2 | | 1 |
| | | 1 | 4 | | |
| | | 1 | 2 | | |
| | | | 2 | | |
| | | | | 7 | 14 |
| | | | | | 1 |
| | | | | 2 | 2 |
| | | 6 | 20 | 2 | 9 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Sensitisation | | 1 |
| Sensitive skin | 2 | 8 |
| Sensitivity to weather change | 1 | 1 |
| Sensorimotor disorder | | 1 |
| Sensory disturbance | 5 | 10 |
| Sensory loss | 1 | 6 |
| Sepsis | 2 | 4 |
| Serum sickness | | 1 |
| Shock | 1 | 1 |
| Shock symptom | 2 | 4 |
| Sialoadenitis | 1 | 1 |
| Sinus congestion | 2 | 12 |
| Sinus disorder | 7 | 13 |
| Sinus headache | 7 | 12 |
| Sinusitis | 6 | 14 |
| Sinus pain | 2 | 5 |
| Sinus rhythm | | 1 |
| Sinus tachycardia | 1 | 6 |
| Sitting disability | 1 | 1 |
| Sjogren's syndrome | 1 | 1 |
| Skeletal injury | 1 | 1 |
| Skin burning sensation | 10 | 19 |
| Skin depigmentation | 1 | 1 |
| Skin discolouration | 8 | 20 |
| Skin discomfort | 1 | 1 |
| Skin disorder | 7 | 19 |
| Skin exfoliation | 5 | 9 |
| Skin fissures | 1 | 1 |
| Skin haemorrhage | 1 | 1 |
| Skin indentation | | 1 |
| Skin injury | | 1 |
| Skin irritation | 2 | 9 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|---|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | 2 | 8 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | 5 | 9 | | 1 |
| | | | 4 | 1 | 2 |
| | | | | 2 | 4 |
| | | | | | 1 |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | | 1 | 1 |
| | | 2 | 12 | | |
| | | 6 | 12 | 1 | 1 |
| | | 7 | 12 | | |
| | | 6 | 14 | | |
| | | 2 | 5 | | |
| | | | 1 | | |
| | | 1 | 3 | | 3 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 9 | 18 | 1 | 1 |
| | | 1 | 1 | | |
| | | 7 | 17 | 1 | 3 |
| | | 1 | 1 | | |
| | | 5 | 16 | 2 | 3 |
| | | 5 | 8 | | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 9 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Skin laceration | 3 | 5 |
| Skin laxity | 1 | 1 |
| Skin lesion | 8 | 9 |
| Skin mass | 1 | 1 |
| Skin reaction | 2 | 5 |
| Skin swelling | 2 | 4 |
| Skin tightness | | 3 |
| Skin warm | | 2 |
| Sleep disorder | 8 | 24 |
| Sleep disorder due to a general medical condition | 1 | 3 |
| Sleep disorder due to general medical condition, insomnia type | 1 | 3 |
| Sleep paralysis | 1 | 2 |
| Sleep terror | 1 | 1 |
| Sluggishness | 3 | 7 |
| Small intestinal obstruction | | 1 |
| Sneezing | 10 | 32 |
| Snoring | | 2 |
| Somnolence | 36 | 108 |
| Speech disorder | 17 | 36 |
| Spinal cord disorder | 1 | 1 |
| Spinal disorder | 1 | 2 |
| Spinal fusion surgery | | 1 |
| Spinal pain | 7 | 18 |
| Spinal stenosis | 1 | 1 |
| Splenomegaly | 2 | 2 |
| Sputum discoloured | | 2 |
| Staring | 1 | 2 |
| Status asthmaticus | | 1 |
| Stevens-Johnson syndrome | | 1 |
| Stiff tongue | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | 1 | 2 |
| | | 1 | 1 | | |
| | | 8 | 9 | | |
| | | 1 | 1 | | |
| | | 1 | 3 | 1 | 2 |
| | | 2 | 4 | | |
| | | | 2 | | 1 |
| | | | 2 | | |
| | | 8 | 24 | | |
| | | 1 | 3 | | |
| | | 1 | 3 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | 3 | 7 | | |
| | | | | | 1 |
| | | 10 | 32 | | |
| | | | 1 | | 1 |
| | | 33 | 99 | 3 | 9 |
| | | 8 | 22 | 9 | 14 |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | | | | 1 |
| | | 7 | 17 | | 1 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | | 1 | | 1 |
| | | | | 1 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |

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FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------|------------------------------------|--------------------------------------|
| Stomatitis | 2 | 14 |
| Strabismus | 1 | 1 |
| Strawberry tongue | | 1 |
| Streptococcal infection | 1 | 2 |
| Streptococcus test positive | 1 | 2 |
| Stress | 8 | 14 |
| Stridor | 1 | 5 |
| Subarachnoid haemorrhage | 1 | 1 |
| Subcutaneous abscess | 1 | 1 |
| Sudden death | | 1 |
| Sudden hearing loss | 1 | 3 |
| Suicidal ideation | 1 | 1 |
| Suicide attempt | 1 | 1 |
| Sunburn | | 2 |
| Superficial vein prominence | | 1 |
| Suppressed lactation | | 1 |
| Supraventricular tachycardia | 1 | 4 |
| Suspected COVID-19 | 5 | 27 |
| Suture related complication | | 1 |
| Swelling | 43 | 140 |
| Swelling face | 52 | 130 |
| Swelling of eyelid | 2 | 17 |
| Swollen tongue | 25 | 72 |
| Syncope | 43 | 77 |
| Systemic immune activation | 1 | 1 |
| Systemic lupus erythematosus | | 1 |
| Systemic scleroderma | | 1 |
| Tachycardia | 25 | 158 |
| Tachyphrenia | 1 | 4 |
| Tachypnoea | 1 | 6 |
| Taste disorder | 11 | 33 |
| Tearfulness | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 13 | | 1 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | | 1 |
| | | 1 | 2 | | |
| | | 8 | 14 | | |
| | | | | 1 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | 1 | 3 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | | 1 | 1 | 3 |
| | | 1 | 7 | 4 | 20 |
| | | | | | 1 |
| | | 32 | 119 | 11 | 21 |
| | | 37 | 102 | 15 | 28 |
| | | 1 | 16 | 1 | 1 |
| | | 15 | 43 | 10 | 29 |
| | | | | 43 | 77 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | | | 1 |
| | | 19 | 106 | 6 | 52 |
| | | 1 | 4 | | |
| | | 1 | 3 | | 3 |
| | | 10 | 31 | 1 | 2 |
| | | | 1 | | |

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|---------------------------------|------------------------------------|--------------------------------------|
| Temperature intolerance | 4 | 4 |
| Temperature regulation disorder | 1 | 2 |
| Tenderness | 6 | 22 |
| Tendonitis | 1 | 2 |
| Tendon pain | | 2 |
| Tenosynovitis | 1 | 1 |
| Tension | 2 | 2 |
| Tension headache | 3 | 6 |
| Terminal insomnia | | 3 |
| Tetany | | 2 |
| Therapeutic response unexpected | 8 | 13 |
| Thermal burn | | 1 |
| Thinking abnormal | 5 | 10 |
| Thirst | 7 | 23 |
| Thirst decreased | 1 | 1 |
| Throat clearing | 3 | 5 |
| Throat irritation | 30 | 102 |
| Throat tightness | 28 | 108 |
| Thrombocytopenia | 3 | 6 |
| Thrombosis | 9 | 10 |
| Thyroid disorder | 1 | 3 |
| Thyroid pain | | 1 |
| Tic | | 1 |
| Tinnitus | 26 | 73 |
| Tongue blistering | | 1 |
| Tongue discolouration | 1 | 4 |
| Tongue discomfort | 5 | 16 |
| Tongue disorder | 4 | 11 |
| Tongue dry | 1 | 2 |
| Tongue erythema | | 3 |
| Tongue haematoma | | 1 |
| Tongue haemorrhage | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 4 | | |
| | | 1 | 2 | | |
| | | 6 | 22 | | |
| | | 1 | 2 | | |
| | | | 2 | | |
| | | 1 | 1 | | |
| | | 2 | 2 | | |
| | | 3 | 6 | | |
| | | | 3 | | |
| | | | | | 2 |
| | | 8 | 13 | | |
| | | | 1 | | |
| | | 5 | 10 | | |
| | | 7 | 22 | | 1 |
| | | 1 | 1 | | |
| | | 2 | 3 | 1 | 2 |
| | | 24 | 81 | 6 | 21 |
| | | 13 | 49 | 15 | 59 |
| | | | | 3 | 6 |
| | | | | 9 | 10 |
| | | 1 | 3 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 18 | 56 | 8 | 17 |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | 4 | 14 | 1 | 2 |
| | | 4 | 9 | | 2 |
| | | 1 | 2 | | |
| | | | 3 | | |
| | | | 1 | | |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Tongue injury | | 1 |
| Tongue movement disturbance | | 1 |
| Tongue oedema | | 1 |
| Tongue pruritus | 4 | 11 |
| Tongue ulceration | 1 | 2 |
| Tonsillar disorder | 1 | 1 |
| Tonsillar erythema | | 1 |
| Tonsillar hypertrophy | 3 | 6 |
| Tonsillolith | | 1 |
| Tooth abscess | 1 | 1 |
| Toothache | 9 | 20 |
| Tooth disorder | 2 | 2 |
| Tracheitis | 1 | 1 |
| Tracheomalacia | | 1 |
| Transient ischaemic attack | 2 | 4 |
| Tremor | 50 | 160 |
| Trigeminal nerve disorder | 1 | 1 |
| Trigeminal neuralgia | 4 | 6 |
| Trigeminal neuritis | | 1 |
| Trismus | 1 | 4 |
| Troponin increased | 1 | 3 |
| Tryptase decreased | | 1 |
| Tryptase increased | | 1 |
| Tuberculosis | | 2 |
| Tunnel vision | 2 | 5 |
| Type 1 diabetes mellitus | 1 | 1 |
| Type 2 diabetes mellitus | 1 | 1 |
| Type III immune complex mediated reaction | | 1 |
| Type IV hypersensitivity reaction | | 1 |
| Ulcer | | 1 |
| Underdose | 25 | 53 |
| Undifferentiated connective tissue disease | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | 2 | 8 | 2 | 3 |
| | | 1 | 2 | | |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 3 | 6 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 6 | 17 | 3 | 3 |
| | | 2 | 2 | | |
| | | 1 | 1 | | |
| | | | | | 1 |
| | | | | 2 | 4 |
| | | 41 | 129 | 9 | 31 |
| | | | | 1 | 1 |
| | | 3 | 4 | 1 | 2 |
| | | | 1 | | |
| | | | 3 | 1 | 1 |
| | | | | 1 | 3 |
| | | | 1 | | |
| | | | 1 | | |
| | | | | | 2 |
| | | | | 2 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 1 |
| | | | 1 | | |
| | | | 1 | | |
| | | 25 | 53 | | |
| | | | | | 1 |

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Gender

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------------------|------------------------------------|--------------------------------------|
| Unresponsive to stimuli | 2 | 5 |
| Upper-airway cough syndrome | 1 | 7 |
| Upper airway obstruction | | 1 |
| Upper limb fracture | | 1 |
| Upper respiratory tract congestion | 6 | 26 |
| Upper respiratory tract infection | 4 | 7 |
| Urethral disorder | 1 | 1 |
| Urge incontinence | | 1 |
| Urinary incontinence | 1 | 4 |
| Urinary retention | 2 | 3 |
| Urinary tract infection | 12 | 22 |
| Urinary tract infection bacterial | 1 | 1 |
| Urine analysis abnormal | | 1 |
| Urine odour abnormal | 1 | 1 |
| Urine output increased | 1 | 2 |
| Urticaria | 66 | 284 |
| Use of accessory respiratory muscles | 1 | 1 |
| Uterine contractions during pregnancy | | 1 |
| Uterine haemorrhage | | 1 |
| Uterine inflammation | 1 | 1 |
| Uveitis | | 1 |
| Vaccination error | | 1 |
| Vaccination failure | 2 | 2 |
| Vaccination site bruising | 12 | 33 |
| Vaccination site cellulitis | 5 | 9 |
| Vaccination site coldness | 1 | 1 |
| Vaccination site discharge | | 1 |
| Vaccination site discolouration | 6 | 10 |
| Vaccination site discomfort | 6 | 23 |
| Vaccination site erythema | 76 | 286 |
| Vaccination site extravasation | 2 | 4 |
| Vaccination site haemorrhage | 10 | 20 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | 2 | 4 |
| | | 1 | 7 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | 6 | 25 | | 1 |
| | | 4 | 7 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 1 | 4 | | |
| | | 1 | 1 | 1 | 2 |
| | | 8 | 17 | 4 | 5 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 1 | 2 | | |
| | | 51 | 221 | 15 | 63 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | |
| | | | | 2 | 2 |
| | | 11 | 31 | 1 | 2 |
| | | 1 | 3 | 4 | 6 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 5 | 9 | 1 | 1 |
| | | 5 | 21 | 1 | 2 |
| | | 72 | 275 | 4 | 11 |
| | | 2 | 4 | | |
| | | 8 | 18 | 2 | 2 |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Vaccination site hyperaesthesia | | 1 |
| Vaccination site hypersensitivity | | 2 |
| Vaccination site hypoaesthesia | 3 | 14 |
| Vaccination site induration | 6 | 32 |
| Vaccination site infection | | 5 |
| Vaccination site inflammation | 5 | 13 |
| Vaccination site injury | 1 | 2 |
| Vaccination site irritation | 1 | 2 |
| Vaccination site joint erythema | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 8 |
| Vaccination site joint pain | 1 | 4 |
| Vaccination site lymphadenopathy | 5 | 10 |
| Vaccination site macule | 1 | 4 |
| Vaccination site mass | 18 | 49 |
| Vaccination site movement impairment | 5 | 33 |
| Vaccination site nodule | 1 | 11 |
| Vaccination site oedema | | 2 |
| Vaccination site pain | 354 | 1,191 |
| Vaccination site pallor | | 1 |
| Vaccination site papule | 1 | 2 |
| Vaccination site paraesthesia | 3 | 18 |
| Vaccination site pruritus | 43 | 134 |
| Vaccination site rash | 22 | 49 |
| Vaccination site reaction | 3 | 10 |
| Vaccination site scab | 1 | 3 |
| Vaccination site swelling | 100 | 275 |
| Vaccination site urticaria | 4 | 21 |
| Vaccination site vesicles | 1 | 9 |
| Vaccination site warmth | 44 | 128 |
| Vaginal discharge | 1 | 1 |
| Vaginal haemorrhage | 1 | 8 |
| Vaginal infection | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | 2 | | |
| | | 2 | 13 | 1 | 1 |
| | | 6 | 32 | | |
| | | | 5 | | |
| | | 4 | 11 | 1 | 2 |
| | | 1 | 2 | | |
| | | 1 | 2 | | |
| | | 1 | 1 | | |
| | | 1 | 6 | | 2 |
| | | 1 | 3 | | 1 |
| | | 4 | 9 | 1 | 1 |
| | | 1 | 4 | | |
| | | 18 | 45 | | 4 |
| | | 5 | 32 | | 1 |
| | | | 10 | 1 | 1 |
| | | | 2 | | |
| | | 350 | 1169 | 4 | 22 |
| | | | 1 | | |
| | | 1 | 2 | | |
| | | 3 | 15 | | 3 |
| | | 41 | 128 | 2 | 6 |
| | | 20 | 47 | 2 | 2 |
| | | 3 | 10 | | |
| | | 1 | 3 | | |
| | | 94 | 265 | 6 | 10 |
| | | 4 | 21 | | |
| | | 1 | 9 | | |
| | | 39 | 121 | 5 | 7 |
| | | 1 | 1 | | |
| | | 1 | 4 | | 4 |
| | | | 1 | | |

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Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Vaginal lesion | 1 | 1 |
| Varicella | | 2 |
| Varicella zoster virus infection | | 1 |
| Varicose vein | | 1 |
| Vascular pain | | 1 |
| Vasculitic rash | 1 | 1 |
| Vasodilatation | | 1 |
| Vein discolouration | 2 | 3 |
| Vein disorder | 1 | 1 |
| Ventricular extrasystoles | 5 | 10 |
| Ventricular tachycardia | | 1 |
| Vertigo | 35 | 89 |
| Vertigo positional | | 2 |
| Viral infection | 2 | 3 |
| Viral rash | | 1 |
| Viral upper respiratory tract infection | 1 | 1 |
| Vision blurred | 21 | 69 |
| Visual field defect | 3 | 4 |
| Visual impairment | 22 | 39 |
| Vitamin B12 decreased | 1 | 1 |
| Vlth nerve paralysis | 1 | 1 |
| Vitreous floaters | 2 | 2 |
| Vocal cord disorder | 3 | 3 |
| Vocal cord paralysis | | 1 |
| Volvulus | 1 | 1 |
| Vomiting | 122 | 357 |
| Vomiting projectile | 2 | 4 |
| Vulval disorder | 1 | 1 |
| Vulvovaginal mycotic infection | | 1 |
| Vulvovaginal pruritus | | 1 |
| Vulvovaginal rash | | 1 |
| Vulvovaginal swelling | | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 2 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | 2 | 3 | | |
| | | 1 | 1 | | |
| | | 2 | 5 | 3 | 5 |
| | | | | | 1 |
| | | 30 | 81 | 5 | 8 |
| | | | 1 | | 1 |
| | | | 1 | 2 | 2 |
| | | | 1 | | |
| | | 1 | 1 | | |
| | | 19 | 57 | 2 | 12 |
| | | 3 | 4 | | |
| | | 19 | 34 | 3 | 5 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 2 | 2 | | |
| | | | | 3 | 3 |
| | | | 1 | | |
| | | | | 1 | 1 |
| | | 109 | 330 | 13 | 27 |
| | | 2 | 4 | | |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | | | 1 |
| | | | | | 1 |
| | | | | | 1 |

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Gender

FEMALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Weight decreased | 6 | 19 |
| Weight fluctuation | 2 | 2 |
| Weight increased | | 4 |
| Wheezing | 9 | 33 |
| White blood cell count decreased | 4 | 5 |
| White blood cell count increased | 4 | 8 |
| White matter lesion | 1 | 1 |
| Winged scapula | 1 | 1 |
| Withdrawal bleed | 1 | 1 |
| Wound | | 1 |
| Wound closure | 1 | 1 |
| Wound haemorrhage | 1 | 2 |
| Wrong product administered | 1 | 5 |
| Wrong schedule | | 1 |
| Wrong technique in device usage process | 2 | 2 |
| Wrong technique in product usage process | 8 | 20 |
| Xanthopsia | 1 | 1 |
| | 12,571 | 37,721 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|----|---------|-------|------|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | 6 | 15 | | 4 | | |
| | | 2 | 2 | | | | |
| | | | 4 | | | | |
| | | 6 | 18 | 3 | 15 | | |
| | | 3 | 4 | 1 | 1 | | |
| | | 3 | 4 | 1 | 4 | | |
| | | | | 1 | 1 | | |
| | | 1 | 1 | | | | |
| | | 1 | 1 | | | | |
| | | | 1 | | | | |
| | | 1 | 1 | | | | |
| | | 1 | 1 | | 1 | | |
| | | 1 | 5 | | | | |
| | | | 1 | | | | |
| | | 2 | 2 | | | | |
| | | 7 | 18 | 1 | 2 | | |
| | | 1 | 1 | | | | |
| | | 4 | 4 | 10380 | 32064 | 2191 | 5657 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 10 | 20 | 10 | 17 | | 3 |
| Abdominal distension | 1 | 5 | 1 | 4 | | 1 |
| Abdominal pain | 6 | 19 | 4 | 15 | 2 | 4 |
| Abdominal pain lower | 1 | 2 | 1 | 2 | | |
| Abdominal pain upper | 14 | 29 | 12 | 26 | 2 | 3 |
| Abdominal rigidity | 1 | 1 | 1 | 1 | | |
| Abnormal dreams | 5 | 6 | 4 | 5 | 1 | 1 |
| Abnormal faeces | 1 | 2 | 1 | 2 | | |
| Abnormal sensation in eye | | 1 | | 1 | | |
| Accidental exposure to product | | 3 | | 3 | | |
| Accidental overdose | 1 | 4 | | 3 | 1 | 1 |
| Accidental underdose | | 2 | | 2 | | |
| Acne | 1 | 2 | 1 | 2 | | |
| Acoustic neuritis | | 1 | | | | 1 |
| Acute kidney injury | | 1 | | | | 1 |
| Acute myocardial infarction | | 2 | | | | 2 |
| Acute respiratory distress syndrome | | 1 | | | | 1 |
| Administration site warmth | 1 | 1 | 1 | 1 | | |
| Adrenocortical insufficiency acute | 1 | 1 | | | 1 | 1 |
| Adverse event | 1 | 1 | 1 | 1 | | |
| Ageusia | 8 | 22 | 8 | 20 | | 2 |
| Agitation | | 3 | | 3 | | |
| Allergy to vaccine | 4 | 10 | 4 | 8 | | 2 |
| Alopecia | 1 | 2 | 1 | 2 | | |
| Amnesia | 1 | 2 | | 1 | 1 | 1 |
| Anaemia | 2 | 2 | | | 2 | 2 |
| Anaphylactic reaction | 3 | 6 | | | 3 | 6 |
| Anaphylactic shock | | 2 | | | | 2 |
| Aneurysm ruptured | 1 | 1 | | | 1 | 1 |
| Anger | 1 | 2 | | 1 | 1 | 1 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Angioedema | 3 | 4 | | | 3 | 4 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------|------------------------------------|--------------------------------------|
| Anosmia | 8 | 28 |
| Anterior chamber cell | 1 | 1 |
| Antibody test abnormal | 1 | 1 |
| Antibody test negative | 1 | 1 |
| Anxiety | 7 | 18 |
| Aphasia | 1 | 3 |
| Aphonia | 1 | 2 |
| Aphthous ulcer | 1 | 3 |
| Appendicitis | 1 | 3 |
| Application site pruritus | 1 | 1 |
| Areflexia | 1 | 1 |
| Arrhythmia | 4 | 6 |
| Arteriospasm coronary | | 1 |
| Arthralgia | 72 | 197 |
| Arthritis | 4 | 8 |
| Arthropathy | 2 | 6 |
| Arthropod bite | | 1 |
| Asthenia | 44 | 109 |
| Asthenopia | | 1 |
| Asthma | 5 | 6 |
| Asymptomatic COVID-19 | 1 | 2 |
| Ataxia | | 1 |
| Atrial fibrillation | 5 | 8 |
| Autoimmune disorder | | 1 |
| Autoimmune haemolytic anaemia | 1 | 1 |
| Autoscopy | 1 | 1 |
| Axillary mass | 1 | 3 |
| Axillary pain | 6 | 17 |
| Back disorder | 2 | 2 |
| Back injury | 1 | 1 |
| Back pain | 17 | 57 |
| Balance disorder | 5 | 15 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 8 | 25 | | 3 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 14 | 3 | 4 |
| | 2 | 1 | 1 |
| 1 | 2 | | |
| 1 | 3 | | |
| | | 1 | 3 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 4 | 6 |
| | | | 1 |
| 69 | 190 | 3 | 7 |
| 4 | 7 | | 1 |
| 2 | 6 | | |
| | 1 | | |
| 38 | 96 | 6 | 13 |
| | 1 | | |
| 4 | 4 | 1 | 2 |
| | | 1 | 2 |
| | | | 1 |
| | | 5 | 8 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 3 | | |
| 6 | 17 | | |
| 2 | 2 | | |
| | | 1 | 1 |
| 15 | 52 | 2 | 5 |
| 4 | 13 | 1 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|------------------------------------|------------------------------------|--------------------------------------|
| Basal ganglia haemorrhage | | 2 |
| Bedridden | | 2 |
| Behaviour disorder | 1 | 1 |
| Belligerence | 1 | 1 |
| Bilirubin urine present | | 1 |
| Bladder pain | 1 | 1 |
| Blepharochalasis | | 1 |
| Blepharospasm | | 1 |
| Blindness | 2 | 4 |
| Blindness transient | 2 | 2 |
| Blister | 4 | 10 |
| Blood bilirubin increased | 1 | 1 |
| Blood chloride decreased | 1 | 1 |
| Blood cholesterol increased | 1 | 1 |
| Blood count abnormal | 1 | 1 |
| Blood creatinine increased | | 1 |
| Blood glucose abnormal | 1 | 1 |
| Blood glucose decreased | 2 | 4 |
| Blood glucose fluctuation | | 1 |
| Blood glucose increased | 8 | 14 |
| Blood iron decreased | 2 | 2 |
| Blood ketone body increased | 1 | 1 |
| Blood pressure abnormal | 1 | 2 |
| Blood pressure decreased | 1 | 2 |
| Blood pressure diastolic increased | | 2 |
| Blood pressure fluctuation | 3 | 3 |
| Blood pressure increased | 11 | 24 |
| Blood pressure systolic increased | 1 | 1 |
| Blood sodium decreased | 1 | 1 |
| Blood urine present | 4 | 6 |
| Body height decreased | 2 | 4 |
| Body temperature abnormal | 1 | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 2 |
| | 2 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 2 | 4 |
| | | 2 | 2 |
| 4 | 10 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 2 | 2 | 2 |
| | 1 | | |
| 6 | 10 | 2 | 4 |
| | | 2 | 2 |
| | | 1 | 1 |
| | 1 | 1 | 1 |
| 1 | 1 | | 1 |
| | 2 | | |
| 3 | 3 | | |
| 5 | 14 | 6 | 10 |
| | | 1 | 1 |
| | | 1 | 1 |
| 2 | 4 | 2 | 2 |
| 1 | 3 | 1 | 1 |
| 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Body temperature decreased | 2 | 4 | 2 | 4 | | |
| Body temperature increased | 12 | 20 | 12 | 20 | | |
| Bone pain | 3 | 7 | 3 | 7 | | |
| Bone swelling | | 1 | | 1 | | |
| Bradycardia | | 1 | | | | 1 |
| Brain oedema | | 1 | | | | 1 |
| Brain stem syndrome | 1 | 1 | | | 1 | 1 |
| Breath odour | | 2 | | 2 | | |
| Bronchitis | 1 | 4 | 1 | 4 | | |
| Bundle branch block left | 1 | 1 | 1 | 1 | | |
| Burning sensation | 4 | 15 | 2 | 11 | 2 | 4 |
| Butterfly rash | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 2 | 8 | | | 2 | 8 |
| Cardiac disorder | 2 | 4 | | 2 | 2 | 2 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardiac failure chronic | 1 | 1 | | | 1 | 1 |
| Cardiac failure congestive | 2 | 3 | | | 2 | 3 |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Cardiomyopathy | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | | 1 | | | | 1 |
| Cellulitis | 2 | 2 | | | 2 | 2 |
| Cerebral haemorrhage | 1 | 2 | | | 1 | 2 |
| Cerebrovascular accident | 9 | 18 | | | 9 | 18 |
| Chest discomfort | 12 | 28 | 6 | 19 | 6 | 9 |
| Chest injury | 1 | 1 | | | 1 | 1 |
| Chest pain | 18 | 29 | 9 | 18 | 9 | 11 |
| Chills | 165 | 512 | 160 | 494 | 5 | 18 |
| Choking | | 1 | | | | 1 |
| Chromaturia | 2 | 3 | 2 | 3 | | |
| Chronic myeloid leukaemia recurrent | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 2 | 4 | | |
| 12 | 20 | | |
| 3 | 7 | | |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| | | 1 | 1 |
| | 2 | | |
| 1 | 4 | | |
| 1 | 1 | | |
| 2 | 11 | 2 | 4 |
| 1 | 1 | | |
| | | 2 | 8 |
| | 2 | 2 | 2 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | 2 | 2 |
| | | 1 | 2 |
| | | 9 | 18 |
| 6 | 19 | 6 | 9 |
| | | 1 | 1 |
| 9 | 18 | 9 | 11 |
| 160 | 494 | 5 | 18 |
| | | | 1 |
| 2 | 3 | | |
| | | 1 | 1 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circumstance or information capable of leading to medication error | 8 | 25 | 8 | 25 | | |
| Claustrophobia | | 1 | | 1 | | |
| Clumsiness | 1 | 2 | 1 | 2 | | |
| Cluster headache | 1 | 1 | 1 | 1 | | |
| Coagulopathy | | 1 | | | | 1 |
| Cognitive disorder | 3 | 4 | | | 3 | 4 |
| Cold sweat | 6 | 16 | 5 | 15 | 1 | 1 |
| Coma | 2 | 3 | | | 2 | 3 |
| Computerised tomogram normal | 1 | 1 | 1 | 1 | | |
| Condition aggravated | 7 | 21 | 5 | 17 | 2 | 4 |
| Confusional state | 8 | 12 | 3 | 6 | 5 | 6 |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Conjunctival irritation | | 1 | | 1 | | |
| Conjunctival oedema | | 1 | | 1 | | |
| Constipation | 5 | 6 | 5 | 6 | | |
| Contraindicated product administered | | 1 | | 1 | | |
| Contraindication to vaccination | | 1 | | 1 | | |
| Contusion | 8 | 13 | 7 | 12 | 1 | 1 |
| Coordination abnormal | | 2 | | 1 | | 1 |
| Corneal disorder | 1 | 1 | | | 1 | 1 |
| Corneal graft rejection | 1 | 1 | | | 1 | 1 |
| Corneal infiltrates | 1 | 1 | | | 1 | 1 |
| Cough | 29 | 86 | 24 | 77 | 5 | 9 |
| COVID-19 | 85 | 202 | 4 | 10 | 81 | 192 |
| COVID-19 pneumonia | 3 | 4 | | | 3 | 4 |
| C-reactive protein increased | | 2 | | 2 | | |
| Crying | 2 | 2 | 1 | 1 | 1 | 1 |
| CSF protein increased | 1 | 1 | | | 1 | 1 |
| Cystitis | 1 | 2 | 1 | 1 | | 1 |
| Deafness | 6 | 10 | | | 6 | 10 |
| Deafness neurosensory | | 4 | | | | 4 |

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MALE

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|----------------------------|------------------------------------|--------------------------------------|
| Deafness unilateral | 1 | 1 |
| Death | 10 | 24 |
| Decreased appetite | 14 | 33 |
| Deep vein thrombosis | 3 | 4 |
| Defaecation urgency | 1 | 1 |
| Dehydration | 4 | 10 |
| Delirium | 3 | 6 |
| Dementia | 2 | 2 |
| Dental restoration failure | | 1 |
| Depression | | 2 |
| Dermatitis | 1 | 3 |
| Dermatitis allergic | | 1 |
| Diabetes mellitus | 2 | 4 |
| Diabetic wound | 1 | 1 |
| Diarrhoea | 46 | 98 |
| Diarrhoea haemorrhagic | 3 | 3 |
| Diplopia | 1 | 2 |
| Discomfort | 10 | 24 |
| Disease recurrence | 9 | 13 |
| Disorientation | 4 | 10 |
| Dissociation | 1 | 1 |
| Disturbance in attention | 5 | 9 |
| Diverticulitis | 2 | 2 |
| Dizziness | 86 | 188 |
| Dizziness exertional | | 1 |
| Dizziness postural | 3 | 7 |
| Drooling | 1 | 1 |
| Drug hypersensitivity | 1 | 4 |
| Drug ineffective | 87 | 257 |
| Drug interaction | 1 | 4 |
| Dry eye | 1 | 1 |
| Dry mouth | 3 | 15 |

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | | 10 | 24 |
| 14 | 32 | | 1 |
| | | 3 | 4 |
| 1 | 1 | | |
| 3 | 9 | 1 | 1 |
| | | 3 | 6 |
| | | 2 | 2 |
| | 1 | | |
| | 2 | | |
| 1 | 3 | | |
| | | | 1 |
| | | 2 | 4 |
| | | 1 | 1 |
| 41 | 92 | 5 | 6 |
| | | 3 | 3 |
| | 1 | 1 | 1 |
| 9 | 23 | 1 | 1 |
| 2 | 5 | 7 | 8 |
| 3 | 7 | 1 | 3 |
| 1 | 1 | | |
| 3 | 6 | 2 | 3 |
| | | 2 | 2 |
| 77 | 171 | 9 | 17 |
| | 1 | | |
| 3 | 6 | | 1 |
| | | 1 | 1 |
| 1 | 4 | | |
| 2 | 7 | 85 | 250 |
| | 3 | 1 | 1 |
| | | 1 | 1 |
| 3 | 14 | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--------------------------------|------------------------------------|--------------------------------------|
| Dry skin | 1 | 1 |
| Dry throat | 1 | 6 |
| Dysaesthesia | 1 | 1 |
| Dysarthria | 1 | 3 |
| Dysentery | 1 | 1 |
| Dysgeusia | 5 | 16 |
| Dyslexia | | 1 |
| Dyspepsia | 1 | 10 |
| Dysphagia | | 7 |
| Dysphemia | | 1 |
| Dysphonia | 1 | 6 |
| Dyspnoea | 26 | 75 |
| Dyspnoea exertional | 4 | 5 |
| Dysstasia | 5 | 8 |
| Dysuria | 2 | 2 |
| Ear congestion | 1 | 1 |
| Ear discomfort | 4 | 6 |
| Ear disorder | 1 | 3 |
| Ear pain | 1 | 2 |
| Ear pruritus | | 1 |
| Eating disorder | | 1 |
| Ecchymosis | | 1 |
| Eczema | 1 | 1 |
| Ejection fraction abnormal | | 1 |
| Ejection fraction decreased | 1 | 1 |
| Electrocardiogram abnormal | | 1 |
| Electrocardiogram QT prolonged | 1 | 1 |
| Encephalitis | 3 | 3 |
| Energy increased | 1 | 1 |
| Eosinophil count decreased | 1 | 1 |
| Eosinophil count increased | 1 | 1 |
| Epistaxis | 6 | 11 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 1 | 5 | | 1 |
| 1 | 1 | | |
| 1 | 2 | | 1 |
| | | 1 | 1 |
| 5 | 15 | | 1 |
| | 1 | | |
| | 9 | 1 | 1 |
| | 6 | | 1 |
| | 1 | | |
| | 4 | 1 | 2 |
| 14 | 47 | 12 | 28 |
| 4 | 5 | | |
| 4 | 6 | 1 | 2 |
| 2 | 2 | | |
| 1 | 1 | | |
| 4 | 5 | | 1 |
| 1 | 3 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 4 | 9 | 2 | 2 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---------------------------|------------------------------------|--------------------------------------|
| Erectile dysfunction | 4 | 4 |
| Eructation | 1 | 2 |
| Erythema | 14 | 30 |
| Erythema of eyelid | | 1 |
| Exposure to SARS-CoV-2 | 3 | 12 |
| Exposure via breast milk | 4 | 12 |
| Exposure via skin contact | | 2 |
| Extrasystoles | 2 | 2 |
| Eye contusion | | 1 |
| Eye disorder | 1 | 6 |
| Eye haemorrhage | 1 | 3 |
| Eye inflammation | | 1 |
| Eye irritation | | 3 |
| Eyelid oedema | | 1 |
| Eyelid pain | | 1 |
| Eye movement disorder | 2 | 2 |
| Eye oedema | 1 | 2 |
| Eye pain | 5 | 13 |
| Eye pruritus | | 2 |
| Eye swelling | 2 | 13 |
| Face injury | | 1 |
| Face oedema | 1 | 1 |
| Facet joint syndrome | | 1 |
| Facial pain | 4 | 7 |
| Facial paralysis | 23 | 39 |
| Facial paresis | 1 | 1 |
| Faeces soft | 1 | 2 |
| Fall | 16 | 21 |
| Fasciitis | 2 | 2 |
| Fatigue | 146 | 452 |
| Fear | | 1 |
| Febrile convulsion | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 4 | 4 |
| 1 | 2 | | |
| 13 | 28 | 1 | 2 |
| | 1 | | |
| 2 | 9 | 1 | 3 |
| 4 | 12 | | |
| | 2 | | |
| 2 | 2 | | |
| | 1 | | |
| 1 | 4 | | 2 |
| | | 1 | 3 |
| | 1 | | |
| | 3 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | 1 | 1 |
| 1 | 2 | | |
| 4 | 12 | 1 | 1 |
| | 2 | | |
| 2 | 12 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 3 | 5 | 1 | 2 |
| 1 | 1 | 22 | 38 |
| | | 1 | 1 |
| 1 | 2 | | |
| 7 | 10 | 9 | 11 |
| | | 2 | 2 |
| 141 | 439 | 5 | 13 |
| | 1 | | |
| | | 1 | 1 |

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Gender

MALE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|------------------------------------|--|--|
| Feeding disorder | 3 | 6 |
| Feeling abnormal | 35 | 91 |
| Feeling cold | 5 | 23 |
| Feeling drunk | 3 | 7 |
| Feeling hot | 16 | 37 |
| Feeling jittery | | 3 |
| Feeling of body temperature change | 1 | 1 |
| Fibrin D dimer increased | | 1 |
| Fibromyalgia | 1 | 2 |
| Fine motor skill dysfunction | | 1 |
| Flank pain | | 1 |
| Flatulence | 1 | 2 |
| Fluid intake reduced | | 1 |
| Fluid retention | 1 | 1 |
| Flushing | 4 | 18 |
| Formication | | 1 |
| Frequent bowel movements | 1 | 1 |
| Fungal infection | 1 | 1 |
| Gait disturbance | 15 | 28 |
| Gait inability | 5 | 9 |
| Gastric disorder | 2 | 4 |
| Gastritis | | 2 |
| Gastrointestinal disorder | 1 | 3 |
| Gastrointestinal hypomotility | 1 | 1 |
| Gastrointestinal inflammation | 1 | 1 |
| Gastrointestinal pain | 1 | 2 |
| Gastrooesophageal reflux disease | 1 | 2 |
| Generalised tonic-clonic seizure | 2 | 2 |
| Gingival bleeding | 1 | 1 |
| Gingival discolouration | | 1 |
| Gingival erythema | 1 | 1 |
| Gingival pain | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 6 | | |
| 32 | 86 | 3 | 5 |
| 5 | 23 | | |
| 2 | 5 | 1 | 2 |
| 16 | 36 | | 1 |
| | 3 | | |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| 3 | 15 | 1 | 3 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 11 | 23 | 4 | 5 |
| 4 | 7 | 1 | 2 |
| 2 | 4 | | |
| | 2 | | |
| 1 | 3 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 2 | | |
| | | 2 | 2 |
| 1 | 1 | | |
| | | | 1 |
| 1 | 1 | | |
| | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Gingival swelling | 2 | 3 | 2 | 3 | | |
| Glaucoma | | 1 | | | | 1 |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Glycosylated haemoglobin increased | 1 | 2 | | | 1 | 2 |
| Good syndrome | 1 | 1 | | | 1 | 1 |
| Gout | 2 | 6 | 1 | 5 | 1 | 1 |
| Groin pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Guillain-Barre syndrome | 4 | 5 | | | 4 | 5 |
| Haematochezia | 6 | 6 | | | 6 | 6 |
| Haematocrit decreased | 1 | 1 | | | 1 | 1 |
| Haematuria | 1 | 2 | 1 | 1 | | 1 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Haemolytic anaemia | 1 | 2 | | | 1 | 2 |
| Haemoptysis | | 3 | | 3 | | |
| Haemorrhage | 5 | 7 | | | 5 | 7 |
| Haemorrhage intracranial | | 1 | | | | 1 |
| Haemorrhage urinary tract | 1 | 1 | | | 1 | 1 |
| Haemorrhagic stroke | 1 | 2 | | | 1 | 2 |
| Haemorrhoids | 1 | 1 | 1 | 1 | | |
| Hallucination | 5 | 6 | | | 5 | 6 |
| Hangover | | 2 | | 2 | | |
| Headache | 174 | 536 | 159 | 510 | 15 | 26 |
| Head discomfort | 4 | 8 | 4 | 8 | | |
| Head injury | 1 | 3 | 1 | 1 | | 2 |
| Head titubation | 1 | 2 | 1 | 2 | | |
| Heart rate abnormal | | 1 | | 1 | | |
| Heart rate decreased | 2 | 5 | 1 | 3 | 1 | 2 |
| Heart rate increased | 15 | 45 | 11 | 39 | 4 | 6 |
| Heart rate irregular | 3 | 5 | 3 | 5 | | |
| Hemiparesis | | 2 | | | | 2 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hepatic enzyme increased | 1 | 1 | 1 | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hepatitis | 2 | 2 | | | 2 | 2 |
| Hepatitis acute | 1 | 1 | | | 1 | 1 |
| Hepatomegaly | 1 | 1 | | | 1 | 1 |
| Hereditary haemorrhagic telangiectasia | 1 | 1 | 1 | 1 | | |
| Herpes simplex | 1 | 3 | | 2 | 1 | 1 |
| Herpes zoster | 7 | 16 | 5 | 14 | 2 | 2 |
| Hiccups | 2 | 4 | 2 | 4 | | |
| Hip fracture | 2 | 2 | | | 2 | 2 |
| Hordeolum | | 1 | | 1 | | |
| Hot flush | 2 | 6 | 2 | 6 | | |
| Hunger | | 1 | | 1 | | |
| Hyperacusis | | 1 | | | | 1 |
| Hyperaesthesia | 1 | 4 | 1 | 4 | | |
| Hyperaesthesia teeth | 2 | 2 | 2 | 2 | | |
| Hyperglycaemia | 1 | 2 | 1 | 1 | | 1 |
| Hyperhidrosis | 22 | 65 | 22 | 61 | | 4 |
| Hypersensitivity | 9 | 16 | 5 | 10 | 4 | 6 |
| Hypersomnia | 4 | 9 | 3 | 8 | 1 | 1 |
| Hypertension | 16 | 29 | 13 | 22 | 3 | 7 |
| Hypertensive crisis | | 1 | | | | 1 |
| Hyperthermia | 1 | 2 | 1 | 2 | | |
| Hyperventilation | 2 | 4 | 1 | 2 | 1 | 2 |
| Hypervigilance | | 1 | | 1 | | |
| Hypoacusis | 4 | 8 | 4 | 8 | | |
| Hypoaesthesia | 17 | 60 | 11 | 49 | 6 | 11 |
| Hypoaesthesia eye | | 1 | | 1 | | |
| Hypoaesthesia oral | 3 | 11 | 3 | 11 | | |
| Hypoaesthesia teeth | 1 | 1 | 1 | 1 | | |
| Hypogeusia | | 3 | | 3 | | |
| Hypoglycaemia | 2 | 3 | 2 | 3 | | |
| Hypophagia | | 2 | | 2 | | |
| Hypopnoea | 1 | 2 | | 1 | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Hyposmia | | 1 |
| Hypotension | 4 | 8 |
| Hypothermia | 1 | 1 |
| Hypotonia | 1 | 1 |
| Hypoxia | | 2 |
| Illrd nerve paralysis | 1 | 1 |
| Illness | 11 | 30 |
| Immune system disorder | 1 | 2 |
| Immune thrombocytopenia | 2 | 4 |
| Immunodeficiency | 1 | 1 |
| Impaired driving ability | | 1 |
| Impaired work ability | | 3 |
| Inappropriate schedule of product administration | 38 | 112 |
| Incision site haemorrhage | | 1 |
| Incoherent | 1 | 1 |
| Incomplete course of vaccination | | 3 |
| Incontinence | | 1 |
| Incorrect dosage administered | 1 | 1 |
| Incorrect dose administered | 1 | 2 |
| Incorrect route of product administration | 1 | 16 |
| Increased appetite | | 1 |
| Increased bronchial secretion | | 1 |
| Infantile vomiting | | 1 |
| Infant irritability | | 2 |
| Inflammation | | 3 |
| Influenza | 5 | 10 |
| Influenza like illness | 17 | 68 |
| Inhibitory drug interaction | | 1 |
| Initial insomnia | | 2 |
| Injection site erythema | 1 | 1 |
| Injection site extravasation | | 2 |
| Injection site hypoaesthesia | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 2 | 3 | 2 | 5 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 2 |
| | | 1 | 1 |
| 11 | 30 | | |
| 1 | 1 | | 1 |
| | | 2 | 4 |
| | | 1 | 1 |
| | 1 | | |
| | 3 | | |
| 38 | 112 | | |
| | | | 1 |
| 1 | 1 | | |
| | 3 | | |
| | | | 1 |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 16 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 2 | | 1 |
| 4 | 8 | 1 | 2 |
| 16 | 64 | 1 | 4 |
| | 1 | | |
| | 2 | | |
| 1 | 1 | | |
| | 2 | | |
| | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Injection site pain | 1 | 10 |
| Injury | | 1 |
| Insomnia | 11 | 33 |
| Inspiratory capacity decreased | 1 | 1 |
| International normalised ratio decreased | 1 | 2 |
| International normalised ratio increased | | 2 |
| Intervertebral disc protrusion | | 1 |
| Intrusive thoughts | | 1 |
| Irregular breathing | 1 | 1 |
| Irritability | | 2 |
| Irritable bowel syndrome | 2 | 3 |
| Ischaemic stroke | 2 | 2 |
| Jaundice | 1 | 2 |
| Joint effusion | 1 | 1 |
| Joint injury | 1 | 1 |
| Joint range of motion decreased | 4 | 6 |
| Joint stiffness | | 1 |
| Joint swelling | 6 | 11 |
| Keratic precipitates | 1 | 1 |
| Kidney infection | 2 | 2 |
| Laboratory test normal | 1 | 1 |
| Lacrimation increased | 1 | 2 |
| Lacunar infarction | 1 | 1 |
| Laryngeal oedema | 1 | 1 |
| Lethargy | 8 | 24 |
| Leukaemia | 1 | 1 |
| Leukocytosis | | 1 |
| Ligament sprain | 1 | 1 |
| Limb discomfort | 7 | 18 |
| Limb injury | 2 | 3 |
| Limb mass | 1 | 1 |
| Lip disorder | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 10 | | |
| | 1 | | |
| 11 | 32 | | 1 |
| 1 | 1 | | |
| | 1 | 1 | 1 |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| 1 | 2 | 1 | 1 |
| | | 2 | 2 |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 4 | 6 | | |
| | 1 | | |
| 5 | 9 | 1 | 2 |
| | | 1 | 1 |
| | | 2 | 2 |
| 1 | 1 | | |
| 1 | 1 | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 8 | 22 | | 2 |
| | | 1 | 1 |
| | 1 | | |
| 1 | 1 | | |
| 7 | 17 | | 1 |
| 2 | 3 | | |
| 1 | 1 | | |
| | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Lip pruritus | 1 | 1 |
| Lip swelling | 5 | 15 |
| Liquid product physical issue | 2 | 2 |
| Liver function test abnormal | | 1 |
| Liver function test increased | 1 | 1 |
| Liver injury | | 1 |
| Loss of consciousness | 20 | 27 |
| Loss of personal independence in daily activities | 4 | 6 |
| Lumbar puncture abnormal | 1 | 1 |
| Lung infiltration | 1 | 3 |
| Lymphadenitis | 1 | 2 |
| Lymphadenopathy | 24 | 82 |
| Lymphangitis | 1 | 1 |
| Lymph node pain | 2 | 13 |
| Lymphoedema | | 2 |
| Macule | 1 | 1 |
| Madarosis | 1 | 1 |
| Malaise | 57 | 179 |
| Malnutrition | | 1 |
| Mass | 1 | 1 |
| Memory impairment | | 2 |
| Meningitis | | 1 |
| Meningitis aseptic | 1 | 1 |
| Meningitis noninfective | 1 | 1 |
| Meningitis viral | 2 | 3 |
| Mental fatigue | 1 | 2 |
| Mental impairment | 3 | 4 |
| Middle insomnia | 1 | 4 |
| Migraine | 8 | 17 |
| Migraine with aura | 1 | 1 |
| Mobility decreased | 5 | 7 |
| Monocyte count increased | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 5 | 14 | | 1 |
| 2 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 20 | 27 |
| 2 | 4 | 2 | 2 |
| | | 1 | 1 |
| | 1 | 1 | 2 |
| 1 | 2 | | |
| 23 | 77 | 1 | 5 |
| | | 1 | 1 |
| 2 | 13 | | |
| | 2 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| 53 | 168 | 4 | 11 |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | |
| | | | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 2 | 3 |
| 1 | 2 | | |
| | | 3 | 4 |
| 1 | 4 | | |
| 7 | 16 | 1 | 1 |
| 1 | 1 | | |
| 5 | 6 | | 1 |
| | 1 | | |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|-------------------------------------|------------------------------------|--------------------------------------|
| Monoplegia | 1 | 1 |
| Motion sickness | | 2 |
| Motor dysfunction | | 1 |
| Mouth haemorrhage | 1 | 1 |
| Mouth swelling | 1 | 1 |
| Movement disorder | 2 | 5 |
| Mucosal disorder | | 1 |
| Multiple organ dysfunction syndrome | | 1 |
| Muscle discomfort | 1 | 2 |
| Muscle fatigue | | 2 |
| Muscle spasms | 6 | 16 |
| Muscle strain | | 1 |
| Muscle swelling | | 1 |
| Muscle tightness | 3 | 5 |
| Muscle twitching | 2 | 5 |
| Muscular weakness | 14 | 27 |
| Musculoskeletal chest pain | 2 | 4 |
| Musculoskeletal discomfort | | 3 |
| Musculoskeletal disorder | 1 | 3 |
| Musculoskeletal pain | 2 | 5 |
| Musculoskeletal stiffness | 14 | 25 |
| Myalgia | 69 | 261 |
| Myocardial infarction | 5 | 9 |
| Myoclonus | 1 | 1 |
| Myositis | 1 | 2 |
| Nasal congestion | 10 | 38 |
| Nasal discomfort | 2 | 4 |
| Nasal dryness | | 3 |
| Nasal pruritus | 1 | 1 |
| Nasopharyngitis | 10 | 21 |
| Nausea | 81 | 232 |
| Near death experience | 1 | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 2 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 3 | 2 | 2 |
| | 1 | | |
| | | | 1 |
| 1 | 2 | | |
| | 2 | | |
| 3 | 11 | 3 | 5 |
| | 1 | | |
| | 1 | | |
| 3 | 5 | | |
| 2 | 5 | | |
| 7 | 17 | 7 | 10 |
| 1 | 3 | 1 | 1 |
| | 3 | | |
| | 1 | 1 | 2 |
| 2 | 4 | | 1 |
| 14 | 24 | | 1 |
| 69 | 251 | | 10 |
| | | 5 | 9 |
| | | 1 | 1 |
| 1 | 1 | | 1 |
| 10 | 38 | | |
| 2 | 4 | | |
| | 2 | | 1 |
| 1 | 1 | | |
| 10 | 21 | | |
| 75 | 219 | 6 | 13 |
| | | 1 | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neck mass | | 1 | | 1 | | |
| Neck pain | 10 | 32 | 7 | 26 | 3 | 6 |
| Needle issue | 1 | 4 | 1 | 4 | | |
| Nerve compression | 1 | 1 | 1 | 1 | | |
| Nervousness | 1 | 5 | 1 | 5 | | |
| Nervous system disorder | | 1 | | | | 1 |
| Neuralgia | 3 | 5 | 2 | 4 | 1 | 1 |
| Neurological examination normal | 1 | 1 | 1 | 1 | | |
| Neurological symptom | | 1 | | | | 1 |
| Neuropathy peripheral | 1 | 3 | | | 1 | 3 |
| Nightmare | 1 | 3 | 1 | 3 | | |
| Night sweats | 7 | 17 | 7 | 14 | | 3 |
| Nipple pain | | 1 | | 1 | | |
| Nipple swelling | | 1 | | 1 | | |
| No adverse event | 4 | 4 | 4 | 4 | | |
| Nocturia | | 1 | | 1 | | |
| Nodal rhythm | | 1 | | 1 | | |
| Nodule | | 1 | | 1 | | |
| Noninfective encephalitis | 1 | 2 | | | 1 | 2 |
| Noninfective gingivitis | 1 | 2 | 1 | 2 | | |
| Nystagmus | 1 | 1 | 1 | 1 | | |
| Occipital neuralgia | | 1 | | 1 | | |
| Occupational exposure to SARS-CoV-2 | | 1 | | | | 1 |
| Ocular discomfort | 2 | 3 | 2 | 3 | | |
| Ocular hyperaemia | | 3 | | 3 | | |
| Odynophagia | 1 | 2 | 1 | 1 | | 1 |
| Oedema | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | 1 | 1 | 1 | 1 | | |
| Off label use | 22 | 54 | 22 | 54 | | |
| Oral discomfort | 1 | 2 | 1 | 2 | | |
| Oral disorder | 2 | 3 | 2 | 3 | | |
| Oral herpes | 2 | 4 | 2 | 4 | | |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 7 | 26 | 3 | 6 |
| 1 | 4 | | |
| 1 | 1 | | |
| 1 | 5 | | |
| | | | 1 |
| 2 | 4 | 1 | 1 |
| 1 | 1 | | |
| | | | 1 |
| | | 1 | 3 |
| 1 | 3 | | |
| 7 | 14 | | 3 |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 1 | 2 |
| 1 | 2 | | |
| 1 | 1 | | |
| | 1 | | |
| | | | 1 |
| 2 | 3 | | |
| | 3 | | |
| 1 | 1 | | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 22 | 54 | | |
| 1 | 2 | | |
| 2 | 3 | | |
| 2 | 4 | | |

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Gender

MALE

| Preferred Term | Interval Total # | Cumulative Total # |
|--------------------------------|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Oral mucosal blistering | 1 | 1 |
| Oral pain | 2 | 4 |
| Orchitis | | 1 |
| Organising pneumonia | | 1 |
| Oropharyngeal discomfort | 1 | 2 |
| Oropharyngeal pain | 11 | 40 |
| Oropharyngeal spasm | 1 | 1 |
| Oropharyngeal swelling | | 1 |
| Osteoarthritis | 1 | 1 |
| Overdose | 5 | 9 |
| Oxygen saturation decreased | 11 | 13 |
| Pain | 123 | 359 |
| Painful respiration | 1 | 1 |
| Pain in extremity | 120 | 284 |
| Pain in jaw | 1 | 6 |
| Pain of skin | | 2 |
| Pallor | 5 | 8 |
| Palpable purpura | 1 | 1 |
| Palpitations | 15 | 33 |
| Pancreatitis | 1 | 1 |
| Pancytopenia | | 1 |
| Panic attack | 1 | 3 |
| Paraesthesia | 26 | 63 |
| Paraesthesia oral | 4 | 12 |
| Paraganglion neoplasm | 1 | 1 |
| Paralysis | 2 | 3 |
| Paranasal sinus discomfort | | 1 |
| Paranasal sinus hypersecretion | 1 | 2 |
| Parkinson's disease | 1 | 1 |
| Parosmia | | 3 |
| Pemphigoid | 1 | 1 |
| Penile haemorrhage | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 1 | | |
| 2 | 3 | | 1 |
| | 1 | | |
| | | | 1 |
| | 1 | 1 | 1 |
| 11 | 39 | | 1 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 1 | | |
| 5 | 9 | | |
| 2 | 4 | 9 | 9 |
| 119 | 346 | 4 | 13 |
| 1 | 1 | | |
| 115 | 274 | 5 | 10 |
| | 5 | 1 | 1 |
| | 2 | | |
| 3 | 6 | 2 | 2 |
| 1 | 1 | | |
| 14 | 30 | 1 | 3 |
| | | 1 | 1 |
| | | | 1 |
| 1 | 3 | | |
| 21 | 50 | 5 | 13 |
| 4 | 12 | | |
| | | 1 | 1 |
| | | 2 | 3 |
| | 1 | | |
| 1 | 2 | | |
| | | 1 | 1 |
| | 3 | | |
| | | 1 | 1 |
| | | | 1 |

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Gender

MALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pericardial disease | | 1 | | | | 1 |
| Pericarditis | 2 | 5 | | | 2 | 5 |
| Periorbital oedema | | 1 | | 1 | | |
| Periorbital swelling | 4 | 8 | 4 | 7 | | 1 |
| Peripheral coldness | 2 | 4 | 2 | 4 | | |
| Peripheral nerve injury | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 19 | 41 | 19 | 40 | | 1 |
| Peroneal nerve palsy | 1 | 3 | | 1 | 1 | 2 |
| Petechiae | | 1 | | 1 | | |
| Pharyngeal erythema | | 1 | | | | 1 |
| Pharyngeal hypoaesthesia | | 1 | | | | 1 |
| Pharyngeal inflammation | 1 | 3 | 1 | 3 | | |
| Pharyngeal swelling | 1 | 11 | 1 | 6 | | 5 |
| Photophobia | | 2 | | 2 | | |
| Photopsia | | 2 | | 1 | | 1 |
| Platelet count decreased | 3 | 4 | | | 3 | 4 |
| Pneumonia | 8 | 12 | | | 8 | 12 |
| Pollakiuria | 1 | 6 | 1 | 6 | | |
| Polyarthritits | 1 | 1 | | | 1 | 1 |
| Polycythaemia | 1 | 1 | 1 | 1 | | |
| Polymyalgia rheumatica | 1 | 1 | | | 1 | 1 |
| Polyneuropathy | | 1 | | | | 1 |
| Polyuria | | 3 | | 3 | | |
| Poor quality product administered | 6 | 16 | 6 | 16 | | |
| Poor quality sleep | 4 | 9 | 4 | 9 | | |
| Post procedural haemorrhage | | 1 | | | | 1 |
| Postural orthostatic tachycardia syndrome | 1 | 1 | | | 1 | 1 |
| Posturing | | 1 | | | | 1 |
| Pressure of speech | | 1 | | | | 1 |
| Presyncope | 3 | 7 | 3 | 6 | | 1 |
| Procedural pain | | 1 | | 1 | | |
| Product administered at inappropriate site | 1 | 8 | 1 | 8 | | |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | | | 1 |
| | | 2 | 5 |
| | 1 | | |
| 4 | 7 | | 1 |
| 2 | 4 | | |
| | | 1 | 1 |
| 19 | 40 | | 1 |
| | 1 | 1 | 2 |
| | 1 | | |
| | | | 1 |
| | | | 1 |
| 1 | 3 | | |
| 1 | 6 | | 5 |
| | 2 | | |
| | 1 | | 1 |
| | | 3 | 4 |
| | | 8 | 12 |
| 1 | 6 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | 3 | | |
| 6 | 16 | | |
| 4 | 9 | | |
| | | | 1 |
| | | 1 | 1 |
| | | | 1 |
| | | | 1 |
| 3 | 6 | | 1 |
| | 1 | | |
| 1 | 8 | | |

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Gender

MALE

| Preferred Term | Interval Total # | Cumulative Total # |
|--|------------------|--------------------|
| | Spontaneous AE | Spontaneous AE |
| Product administered to patient of inappropriate age | | 3 |
| Product administration error | 1 | 2 |
| Product colour issue | 1 | 1 |
| Product dose omission issue | 3 | 3 |
| Productive cough | 2 | 3 |
| Product leakage | | 2 |
| Product preparation error | 4 | 13 |
| Product preparation issue | 1 | 3 |
| Product prescribing error | 1 | 2 |
| Product quality issue | 1 | 1 |
| Product temperature excursion issue | 1 | 3 |
| Product use issue | 18 | 55 |
| Pruritus | 23 | 62 |
| Psoriasis | 2 | 2 |
| Psychomotor hyperactivity | | 1 |
| Pulmonary pain | 1 | 1 |
| Pulmonary thrombosis | 1 | 1 |
| Pulse abnormal | 2 | 2 |
| Purpura | 1 | 1 |
| Pustule | 1 | 3 |
| Pyrexia | 164 | 536 |
| Rash | 29 | 73 |
| Rash erythematous | 3 | 8 |
| Rash macular | 2 | 5 |
| Rash maculo-papular | 1 | 6 |
| Rash papular | 2 | 3 |
| Rash pruritic | 7 | 20 |
| Rash vesicular | 3 | 4 |
| Raynaud's phenomenon | | 1 |
| Red blood cell sedimentation rate increased | | 1 |
| Red blood cells urine positive | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 3 | | |
| | 1 | 1 | 1 |
| 1 | 1 | | |
| 3 | 3 | | |
| 2 | 3 | | |
| | 2 | | |
| 4 | 13 | | |
| 1 | 3 | | |
| 1 | 2 | | |
| 1 | 1 | | |
| 1 | 3 | | |
| 18 | 55 | | |
| 20 | 56 | 3 | 6 |
| 2 | 2 | | |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | 1 | 1 |
| | | 1 | 1 |
| 1 | 2 | | 1 |
| 151 | 507 | 13 | 29 |
| 23 | 63 | 6 | 10 |
| 3 | 7 | | 1 |
| 2 | 5 | | |
| 1 | 6 | | |
| 2 | 3 | | |
| 6 | 19 | 1 | 1 |
| 3 | 4 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |

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Gender

MALE

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Renal atrophy | 1 | 1 | | | 1 | 1 |
| Renal disorder | 2 | 4 | | 2 | 2 | 2 |
| Renal failure | 1 | 2 | | | 1 | 2 |
| Renal haemorrhage | 1 | 1 | | | 1 | 1 |
| Renal impairment | 1 | 1 | | | 1 | 1 |
| Renal pain | 3 | 5 | 3 | 5 | | |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | | 1 | | | | 1 |
| Respiratory disorder | 1 | 2 | 1 | 2 | | |
| Respiratory distress | | 2 | | | | 2 |
| Respiratory failure | 1 | 2 | | | 1 | 2 |
| Respiratory rate increased | | 1 | | 1 | | |
| Respiratory symptom | 1 | 1 | 1 | 1 | | |
| Respiratory tract congestion | | 1 | | 1 | | |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Restlessness | 2 | 5 | 2 | 4 | | 1 |
| Retching | 4 | 7 | 4 | 7 | | |
| Rhinalgia | 1 | 3 | 1 | 3 | | |
| Rhinitis | | 2 | | 2 | | |
| Rhinorrhoea | 12 | 37 | 11 | 35 | 1 | 2 |
| Salivary hypersecretion | 1 | 1 | 1 | 1 | | |
| SARS-CoV-1 test positive | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 9 | 15 | 9 | 15 | | |
| SARS-CoV-2 ant body test positive | | 2 | | 1 | | 1 |
| SARS-CoV-2 test false positive | | 2 | | 2 | | |
| SARS-CoV-2 test positive | 11 | 68 | 5 | 14 | 6 | 54 |
| Scar | 1 | 1 | | | 1 | 1 |
| Sciatica | 5 | 5 | 3 | 3 | 2 | 2 |
| Scrotal disorder | 1 | 1 | 1 | 1 | | |
| Scrotal erythema | 1 | 1 | 1 | 1 | | |
| Scrotal inflammation | 1 | 1 | 1 | 1 | | |
| Scrotal pain | 1 | 1 | 1 | 1 | | |

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|---------------------------|------------------------------------|--------------------------------------|
| Secretion discharge | | 1 |
| Sedation | 1 | 1 |
| Seizure | 11 | 16 |
| Sensation of foreign body | 1 | 3 |
| Sensitive skin | 2 | 3 |
| Sensory disturbance | 1 | 3 |
| Sensory loss | 2 | 4 |
| Sepsis | 2 | 3 |
| Serotonin syndrome | | 1 |
| Shock | 1 | 1 |
| Sinus congestion | 1 | 6 |
| Sinus disorder | 4 | 8 |
| Sinus headache | 2 | 4 |
| Sinusitis | 1 | 8 |
| Sinus pain | | 5 |
| Sinus tarsi syndrome | | 1 |
| Sitophobia | | 1 |
| Skin burning sensation | | 5 |
| Skin discolouration | 1 | 4 |
| Skin disorder | 2 | 3 |
| Skin exfoliation | 1 | 1 |
| Skin injury | | 1 |
| Skin irritation | 1 | 2 |
| Skin lesion | | 1 |
| Skin mass | | 1 |
| Skin odour abnormal | | 1 |
| Skin oedema | 1 | 1 |
| Skin reaction | 1 | 2 |
| Skin swelling | 1 | 3 |
| Skin ulcer | 1 | 1 |
| Sleep disorder | 2 | 10 |

| Spontaneous | | | |
|-------------|---|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 1 | | |
| | | 11 | 16 |
| 1 | 2 | | 1 |
| 2 | 3 | | |
| 1 | 3 | | |
| | 2 | 2 | 2 |
| | | 2 | 3 |
| | | | 1 |
| | | 1 | 1 |
| 1 | 5 | | 1 |
| 4 | 8 | | |
| 2 | 4 | | |
| 1 | 7 | | 1 |
| | 5 | | |
| | 1 | | |
| | 1 | | |
| | 5 | | |
| 1 | 4 | | |
| 2 | 3 | | |
| 1 | 1 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 1 | 3 | | |
| 1 | 1 | | |
| 2 | 9 | | 1 |

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Gender

MALE

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|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sleep disorder due to a general medical condition | | 1 | | 1 | | |
| Sleep talking | | 1 | | 1 | | |
| Slow response to stimuli | | 1 | | 1 | | |
| Sluggishness | 2 | 5 | 2 | 5 | | |
| Small intestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Small intestinal obstruction | 1 | 1 | | | 1 | 1 |
| Sneezing | 4 | 9 | 4 | 9 | | |
| Snoring | 1 | 1 | 1 | 1 | | |
| Soft tissue injury | 1 | 1 | 1 | 1 | | |
| Somatic symptom disorder | | 1 | | 1 | | |
| Somnolence | 10 | 33 | 10 | 33 | | |
| Speech disorder | 5 | 8 | 5 | 8 | | |
| Spinal cord disorder | 1 | 1 | | | 1 | 1 |
| Spinal pain | 2 | 2 | 2 | 2 | | |
| Splenomegaly | 1 | 1 | | | 1 | 1 |
| Staphylococcal infection | 1 | 2 | | | 1 | 2 |
| Staphylococcal skin infection | | 1 | | | | 1 |
| Staring | 1 | 1 | 1 | 1 | | |
| Stoma site haemorrhage | 1 | 1 | | | 1 | 1 |
| Stomatitis haemorrhagic | 1 | 1 | | | 1 | 1 |
| Stress | | 1 | | 1 | | |
| Subarachnoid haemorrhage | 1 | 1 | | | 1 | 1 |
| Subdural haemorrhage | 1 | 1 | | | 1 | 1 |
| Substance abuse | | 1 | | | | 1 |
| Suffocation feeling | | 1 | | 1 | | |
| Supraventricular extrasystoles | | 1 | | | | 1 |
| Supraventricular tachycardia | 1 | 3 | | 1 | 1 | 2 |
| Suspected COVID-19 | | 10 | | | | 10 |
| Swelling | 8 | 29 | 8 | 26 | | 3 |
| Swelling face | 7 | 19 | 6 | 17 | 1 | 2 |
| Swelling of eyelid | | 7 | | 7 | | |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 2 | 5 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| 4 | 9 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 10 | 33 | | |
| 5 | 8 | | |
| | | 1 | 1 |
| 2 | 2 | | |
| | | 1 | 1 |
| | | 1 | 2 |
| | | | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | | 1 |
| | 1 | 1 | 2 |
| | | | 10 |
| 8 | 26 | | 3 |
| 6 | 17 | 1 | 2 |
| | 7 | | |

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|---|------------------------------------|--------------------------------------|
| Swollen tongue | 4 | 9 |
| Syncope | 14 | 18 |
| Synovial cyst | 1 | 1 |
| Synovitis | 1 | 1 |
| Syringe issue | 1 | 2 |
| Systemic inflammatory response syndrome | | 1 |
| Systolic hypertension | 1 | 1 |
| Tachycardia | 5 | 26 |
| Tachyphrenia | | 1 |
| Taste disorder | 2 | 7 |
| Temperature intolerance | 2 | 3 |
| Tenderness | 1 | 2 |
| Tendonitis | | 2 |
| Tenosynovitis | | 1 |
| Tension | | 2 |
| Tension headache | 1 | 4 |
| Terminal insomnia | 1 | 1 |
| Testicular pain | 2 | 2 |
| Testicular swelling | | 1 |
| Therapeutic response unexpected | 4 | 4 |
| Thinking abnormal | 2 | 3 |
| Thirst | | 3 |
| Throat irritation | 5 | 16 |
| Throat tightness | 2 | 6 |
| Thrombocytopenia | 2 | 2 |
| Thrombosis | 4 | 5 |
| Thrombotic thrombocytopenic purpura | 1 | 2 |
| Thyroid cancer | 1 | 1 |
| Tinnitus | 4 | 23 |
| Tongue coated | | 1 |
| Tongue disorder | | 1 |
| Tongue pruritus | | 1 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 3 | 5 | 1 | 4 |
| | | 14 | 18 |
| 1 | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| | | | 1 |
| | | 1 | 1 |
| | 19 | 5 | 7 |
| | 1 | | |
| 2 | 7 | | |
| 2 | 3 | | |
| 1 | 2 | | |
| | 1 | | 1 |
| | 1 | | |
| | 2 | | |
| 1 | 4 | | |
| 1 | 1 | | |
| 2 | 2 | | |
| | 1 | | |
| 4 | 4 | | |
| 2 | 3 | | |
| | 3 | | |
| 5 | 15 | | 1 |
| 1 | 5 | 1 | 1 |
| | | 2 | 2 |
| | | 4 | 5 |
| | | 1 | 2 |
| | | 1 | 1 |
| 3 | 17 | 1 | 6 |
| | 1 | | |
| | 1 | | |
| | 1 | | |

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|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tonic clonic movements | 1 | 1 | | | 1 | 1 |
| Tonsillitis | | 1 | | 1 | | |
| Toothache | 1 | 4 | 1 | 4 | | |
| Torsade de pointes | 1 | 1 | | | 1 | 1 |
| Transient global amnesia | | 1 | | 1 | | |
| Transient ischaemic attack | 2 | 4 | | | 2 | 4 |
| Tremor | 15 | 34 | 10 | 28 | 5 | 6 |
| Trigeminal nerve disorder | | 1 | | 1 | | |
| Troponin increased | 1 | 1 | | | 1 | 1 |
| Tuberculin test positive | 1 | 1 | 1 | 1 | | |
| Tunnel vision | 2 | 2 | | | 2 | 2 |
| Type IV hypersensitivity reaction | | 1 | | 1 | | |
| Ulcer | 1 | 1 | 1 | 1 | | |
| Underdose | 8 | 21 | 8 | 21 | | |
| Unresponsive to stimuli | 6 | 7 | | | 6 | 7 |
| Upper-airway cough syndrome | 3 | 8 | 3 | 8 | | |
| Upper airway obstruction | | 1 | | | | 1 |
| Upper respiratory tract congestion | 1 | 2 | 1 | 2 | | |
| Upper respiratory tract infection | | 1 | | 1 | | |
| Urethral haemorrhage | 1 | 1 | | | 1 | 1 |
| Urinary assistance device user | 1 | 1 | 1 | 1 | | |
| Urinary incontinence | 1 | 1 | 1 | 1 | | |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary tract disorder | 1 | 1 | 1 | 1 | | |
| Urinary tract infection | 10 | 10 | 5 | 5 | 5 | 5 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Urine abnormality | 1 | 1 | 1 | 1 | | |
| Urine odour abnormal | 1 | 1 | 1 | 1 | | |
| Urticaria | 11 | 37 | 9 | 33 | 2 | 4 |
| Uvulitis | | 1 | | 1 | | |
| Vaccination error | | 1 | | 1 | | |
| Vaccination failure | 1 | 2 | | | 1 | 2 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| | 1 | | |
| 1 | 4 | | |
| | | 1 | 1 |
| | 1 | | |
| | | 2 | 4 |
| 10 | 28 | 5 | 6 |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 2 | 2 |
| | 1 | | |
| 1 | 1 | | |
| 8 | 21 | | |
| | | 6 | 7 |
| 3 | 8 | | |
| | | | 1 |
| 1 | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| | | 1 | 1 |
| 1 | 1 | | |
| 5 | 5 | 5 | 5 |
| | | 1 | 1 |
| 1 | 1 | | |
| 1 | 1 | | |
| 9 | 33 | 2 | 4 |
| | 1 | | |
| | 1 | | |
| | | 1 | 2 |

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|--|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site bruising | 4 | 7 | 3 | 6 | 1 | 1 |
| Vaccination site coldness | 2 | 4 | 2 | 4 | | |
| Vaccination site discharge | 1 | 1 | 1 | 1 | | |
| Vaccination site discolouration | 2 | 4 | 2 | 4 | | |
| Vaccination site discomfort | 5 | 7 | 5 | 7 | | |
| Vaccination site erythema | 13 | 21 | 12 | 20 | 1 | 1 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site haemorrhage | 5 | 10 | 5 | 10 | | |
| Vaccination site hypoaesthesia | | 2 | | 2 | | |
| Vaccination site induration | 2 | 3 | 2 | 3 | | |
| Vaccination site infection | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | | 1 | | 1 | | |
| Vaccination site irritation | | 1 | | 1 | | |
| Vaccination site joint movement impairment | 2 | 2 | 2 | 2 | | |
| Vaccination site joint pain | 2 | 2 | 2 | 2 | | |
| Vaccination site lymphadenopathy | 1 | 2 | 1 | 2 | | |
| Vaccination site mass | 6 | 10 | 6 | 10 | | |
| Vaccination site movement impairment | | 5 | | 5 | | |
| Vaccination site oedema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 127 | 364 | 125 | 361 | 2 | 3 |
| Vaccination site paraesthesia | 1 | 3 | 1 | 3 | | |
| Vaccination site pruritus | 7 | 9 | 6 | 8 | 1 | 1 |
| Vaccination site rash | 3 | 8 | 3 | 8 | | |
| Vaccination site reaction | 1 | 5 | 1 | 5 | | |
| Vaccination site swelling | 11 | 26 | 11 | 26 | | |
| Vaccination site ulcer | | 1 | | 1 | | |
| Vaccination site urticaria | | 4 | | 4 | | |
| Vaccination site vesicles | 1 | 1 | 1 | 1 | | |
| Vaccination site warmth | 1 | 7 | 1 | 7 | | |
| Vascular dementia | 1 | 1 | | | 1 | 1 |
| Ventricular arrhythmia | 1 | 1 | | | 1 | 1 |
| Ventricular extrasystoles | 1 | 2 | | 1 | 1 | 1 |

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|--|------------------------------------|--------------------------------------|-------------|------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ventricular fibrillation | 2 | 3 | | | 2 | 3 |
| Ventricular tachycardia | | 1 | | | | 1 |
| Vertigo | 13 | 24 | 12 | 22 | 1 | 2 |
| Viral infection | | 1 | | 1 | | |
| Vision blurred | 10 | 23 | 7 | 18 | 3 | 5 |
| Visual impairment | 6 | 9 | 3 | 6 | 3 | 3 |
| Vitamin D decreased | 1 | 1 | 1 | 1 | | |
| Vlth nerve paralysis | 1 | 1 | | | 1 | 1 |
| Vomiting | 34 | 78 | 30 | 69 | 4 | 9 |
| Walking disability | 1 | 1 | | | 1 | 1 |
| Weight decreased | 4 | 7 | 4 | 7 | | |
| Weight increased | | 1 | | 1 | | |
| Wheezing | 2 | 5 | 2 | 5 | | |
| White blood cell count decreased | 1 | 1 | 1 | 1 | | |
| White blood cell count increased | 2 | 3 | 1 | 1 | 1 | 2 |
| Wound | 1 | 2 | 1 | 2 | | |
| Wrong product administered | 1 | 5 | 1 | 5 | | |
| Wrong technique in product usage process | 3 | 6 | 3 | 6 | | |
| Yellow skin | 1 | 1 | 1 | 1 | | |
| | 3,641 | 9,540 | 2789 | 7831 | 852 | 1709 |

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Gender

UNKNOWN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | | 2 | | 2 | | |
| Abnormal faeces | 1 | 1 | 1 | 1 | | |
| Abnormal sensation in eye | | 1 | | 1 | | |
| Accidental exposure to product | 2 | 4 | 2 | 4 | | |
| Accidental overdose | 2 | 16 | 2 | 16 | | |
| Ageusia | 1 | 3 | 1 | 2 | | 1 |
| Aggression | | 1 | | 1 | | |
| Allergy to vaccine | 1 | 6 | 1 | 6 | | |
| Anaesthesia | | 1 | | 1 | | |
| Anaphylactic reaction | 2 | 18 | | | 2 | 18 |
| Anger | | 1 | | 1 | | |
| Anosmia | 1 | 2 | 1 | 1 | | 1 |
| Antibody test abnormal | 1 | 1 | 1 | 1 | | |
| Antibody test negative | | 1 | | 1 | | |
| Anxiety | 3 | 6 | 2 | 5 | 1 | 1 |
| Aphasia | | 1 | | 1 | | |
| Aphthous ulcer | | 1 | | 1 | | |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 8 | 27 | 8 | 27 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 12 | 1 | 12 | | |
| Asthenopia | | 1 | | 1 | | |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Axillary pain | | 1 | | 1 | | |
| Back disorder | 1 | 1 | 1 | 1 | | |
| Back pain | 3 | 9 | 3 | 9 | | |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Blindness | 2 | 2 | | | 2 | 2 |
| Blood bilirubin increased | 1 | 1 | | | 1 | 1 |
| Blood glucose decreased | | 1 | | | | 1 |

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UNKNOWN

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|--|--|--|
| Blood glucose increased | | 1 |
| Blood immunoglobulin G decreased | 1 | 2 |
| Blood immunoglobulin G increased | | 2 |
| Blood potassium decreased | | 1 |
| Blood pressure decreased | | 1 |
| Blood pressure increased | 4 | 5 |
| Blood sodium decreased | | 1 |
| Blood thyroid stimulating hormone increased | | 1 |
| Body temperature abnormal | | 2 |
| Body temperature decreased | | 2 |
| Body temperature increased | | 3 |
| Bone pain | | 2 |
| Burning sensation | | 1 |
| Cardiac flutter | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 |
| Cerebrovascular accident | 1 | 1 |
| Chest discomfort | 3 | 6 |
| Chest pain | | 1 |
| Chillblains | | 1 |
| Chills | 20 | 65 |
| Circumstance or information capable of leading to medication error | 3 | 13 |
| Cognitive disorder | | 1 |
| Cold sweat | | 2 |
| Condition aggravated | 2 | 3 |
| Confusional state | 1 | 2 |
| Conjunctivitis | | 1 |
| Contusion | | 1 |
| Cough | 1 | 9 |
| COVID-19 | 56 | 143 |
| Cyanosis | | 1 |
| Death | 7 | 10 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 2 | | |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| 2 | 3 | 2 | 2 |
| | 1 | | |
| | 1 | | |
| | 2 | | |
| | 2 | | |
| | 3 | | |
| | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| | | 1 | 1 |
| | | 1 | 1 |
| 3 | 6 | | |
| | 1 | | |
| | 1 | | |
| 20 | 65 | | |
| 3 | 13 | | |
| | 1 | | |
| | 2 | | |
| 2 | 3 | | |
| 1 | 2 | | |
| | 1 | | |
| | 1 | | |
| 1 | 9 | | |
| 2 | 2 | 54 | 141 |
| | 1 | | |
| | | 7 | 10 |

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|------------------------------|--|--|
| Decreased appetite | 1 | 4 |
| Deep vein thrombosis | | 1 |
| Dehydration | | 2 |
| Depressed mood | | 1 |
| Diabetes mellitus | | 1 |
| Diarrhoea | 8 | 21 |
| Diplopia | | 1 |
| Discomfort | | 1 |
| Disturbance in attention | | 3 |
| Dizziness | 6 | 30 |
| Drug ineffective | 66 | 204 |
| Drug interaction | | 1 |
| Dry mouth | | 1 |
| Dry throat | | 3 |
| Dysarthria | | 1 |
| Dysgeusia | 2 | 10 |
| Dyskinesia | | 1 |
| Dyspepsia | | 1 |
| Dysphagia | | 2 |
| Dysphonia | | 1 |
| Dyspnoea | 3 | 11 |
| Dysuria | | 1 |
| Ear pain | 1 | 1 |
| Epistaxis | 1 | 2 |
| Erythema | 2 | 8 |
| Euphoric mood | | 1 |
| Excessive cerumen production | 1 | 1 |
| Exposure to SARS-CoV-2 | 1 | 5 |
| Exposure via breast milk | 6 | 63 |
| Exposure via eye contact | | 1 |
| Exposure via skin contact | 2 | 4 |
| Eye irritation | | 1 |

| Spontaneous | | | |
|-------------|----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 4 | | |
| | | | 1 |
| | 1 | | 1 |
| | 1 | | |
| | | | 1 |
| 8 | 20 | | 1 |
| | 1 | | |
| | 1 | | |
| | 3 | | |
| 6 | 30 | | |
| 1 | 2 | 65 | 202 |
| | 1 | | |
| | 1 | | |
| | 3 | | |
| | 1 | | |
| 2 | 10 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | 1 |
| | 1 | | |
| 3 | 10 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 2 | | |
| 2 | 7 | | 1 |
| | 1 | | |
| 1 | 1 | | |
| 1 | 3 | | 2 |
| 6 | 63 | | |
| | 1 | | |
| 2 | 4 | | |
| | 1 | | |

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|------------------------------------|------------------------------------|--------------------------------------|
| Eye pruritus | | 2 |
| Eye swelling | | 1 |
| Facial asymmetry | | 1 |
| Facial pain | | 1 |
| Facial paralysis | 4 | 14 |
| Fatigue | 11 | 97 |
| Febrile neutropenia | | 1 |
| Feeding disorder | | 1 |
| Feeling abnormal | 5 | 16 |
| Feeling cold | 3 | 9 |
| Feeling hot | 1 | 4 |
| Feeling jittery | | 1 |
| Feeling of body temperature change | | 1 |
| Flushing | 2 | 11 |
| Frustration tolerance decreased | 1 | 1 |
| Gait disturbance | | 1 |
| Gait inability | | 2 |
| Gastrointestinal disorder | | 4 |
| Gingival bleeding | | 1 |
| Gingival pain | | 1 |
| Gingival swelling | | 1 |
| Glassy eyes | | 1 |
| Gout | 1 | 2 |
| Groin pain | | 1 |
| Guillain-Barre syndrome | 1 | 1 |
| Haematochezia | | 1 |
| Haemorrhage | 1 | 1 |
| Headache | 23 | 117 |
| Head discomfort | 1 | 1 |
| Heart rate decreased | | 1 |
| Heart rate increased | 2 | 17 |
| Heart rate irregular | | 1 |

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 2 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| | | 4 | 14 |
| 11 | 95 | | 2 |
| | | | 1 |
| 4 | 15 | 1 | 1 |
| 3 | 9 | | |
| 1 | 3 | | 1 |
| | 1 | | |
| | 1 | | |
| 2 | 10 | | 1 |
| 1 | 1 | | |
| | 1 | | |
| | 2 | | |
| | 4 | | |
| | 1 | | |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | |
| | 1 | | |
| | | 1 | 1 |
| | | | 1 |
| | | 1 | 1 |
| 23 | 115 | | 2 |
| 1 | 1 | | |
| | 1 | | |
| 1 | 16 | 1 | 1 |
| | 1 | | |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Hepatic enzyme increased | 1 | 1 |
| Herpes zoster | 1 | 4 |
| Hiccups | | 1 |
| Hot flush | 1 | 1 |
| Hyperhidrosis | 2 | 4 |
| Hypersensitivity | 6 | 22 |
| Hypersomnia | 1 | 1 |
| Hypertension | 1 | 4 |
| Hypoacusis | 1 | 4 |
| Hypoaesthesia | 1 | 7 |
| Hypoaesthesia eye | | 1 |
| Hypoaesthesia oral | | 4 |
| Hypokinesia | | 3 |
| Hypotonia | | 1 |
| Illness | 8 | 20 |
| Inappropriate schedule of product administration | 6 | 16 |
| Incorrect dose administered | 2 | 7 |
| Incorrect route of product administration | 1 | 13 |
| Induration | | 1 |
| Infantile vomiting | | 1 |
| Infection | 1 | 2 |
| Influenza | | 4 |
| Influenza like illness | 4 | 15 |
| Infrequent bowel movements | | 1 |
| Injection site irritation | 1 | 1 |
| Insomnia | 2 | 5 |
| Intentional product misuse | | 1 |
| Irritability | | 1 |
| Lethargy | | 7 |
| Leukocytosis | | 1 |
| Limb discomfort | 1 | 4 |
| Limb mass | | 1 |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | | 1 | 1 |
| 1 | 4 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 4 | | |
| 4 | 18 | 2 | 4 |
| 1 | 1 | | |
| | 2 | 1 | 2 |
| 1 | 4 | | |
| 1 | 7 | | |
| | 1 | | |
| | 4 | | |
| | 3 | | |
| | 1 | | |
| 8 | 20 | | |
| 6 | 16 | | |
| 2 | 7 | | |
| 1 | 12 | | 1 |
| | | | 1 |
| | 1 | | |
| 1 | 2 | | |
| | 4 | | |
| 4 | 15 | | |
| | 1 | | |
| 1 | 1 | | |
| 2 | 5 | | |
| | 1 | | |
| | 1 | | |
| | 7 | | |
| | | | 1 |
| 1 | 4 | | |
| | | | 1 |

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|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lip oedema | | 1 | | 1 | | |
| Lip pain | | 1 | | 1 | | |
| Lip pruritus | 1 | 3 | 1 | 2 | | 1 |
| Lip swelling | 2 | 3 | 2 | 3 | | |
| Liquid product physical issue | | 5 | | 5 | | |
| Localised infection | | 1 | | 1 | | |
| Loss of consciousness | 1 | 2 | | | 1 | 2 |
| Loss of personal independence in daily activities | | 2 | | 2 | | |
| Lung neoplasm malignant | | 1 | | | | 1 |
| Lymphadenitis | | 1 | | 1 | | |
| Lymphadenopathy | 3 | 19 | 3 | 19 | | |
| Lymph node pain | | 3 | | 3 | | |
| Malaise | 10 | 36 | 8 | 33 | 2 | 3 |
| Mastication disorder | 1 | 1 | 1 | 1 | | |
| Maternal exposure during breast feeding | | 1 | | 1 | | |
| Middle insomnia | | 1 | | 1 | | |
| Migraine | | 4 | | 4 | | |
| Mobility decreased | | 1 | | 1 | | |
| Mouth swelling | | 1 | | 1 | | |
| Movement disorder | | 4 | | 4 | | |
| Mucous stools | | 1 | | 1 | | |
| Muscle fatigue | 1 | 1 | 1 | 1 | | |
| Muscle spasms | | 5 | | 5 | | |
| Muscular weakness | 1 | 2 | 1 | 2 | | |
| Musculoskeletal chest pain | | 3 | | 3 | | |
| Musculoskeletal discomfort | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | | 3 | | 2 | | 1 |
| Myalgia | 6 | 28 | 6 | 28 | | |
| Nasal congestion | | 7 | | 7 | | |
| Nasal discomfort | | 1 | | 1 | | |
| Nasal oedema | | 1 | | 1 | | |
| Nasopharyngitis | 2 | 4 | 2 | 4 | | |

| Spontaneous | | | |
|-------------|----|---------|---|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| | 1 | | |
| 1 | 2 | | 1 |
| 2 | 3 | | |
| | 5 | | |
| | 1 | | |
| | | 1 | 2 |
| | 2 | | |
| | | | 1 |
| | 1 | | |
| 3 | 19 | | |
| | 3 | | |
| 8 | 33 | 2 | 3 |
| 1 | 1 | | |
| | 1 | | |
| | 4 | | |
| | 1 | | |
| | 1 | | |
| | 4 | | |
| | 1 | | |
| 1 | 1 | | |
| | 5 | | |
| 1 | 2 | | |
| | 3 | | |
| 1 | 1 | | |
| | 2 | | 1 |
| 6 | 28 | | |
| | 7 | | |
| | 1 | | |
| | 1 | | |
| 2 | 4 | | |

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|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nausea | 4 | 29 | 4 | 29 | | |
| Neck mass | | 2 | | 2 | | |
| Neck pain | 2 | 5 | 2 | 5 | | |
| Needle issue | | 2 | | 2 | | |
| Nerve compression | | 1 | | 1 | | |
| Nervousness | 1 | 4 | | 3 | 1 | 1 |
| Nervous system disorder | 1 | 1 | 1 | 1 | | |
| Neuralgia | | 2 | | 2 | | |
| Neuritis | | 1 | | 1 | | |
| Neuropathy peripheral | | 1 | | | | 1 |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Nightmare | 2 | 2 | 2 | 2 | | |
| Night sweats | | 4 | | 4 | | |
| No adverse event | 3 | 3 | 3 | 3 | | |
| Occupational exposure to product | | 1 | | 1 | | |
| Ocular hyperaemia | | 1 | | 1 | | |
| Oesophageal pain | | 1 | | 1 | | |
| Off label use | 3 | 7 | 3 | 7 | | |
| Oral dysaesthesia | | 1 | | | | 1 |
| Oral herpes | | 2 | | 2 | | |
| Oral mucosal blistering | | 1 | | 1 | | |
| Oropharyngeal pain | 3 | 8 | 3 | 8 | | |
| Orthostatic hypotension | 1 | 1 | 1 | 1 | | |
| Overdose | 2 | 21 | 2 | 21 | | |
| Oxygen consumption | | 1 | | 1 | | |
| Oxygen saturation decreased | | 1 | | 1 | | |
| Pain | 14 | 78 | 14 | 78 | | |
| Pain in extremity | 19 | 88 | 19 | 87 | | 1 |
| Pain in jaw | | 1 | | 1 | | |
| Palpitations | 4 | 8 | 4 | 7 | | 1 |
| Panic attack | | 1 | | 1 | | |
| Paraesthesia | 1 | 10 | 1 | 9 | | 1 |

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|--|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Paraesthesia oral | 1 | 2 | 1 | 2 | | |
| Pericarditis | | 1 | | | | 1 |
| Peripheral swelling | 1 | 22 | 1 | 22 | | |
| Pharyngeal hypoaesthesia | | 1 | | 1 | | |
| Pharyngeal paraesthesia | | 2 | | 2 | | |
| Pharyngeal swelling | 1 | 5 | 1 | 4 | | 1 |
| Plantar erythema | | 1 | | 1 | | |
| Platelet count decreased | 1 | 2 | | 1 | 1 | 1 |
| Platelet count increased | | 1 | | 1 | | |
| Platelet disorder | 1 | 1 | 1 | 1 | | |
| Pleurisy | | 1 | | | | 1 |
| Pollakiuria | 2 | 2 | 2 | 2 | | |
| Poor feeding infant | | 1 | | 1 | | |
| Poor quality product administered | 24 | 200 | 24 | 200 | | |
| Poor quality sleep | | 1 | | 1 | | |
| Presyncope | | 1 | | 1 | | |
| Product administered at inappropriate site | 1 | 5 | 1 | 5 | | |
| Product administered to patient of inappropriate age | | 1 | | 1 | | |
| Product administration error | 1 | 7 | 1 | 7 | | |
| Product complaint | | 1 | | 1 | | |
| Product container issue | 1 | 1 | 1 | 1 | | |
| Product dose omission issue | | 1 | | 1 | | |
| Productive cough | | 1 | | | | 1 |
| Product leakage | | 3 | | 3 | | |
| Product packaging quantity issue | | 4 | | 4 | | |
| Product preparation error | 8 | 66 | 8 | 66 | | |
| Product preparation issue | 3 | 51 | 3 | 51 | | |
| Product quality issue | | 1 | | 1 | | |
| Product storage error | 1 | 1 | 1 | 1 | | |
| Product temperature excursion issue | 22 | 122 | 22 | 122 | | |
| Product use issue | 5 | 7 | 5 | 7 | | |

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pruritus | 4 | 14 | 4 | 14 | | |
| Psoriatic arthropathy | | 1 | | | | 1 |
| Pulmonary congestion | | 2 | | | | 2 |
| Pulmonary embolism | | 2 | | | | 2 |
| Pyrexia | 23 | 99 | 23 | 97 | | 2 |
| Rash | 8 | 25 | 8 | 25 | | |
| Rash erythematous | 1 | 5 | 1 | 5 | | |
| Renal pain | | 1 | | 1 | | |
| Retching | 1 | 1 | 1 | 1 | | |
| Rhinalgia | | 1 | | 1 | | |
| Rhinorrhoea | 1 | 4 | 1 | 4 | | |
| SARS-CoV-2 ant body test negative | 2 | 3 | 2 | 3 | | |
| SARS-CoV-2 ant body test positive | 1 | 4 | 1 | 4 | | |
| SARS-CoV-2 test positive | 9 | 55 | | | 9 | 55 |
| Sensation of foreign body | | 2 | | 2 | | |
| Sinus disorder | | 1 | | 1 | | |
| Sinusitis | | 2 | | 2 | | |
| Skin discolouration | | 2 | | 1 | | 1 |
| Skin disorder | | 1 | | 1 | | |
| Skin laceration | | 1 | | 1 | | |
| Skin reaction | 1 | 1 | 1 | 1 | | |
| Sleep disorder | | 3 | | 2 | | 1 |
| Sneezing | 1 | 3 | 1 | 3 | | |
| Somnolence | | 3 | | 3 | | |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Spinal pain | 1 | 1 | 1 | 1 | | |
| Sputum discoloured | | 1 | | 1 | | |
| Suspected COVID-19 | 1 | 5 | | | 1 | 5 |
| Swelling | 4 | 7 | 4 | 7 | | |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 1 | 1 | 1 | 1 | | |
| Syncope | 2 | 4 | | | 2 | 4 |

| Spontaneous | | | |
|-------------|----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 14 | | |
| | | | 1 |
| | | | 2 |
| | | | 2 |
| 23 | 97 | | 2 |
| 8 | 25 | | |
| 1 | 5 | | |
| | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| 1 | 4 | | |
| 2 | 3 | | |
| 1 | 4 | | |
| | | 9 | 55 |
| | 2 | | |
| | 1 | | |
| | 2 | | |
| | 1 | | 1 |
| | 1 | | |
| | 1 | | |
| 1 | 1 | | |
| | 2 | | 1 |
| 1 | 3 | | |
| | 3 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | 1 | | |
| | | 1 | 5 |
| 4 | 7 | | |
| 1 | 1 | | |
| 1 | 1 | | |
| | | 2 | 4 |

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|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | | 6 | | 4 | | 2 |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Tenderness | | 1 | | 1 | | |
| Therapeutic response unexpected | 1 | 3 | 1 | 3 | | |
| Thinking abnormal | 1 | 1 | 1 | 1 | | |
| Throat irritation | | 5 | | 3 | | 2 |
| Throat tightness | 1 | 4 | 1 | 4 | | |
| Thrombocytopenia | | 1 | | | | 1 |
| Thrombosis | 1 | 3 | | | 1 | 3 |
| Tinnitus | 1 | 2 | 1 | 2 | | |
| Tongue disorder | | 1 | | 1 | | |
| Tongue erythema | | 1 | | 1 | | |
| Tongue ulceration | | 1 | | 1 | | |
| Toothache | 2 | 2 | 2 | 2 | | |
| Tooth infection | | 1 | | 1 | | |
| Tremor | 3 | 7 | 3 | 7 | | |
| Tunnel vision | | 1 | | | | 1 |
| Underdose | 16 | 82 | 16 | 82 | | |
| Upper respiratory tract congestion | | 1 | | 1 | | |
| Urticaria | 1 | 12 | 1 | 12 | | |
| Vaccination complication | | 2 | | 2 | | |
| Vaccination site bruising | 1 | 1 | 1 | 1 | | |
| Vaccination site discharge | | 2 | | 2 | | |
| Vaccination site discolouration | | 2 | | 2 | | |
| Vaccination site erythema | 3 | 12 | 3 | 12 | | |
| Vaccination site extravasation | | 1 | | 1 | | |
| Vaccination site induration | 2 | 4 | 2 | 3 | | 1 |
| Vaccination site mass | 1 | 2 | 1 | 2 | | |
| Vaccination site pain | 15 | 61 | 15 | 61 | | |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 2 | 4 | 2 | 4 | | |
| Vaccination site rash | | 3 | | 3 | | |

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|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site reaction | | 3 | | 3 | | |
| Vaccination site swelling | 4 | 10 | 4 | 10 | | |
| Vaccination site warmth | 2 | 2 | 2 | 2 | | |
| Vertigo | 2 | 5 | 2 | 5 | | |
| Vessel puncture site haemorrhage | | 1 | | 1 | | |
| Vessel puncture site injury | | 1 | | 1 | | |
| Vision blurred | | 2 | | 2 | | |
| Visual impairment | 1 | 1 | 1 | 1 | | |
| Vitreous floaters | 1 | 1 | 1 | 1 | | |
| Vomiting | 6 | 13 | 6 | 13 | | |
| Von Willebrand's disease | | 1 | | | | 1 |
| Weight decreased | | 1 | | 1 | | |
| Wheezing | 1 | 3 | 1 | 3 | | |
| Wrong product administered | 5 | 8 | 5 | 8 | | |
| Wrong technique in product usage process | 3 | 36 | 3 | 36 | | |
| Yellow skin | 1 | 1 | | | 1 | 1 |
| | 639 | 2,807 | 467 | 2270 | 172 | 537 |

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* I=Interval, C=Cumulative
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Country Where Event Occurred
UNITED STATES MINOR OUTLYING ISLA

Gender

FEMALE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Cough | 1 | 1 | 1 | 1 |
| Inappropriate schedule of product administration | | 1 | | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 |
| Sinus congestion | 1 | 1 | 1 | 1 |
| Vaccination site pain | | 1 | | 1 |
| | 3 | 5 | 3 | 5 |

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APPENDIX 2.5.4: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Patient with Relevant Co-Morbidities by Preferred Term per Country

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 4,953 (Interval) / 8,258 (Cumulative)

Total Number of Adverse Events (PT): 21,652 (Interval) / 36,395 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

AUSTRIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute coronary syndrome | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | 2 | 2 | | | 2 | 2 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Antiphospholipid syndrome | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arthralgia | 4 | 4 | | | 4 | 4 |
| Asthenia | 2 | 4 | 1 | 1 | 1 | 3 |
| Atrial fibrillation | 3 | 3 | | | 3 | 3 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blood creatine phosphokinase MB increased | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure immeasurable | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Breath sounds | 1 | 1 | 1 | 1 | | |
| Bundle branch block right | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bursitis | 1 | 1 | 1 | 1 | | |
| Cachexia | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 2 | | | 1 | 2 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 3 | 3 | 2 | 2 | 1 | 1 |
| Chest discomfort | 3 | 3 | 2 | 2 | 1 | 1 |
| Chest pain | 4 | 4 | 2 | 2 | 2 | 2 |
| Chills | 9 | 9 | 3 | 3 | 6 | 6 |
| Choking | 1 | 1 | | | 1 | 1 |
| Cholestasis | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 4 | 4 | | | 4 | 4 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 2 | 3 | | | 2 | 3 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Death | 7 | 9 | | | 7 | 9 |
| Diarrhoea | 3 | 3 | 3 | 3 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disease progression | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 4 | 3 | 3 | 1 | 1 |
| Dizziness postural | 1 | 1 | 1 | 1 | | |
| Drug ineffective | 2 | 3 | | | 2 | 3 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dry throat | 1 | 1 | 1 | 1 | | |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 5 | 5 | | | 5 | 5 |
| Ear discomfort | 1 | 1 | 1 | 1 | | |
| Eczema | 1 | 1 | | | 1 | 1 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Escherichia sepsis | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fatigue | 10 | 11 | 8 | 8 | 2 | 3 |
| Flushing | 2 | 2 | 1 | 1 | 1 | 1 |
| Formication | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Gastrointestinal disorder | 1 | 1 | 1 | 1 | | |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 4 | 4 | | | 4 | 4 |
| Headache | 13 | 13 | 9 | 9 | 4 | 4 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hypertensive emergency | 1 | 1 | | | 1 | 1 |
| Hyperventilation | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 2 | 2 | | | 2 | 2 |
| Hypogeusia | 1 | 1 | | | 1 | 1 |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Hyposmia | 1 | 1 | | | 1 | 1 |
| Hypotension | 1 | 1 | 1 | 1 | | |
| Hypotonia | 2 | 2 | 1 | 1 | 1 | 1 |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 1 | 1 | | | 1 | 1 |
| Injection site urticaria | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Interleukin level increased | 1 | 1 | | | 1 | 1 |
| Left ventricular failure | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Lip pruritus | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lung infiltration | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Lymph node palpable | 1 | 1 | 1 | 1 | | |
| Marasmus | 1 | 1 | | | 1 | 1 |
| Meningitis bacterial | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Myocardial infarction | | 1 | | | | 1 |
| Myocarditis | 2 | 2 | | | 2 | 2 |
| Nausea | 11 | 13 | 7 | 9 | 4 | 4 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Neuralgic amyotrophy | 1 | 1 | | | 1 | 1 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Obstructive airways disorder | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Off label use | 2 | 2 | 2 | 2 | | |
| Oral pruritus | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Oxygen saturation | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Oxygen saturation immeasurable | 1 | 1 | | | 1 | 1 |
| Pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain in extremity | 4 | 4 | 3 | 3 | 1 | 1 |
| Pallor | 3 | 3 | 1 | 1 | 2 | 2 |
| Palmar erythema | 1 | 1 | | | 1 | 1 |
| Panic attack | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 4 | 4 | 2 | 2 | 2 | 2 |
| Paraesthesia oral | 2 | 2 | | | 2 | 2 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Paresis | 1 | 1 | | | 1 | 1 |
| Pemphigus | 1 | 1 | | | 1 | 1 |
| Pericarditis | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 1 | 1 | 1 | 1 | | |
| Photophobia | 1 | 1 | 1 | 1 | | |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Pneumonia aspiration | 2 | 2 | | | 2 | 2 |
| Presyncope | 7 | 7 | 1 | 1 | 6 | 6 |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Pruritus | 8 | 8 | 1 | 1 | 7 | 7 |
| Pulmonary embolism | 1 | 2 | | | 1 | 2 |
| Pulmonary oedema | | 1 | | | | 1 |
| Pyrexia | 9 | 9 | 3 | 3 | 6 | 6 |
| Rales | 1 | 2 | 1 | 1 | | 1 |
| Rash | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash morbilliform | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Respiratory depression | | 1 | | | | 1 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory rate decreased | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Seizure | 2 | 2 | | | 2 | 2 |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Septic shock | 1 | 1 | | | 1 | 1 |
| Shock | 1 | 1 | | | 1 | 1 |
| Somnolence | 4 | 5 | 2 | 2 | 2 | 3 |
| Speech disorder | 1 | 1 | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Swelling | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Syncope | 4 | 4 | | | 4 | 4 |
| Systemic inflammatory response syndrome | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Throat irritation | 2 | 2 | 1 | 1 | 1 | 1 |
| Tinnitus | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 1 | 1 | 1 | | |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Urinary retention | | 1 | | | | 1 |
| Urticaria | 3 | 3 | | | 3 | 3 |
| Vaccination site discolouration | 1 | 1 | | | 1 | 1 |
| Vaccination site lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 7 | 7 | 6 | 6 | 1 | 1 |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaginal discharge | | 1 | | 1 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 4 | 4 | 3 | 3 | 1 | 1 |
| Vision blurred | 1 | 1 | 1 | 1 | | |
| Vomiting | 3 | 5 | 2 | 4 | 1 | 1 |
| | 311 | 332 | 116 | 121 | 195 | 211 |

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Country Where Event Occurred

BAHRAIN

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Chills | 1 | 1 | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 |
| Pyrexia | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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Country Where Event Occurred

BELGIUM

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Acute kidney injury | 1 | 2 | | | 1 | 2 |
| Acute respiratory failure | 2 | 3 | | | 2 | 3 |
| Agitation | 2 | 4 | | | 2 | 4 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Amnesia | | 1 | | | | 1 |
| Anaphylactic reaction | 5 | 5 | | | 5 | 5 |
| Angle closure glaucoma | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Arthralgia | 4 | 4 | | | 4 | 4 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Asthma exercise induced | 1 | 1 | | | 1 | 1 |
| Balance disorder | 3 | 3 | | | 3 | 3 |
| Blood lactic acid increased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Bradycardia | | 1 | | | | 1 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | | 1 | | | | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 2 | 2 | | | 2 | 2 |
| Cardiovascular disorder | 4 | 8 | | | 4 | 8 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest pain | 2 | 2 | | | 2 | 2 |
| Cheyne-Stokes respiration | 1 | 1 | | | 1 | 1 |
| Chills | 10 | 10 | | | 10 | 10 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Coma | 1 | 1 | | | 1 | 1 |
| Confusional state | | 2 | | | | 2 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cough | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| COVID-19 pneumonia | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 4 | 5 | | | 4 | 5 |
| Diabetic complication | 1 | 1 | | | 1 | 1 |
| Disorientation | | 1 | | | | 1 |
| Dizziness | 4 | 4 | | | 4 | 4 |
| Dizziness postural | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dry throat | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 7 | 8 | | | 7 | 8 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Dystonia | 1 | 1 | | | 1 | 1 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Eye movement disorder | | 1 | | | | 1 |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fall | 3 | 3 | 1 | 1 | 2 | 2 |
| Fatigue | 12 | 13 | 1 | 2 | 11 | 11 |
| Fibrin D dimer increased | 1 | 1 | | | 1 | 1 |
| Gait disturbance | 2 | 2 | | | 2 | 2 |
| Generalised tonic-clonic seizure | 2 | 2 | | | 2 | 2 |
| General physical health deterioration | 3 | 4 | | | 3 | 4 |
| Glaucoma | 1 | 1 | | | 1 | 1 |
| Headache | 16 | 16 | | | 16 | 16 |
| Heart rate increased | 2 | 2 | | | 2 | 2 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Herpes ophthalmic | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypertension | 2 | 2 | | | 2 | 2 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 1 | 2 | | | 1 | 2 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hyponatraemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 3 | | | 2 | 3 |
| Hypovolaemic shock | | 1 | | | | 1 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | | | 1 | 1 |
| Intestinal ischaemia | | 1 | | | | 1 |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | 1 | 1 | 1 | 1 | | |
| Laryngitis | 1 | 1 | | | 1 | 1 |
| Livedo reticularis | 1 | 1 | | | 1 | 1 |
| Liver function test abnormal | 2 | 3 | | | 2 | 3 |
| Lung infiltration | | 1 | | | | 1 |
| Malaise | 11 | 15 | | | 11 | 15 |
| Metabolic acidosis | | 1 | | | | 1 |
| Musculoskeletal stiffness | 2 | 2 | | | 2 | 2 |
| Myalgia | 11 | 11 | | | 11 | 11 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Nausea | 11 | 11 | | | 11 | 11 |
| Neck pain | 2 | 2 | | | 2 | 2 |
| Nervous system disorder | 2 | 3 | | | 2 | 3 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Neutropenia | | 1 | | | | 1 |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Off label use | 2 | 2 | 2 | 2 | | |
| Oral herpes | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 3 | 4 | | | 3 | 4 |
| Pain in extremity | 2 | 2 | | | 2 | 2 |
| Pallor | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Patient elopement | | 1 | | | | 1 |
| Pharyngeal swelling | 1 | 1 | | | 1 | 1 |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Pneumonitis | 1 | 2 | | | 1 | 2 |
| Presyncope | | 2 | | | | 2 |
| Productive cough | 1 | 1 | | | 1 | 1 |
| Product use issue | 2 | 2 | 2 | 2 | | |
| Pulmonary embolism | | 1 | | | | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pyrexia | 10 | 11 | | | 10 | 11 |
| Rales | 1 | 1 | | | 1 | 1 |
| Renal disorder | | 1 | | | | 1 |
| Renal failure | 2 | 2 | | | 2 | 2 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 1 | 3 | | | 1 | 3 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 1 | 1 | | | 1 | 1 |
| Sedation | 1 | 1 | | | 1 | 1 |
| Septic shock | | 1 | | | | 1 |
| Sneezing | 1 | 1 | 1 | 1 | | |
| Somnolence | 2 | 2 | | | 2 | 2 |
| Staring | | 1 | | | | 1 |
| Sudden death | 5 | 6 | | | 5 | 6 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Tachycardia | | 1 | | | | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachypnoea | 1 | 2 | | | 1 | 2 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Troponin increased | 2 | 2 | | | 2 | 2 |
| Unresponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 4 | 4 | | | 4 | 4 |
| Vaccination site reaction | 4 | 4 | | | 4 | 4 |
| Vertigo | 3 | 3 | | | 3 | 3 |
| Vomiting | 2 | 3 | | | 2 | 3 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 258 | 306 | 12 | 13 | 246 | 293 |

* I=Interval, C=Cumulative
 * AE=Adverse Event
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Country Where Event Occurred

BULGARIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 1 | 2 | 1 | 2 | | |
| Asthenia | | 1 | | 1 | | |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 2 | 3 | 2 | 3 | | |
| Chills | 1 | 2 | 1 | 1 | | 1 |
| Diarrhoea | | 1 | | 1 | | |
| Dizziness | 2 | 3 | 2 | 2 | | 1 |
| Dizziness postural | | 1 | | 1 | | |
| Dyspnoea | | 1 | | | | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Fatigue | | 1 | | 1 | | |
| Gait disturbance | 1 | 1 | 1 | 1 | | |
| Headache | | 2 | | 1 | | 1 |
| Head discomfort | | 1 | | | | 1 |
| Hyperhidrosis | | 1 | | | | 1 |
| Myalgia | | 1 | | 1 | | |
| Nausea | 1 | 2 | 1 | 1 | | 1 |
| Pain | | 1 | | 1 | | |
| Pallor | | 1 | | 1 | | |
| Paraesthesia | | 1 | | 1 | | |
| Paraesthesia oral | | 1 | | 1 | | |
| Peripheral coldness | | 1 | | 1 | | |
| Peripheral sensory neuropathy | 1 | 1 | 1 | 1 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Rash | | 1 | | 1 | | |
| Rash erythematous | | 1 | | 1 | | |
| Rash pruritic | | 1 | | 1 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Swelling | | 1 | | 1 | | |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|--------------------------------|--|--|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site erythema | 2 | 2 | 2 | 2 | | |
| Vaccination site extravasation | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 4 | 3 | 4 | | |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 2 | 2 | 2 | 2 | | |
| Vertigo | | 1 | | | | 1 |
| | 22 | 49 | 21 | 40 | 1 | 9 |

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Country Where Event Occurred

CANADA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Agitation | | 1 | | 1 | | |
| Anaphylactic reaction | 1 | 4 | | | 1 | 4 |
| Aphthous ulcer | | 1 | | 1 | | |
| Arthralgia | 1 | 4 | 1 | 3 | | 1 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | 1 | 1 | | |
| Body temperature increased | | 1 | | 1 | | |
| Cellulitis | | 1 | | | | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 2 | 6 | 2 | 6 | | |
| Circumstance or information capable of leading to medication error | | 1 | | 1 | | |
| Cough | 2 | 2 | 2 | 2 | | |
| Deafness | | 1 | | | | 1 |
| Decreased appetite | 1 | 2 | | 1 | 1 | 1 |
| Diarrhoea | | 5 | | 5 | | |
| Diplopia | 1 | 1 | | | 1 | 1 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Disseminated varicella zoster virus infection | | 1 | | | | 1 |
| Dizziness | 1 | 2 | 1 | 2 | | |
| Dysphagia | | 1 | | 1 | | |
| Dyspnoea | 1 | 2 | 1 | 2 | | |
| Ear discomfort | | 1 | | 1 | | |
| Erythema | | 1 | | | | 1 |
| Exposure during pregnancy | 1 | 3 | 1 | 3 | | |
| Face oedema | | 1 | | | | 1 |
| Facial paralysis | | 1 | | | | 1 |
| Fatigue | 4 | 11 | 4 | 10 | | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Feeling cold | | 1 | | 1 | | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | | |
| Fibromyalgia | | 1 | | 1 | | | |
| Flushing | | 1 | | | | | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | | 1 |
| Gout | | 1 | | 1 | | | |
| Headache | 2 | 10 | 2 | 10 | | | |
| Head discomfort | | 1 | | 1 | | | |
| Herpes zoster | | 1 | | 1 | | | |
| Hypersensitivity | 1 | 1 | 1 | 1 | | | |
| Hypertension | | 1 | | | | | 1 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | | 1 |
| Hypokinesia | | 1 | | 1 | | | |
| Illness | | 1 | | 1 | | | |
| Inappropriate schedule of product administration | 1 | 2 | 1 | 2 | | | |
| Influenza like illness | | 1 | | 1 | | | |
| Insomnia | | 1 | | 1 | | | |
| IVth nerve paralysis | 1 | 1 | | | 1 | | 1 |
| Joint swelling | | 1 | | 1 | | | |
| Lethargy | | 1 | | 1 | | | |
| Leukoplakia | | 1 | | 1 | | | |
| Limb discomfort | 1 | 2 | 1 | 2 | | | |
| Lymphadenopathy | | 2 | | 2 | | | |
| Lymphoedema | | 1 | | 1 | | | |
| Malaise | 1 | 3 | 1 | 3 | | | |
| Maternal exposure during pregnancy | | 2 | | 2 | | | |
| Meningitis aseptic | 1 | 1 | | | 1 | | 1 |
| Myalgia | 2 | 7 | 2 | 6 | | | 1 |
| Nasopharyngitis | | 1 | | 1 | | | |
| Nausea | | 1 | | 1 | | | |
| Neck pain | 1 | 1 | | | 1 | | 1 |
| Oedema | | 1 | | 1 | | | |
| Off label use | 3 | 11 | 3 | 11 | | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Oropharyngeal pain | | 1 | | 1 | | | |
| Overdose | | 1 | | 1 | | | |
| Pain | 1 | 5 | 1 | 5 | | | |
| Pain in extremity | 1 | 4 | | 3 | 1 | 1 | |
| Pain in jaw | 1 | 1 | 1 | 1 | | | |
| Paraesthesia | | 2 | | | | 2 | |
| Paraesthesia oral | 1 | 2 | | | 1 | 2 | |
| Peripheral swelling | | 1 | | 1 | | | |
| Petechiae | | 1 | | 1 | | | |
| Pharyngeal swelling | | 1 | | | | 1 | |
| Pneumonia | 1 | 1 | | | 1 | 1 | |
| Product use issue | 3 | 10 | 3 | 10 | | | |
| Pruritus | | 2 | | 1 | | 1 | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 | |
| Pyrexia | 1 | 6 | 1 | 6 | | | |
| Rash | | 2 | | 1 | | 1 | |
| Rash macular | | 1 | | 1 | | | |
| Rash maculo-papular | 1 | 1 | | | 1 | 1 | |
| Rheumatoid arthritis | | 1 | | | | 1 | |
| Secretion discharge | 1 | 1 | 1 | 1 | | | |
| Sinus pain | | 1 | | 1 | | | |
| Skin injury | | 1 | | 1 | | | |
| Somnolence | | 1 | | 1 | | | |
| Swelling | | 1 | | | | 1 | |
| Swollen tongue | | 1 | | | | 1 | |
| Syncope | | 1 | | | | 1 | |
| Systemic lupus erythematosus | 1 | 1 | | | 1 | 1 | |
| Tachycardia | | 2 | | 1 | | 1 | |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | | |
| Throat irritation | | 2 | | 2 | | | |
| Throat tightness | | 1 | | 1 | | | |
| Upper-airway cough syndrome | 1 | 1 | 1 | 1 | | | |
| Urticaria | | 1 | | 1 | | | |

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|--------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pain | 2 | 7 | 2 | 6 | | 1 |
| Varicella | | 1 | | 1 | | |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vital functions abnormal | | 1 | | | | 1 |
| Vomiting | | 3 | | 3 | | |
| Vulval disorder | | 1 | | | | 1 |
| Wheezing | 2 | 2 | 2 | 2 | | |
| | 58 | 200 | 39 | 153 | 19 | 47 |

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Country Where Event Occurred

CHILE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Abdominal pain upper | | 2 | | 1 | | | 1 |
| Chills | | 1 | | 1 | | | |
| Diarrhoea | | 1 | | 1 | | | |
| Dysbiosis | | 1 | | | | | 1 |
| Headache | | 1 | | 1 | | | |
| Hypersensitivity | | 1 | | 1 | | | |
| Lymph node pain | | 1 | | 1 | | | |
| Malaise | | 1 | | 1 | | | |
| Muscle spasms | | 1 | | 1 | | | |
| Nasal congestion | | 1 | | 1 | | | |
| Nausea | | 2 | | 1 | | | 1 |
| Pain | | 1 | | 1 | | | |
| Pain in extremity | | 1 | | 1 | | | |
| Pancreatitis | | 1 | | | | | 1 |
| Pyrexia | | 1 | | 1 | | | |
| Sensory loss | | 1 | | 1 | | | |
| Synovial cyst | | 1 | | 1 | | | |
| Urine analysis abnormal | | 1 | | | | | 1 |
| | | 20 | | 15 | | | 5 |

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Country Where Event Occurred

COLOMBIA

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Candida infection | | 1 | | 1 |
| Chills | | 1 | | 1 |
| Gingivitis | | 1 | | 1 |
| Hypersensitivity | | 1 | | 1 |
| Leukocytosis | | 1 | | 1 |
| Off label use | | 1 | | 1 |
| Oral candidiasis | | 1 | | 1 |
| Product use issue | | 1 | | 1 |
| Pyrexia | | 1 | | 1 |
| Stomatitis | | 1 | | 1 |
| | | 10 | | 10 |

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Country Where Event Occurred

COSTA RICA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Eye pruritus | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | | | 1 | 1 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Headache | 1 | 2 | | 1 | 1 | 1 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Heart rate irregular | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Insomnia | | 1 | | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Loss of personal independence in daily activities | 1 | 1 | | | 1 | 1 |
| Miosis | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Ocular hyperaemia | 1 | 1 | 1 | 1 | | |
| Red blood cell sedimentation rate increased | | 1 | | 1 | | |
| Sensation of foreign body | 1 | 1 | 1 | 1 | | |
| Sleep disorder | | 1 | | 1 | | |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Tachypnoea | 1 | 1 | 1 | 1 | | |

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|-----------------------|--|--|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thirst | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| Vasculitis | | 1 | | 1 | | |
| | 28 | 34 | 9 | 15 | 19 | 19 |

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Country Where Event Occurred

CROATIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | | 1 | | 1 | | |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angioedema | | 1 | | | | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 2 | 2 | 2 | 2 | | |
| Back pain | 1 | 1 | | | 1 | 1 |
| Body temperature increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Bone pain | 3 | 3 | 3 | 3 | | |
| Bronchospasm | | 1 | | | | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 5 | 6 | 4 | 5 | 1 | 1 |
| COVID-19 | 1 | 1 | 1 | 1 | | |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 2 | 1 | 1 | | 1 |
| Dyspnoea | 2 | 3 | | | 2 | 3 |
| Erythema | 3 | 3 | | | 3 | 3 |
| Extensive swelling of vaccinated limb | 5 | 5 | | | 5 | 5 |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Eyelid ptosis | | 1 | | | | 1 |
| Facial paresis | | 1 | | | | 1 |
| Fatigue | 4 | 5 | 4 | 5 | | |
| Fear | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Fibromyalgia | 1 | 1 | | | 1 | 1 |
| Headache | 11 | 14 | 7 | 9 | 4 | 5 |

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|--------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoaesthesia oral | | 1 | | | | 1 |
| Hypotension | 1 | 1 | 1 | 1 | | |
| Lip disorder | | 1 | | | | 1 |
| Lymphadenitis | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Multi-organ disorder | | 1 | | | | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 6 | 6 | 6 | | |
| Nausea | 2 | 2 | 2 | 2 | | |
| Night sweats | 1 | 1 | 1 | 1 | | |
| Pain | | 1 | | 1 | | |
| Pain in extremity | 3 | 3 | 2 | 2 | 1 | 1 |
| Palpitations | 2 | 2 | 1 | 1 | 1 | 1 |
| Panic attack | 1 | 1 | | | 1 | 1 |
| Paraesthesia | | 1 | | | | 1 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Pharyngeal paraesthesia | | 1 | | | | 1 |
| Pharyngeal swelling | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | 1 | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | 1 | 1 | | |
| Pyrexia | 9 | 11 | 8 | 10 | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 1 | 1 | | | 1 | 1 |
| Respiratory tract oedema | | 1 | | | | 1 |
| Skin oedema | 1 | 1 | 1 | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Swelling face | | 1 | | | | 1 |
| Swollen tongue | | 1 | | | | 1 |
| Tachycardia | 3 | 3 | 2 | 2 | 1 | 1 |
| Tachypnoea | | 1 | | | | 1 |
| Tinnitus | 1 | 1 | 1 | 1 | | |

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|---------------------------|--|--|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tongue oedema | | 1 | | | | 1 |
| Tremor | 1 | 2 | 1 | 1 | | 1 |
| Type I hypersensitivity | 3 | 3 | | | 3 | 3 |
| Vaccination site erythema | 7 | 7 | 5 | 5 | 2 | 2 |
| Vaccination site oedema | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site pain | 14 | 15 | 11 | 11 | 3 | 4 |
| Vaccination site swelling | 5 | 5 | 4 | 4 | 1 | 1 |
| Wheezing | | 1 | | | | 1 |
| | 126 | 157 | 81 | 89 | 45 | 68 |

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Country Where Event Occurred

CYPRUS

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Cervix oedema | | 1 | | 1 | | |
| Chills | 2 | 2 | 2 | 2 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Dizziness | 2 | 2 | 2 | 2 | | |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 2 | 2 | 2 | 2 | | |
| Face oedema | 1 | 1 | 1 | 1 | | |
| Facial paresis | 1 | 2 | | | 1 | 2 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 2 | 1 | 2 | | |
| Hypersensitivity | | 1 | | 1 | | |
| Hypertension | | 1 | | | | 1 |
| Hypoacusis | 1 | 1 | 1 | 1 | | |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 4 | 4 | 4 | 4 | | |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Myocardial infarction | | 1 | | | | 1 |
| Nasal congestion | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Rash | | 1 | | 1 | | |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachyarrhythmia | | 1 | | | | 1 |
| Tachycardia | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-----------------------|--|--|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vasculitis | 1 | 1 | 1 | 1 | | |
| | 33 | 42 | 26 | 30 | 7 | 12 |

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Country Where Event Occurred

CZECH REPUBLIC

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergy to vaccine | | 2 | | | | 2 |
| Anaesthesia oral | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | | 1 | | | | 1 |
| Anxiety | 1 | 2 | | 1 | 1 | 1 |
| Apathy | 2 | 2 | 1 | 1 | 1 | 1 |
| Application site coldness | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 5 | 6 | 4 | 5 | 1 | 1 |
| Asthenia | 6 | 7 | 3 | 4 | 3 | 3 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 | | |
| Bacterial rhinitis | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | | 1 | | | | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Chills | 8 | 9 | 7 | 7 | 1 | 2 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Communication disorder | 1 | 1 | | | 1 | 1 |
| Condition aggravated | 1 | 1 | 1 | 1 | | |
| Confusional state | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 1 | 1 | 1 | 1 |
| COVID-19 | 3 | 3 | | | 3 | 3 |
| COVID-19 pneumonia | 2 | 2 | | | 2 | 2 |
| Deafness bilateral | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 2 | 2 | 2 | 2 | | |
| Delirium | 1 | 1 | | | 1 | 1 |
| Dermatitis | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 2 | 4 | 2 | 3 | | 1 |
| Drug ineffective | 2 | 2 | | | 2 | 2 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dysphagia | | 1 | | 1 | | |
| Dyspnoea | 3 | 5 | 2 | 3 | 1 | 2 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Ear swelling | 1 | 1 | | | 1 | 1 |
| Eating disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Erythema | 3 | 5 | | 2 | 3 | 3 |
| Fatigue | 13 | 15 | 9 | 11 | 4 | 4 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Flushing | 1 | 1 | | | 1 | 1 |
| Gastrointestinal hypermotility | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 2 | 2 | | | 2 | 2 |
| Hallucination | 1 | 1 | | | 1 | 1 |
| Headache | 10 | 11 | 7 | 8 | 3 | 3 |
| Head discomfort | 1 | 1 | | | 1 | 1 |
| Hyperphagia | 1 | 1 | 1 | 1 | | |
| Hypersensitivity | 1 | 1 | 1 | 1 | | |
| Hypersomnia | 1 | 1 | | | 1 | 1 |
| Hypertension | 2 | 3 | | 1 | 2 | 2 |
| Hyperventilation | | 1 | | 1 | | |
| Hypoaesthesia | 2 | 3 | | 1 | 2 | 2 |
| Hypoaesthesia oral | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 1 | 1 | 1 | 1 | | |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 2 | 1 | 1 | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoxia | 2 | 2 | | | 2 | 2 |
| Illness | 1 | 1 | | | 1 | 1 |
| Illusion | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Influenza like illness | 3 | 3 | 2 | 2 | 1 | 1 |
| Jaundice | 1 | 1 | 1 | 1 | | |
| Joint effusion | 1 | 1 | | | 1 | 1 |
| Joint stiffness | | 1 | | 1 | | |
| Language disorder | 1 | 1 | | | 1 | 1 |
| Lip swelling | | 1 | | | | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 4 | 4 | 2 | 2 | 2 | 2 |
| Malaise | 2 | 3 | 2 | 3 | | |
| Memory impairment | 1 | 1 | | | 1 | 1 |
| Migraine | 1 | 1 | 1 | 1 | | |
| Mucosal disorder | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 2 | 2 | | | 2 | 2 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal pain | | 1 | | 1 | | |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | 7 | 7 | 6 | 6 | 1 | 1 |
| Nausea | 6 | 8 | 4 | 5 | 2 | 3 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Off label use | 4 | 4 | 4 | 4 | | |
| Oral pruritus | | 1 | | 1 | | |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 2 | 4 | 2 | 3 | | 1 |
| Paraesthesia oral | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 2 | 2 | 2 | 2 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Peripheral swelling | | 1 | | | | 1 | |
| Pharyngeal oedema | 1 | 2 | | 1 | 1 | 1 | |
| Photophobia | | 1 | | 1 | | | |
| Polyarthritits | 1 | 1 | | | 1 | 1 | |
| Poor quality product administered | 1 | 1 | 1 | 1 | | | |
| Presyncope | 1 | 1 | | | 1 | 1 | |
| Product preparation error | 1 | 1 | 1 | 1 | | | |
| Product use issue | 4 | 4 | 4 | 4 | | | |
| Pruritus | 3 | 4 | 1 | 2 | 2 | 2 | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 | |
| Pyrexia | 15 | 15 | 7 | 7 | 8 | 8 | |
| Rash | 3 | 4 | | 1 | 3 | 3 | |
| Rash pruritic | 1 | 1 | | | 1 | 1 | |
| Respiration abnormal | 1 | 1 | | | 1 | 1 | |
| Respiratory acidosis | 1 | 1 | 1 | 1 | | | |
| Respiratory disorder | 1 | 1 | | | 1 | 1 | |
| Respiratory failure | 1 | 1 | | | 1 | 1 | |
| Restlessness | 1 | 1 | 1 | 1 | | | |
| Sepsis | 1 | 1 | | | 1 | 1 | |
| Skin disorder | 1 | 1 | | | 1 | 1 | |
| Spinal pain | 1 | 1 | | | 1 | 1 | |
| Swelling | | 1 | | | | 1 | |
| Swelling face | | 1 | | | | 1 | |
| Swollen tongue | | 1 | | | | 1 | |
| Tachycardia | 2 | 3 | 1 | 2 | 1 | 1 | |
| Tachypnoea | | 1 | | | | 1 | |
| Tension headache | 2 | 2 | 1 | 1 | 1 | 1 | |
| Throat tightness | | 1 | | | | 1 | |
| Tremor | 1 | 1 | 1 | 1 | | | |
| Vaccination failure | 1 | 1 | | | 1 | 1 | |
| Vaccination site erythema | 4 | 4 | 3 | 3 | 1 | 1 | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | | |
| Vaccination site pain | 5 | 5 | 5 | 5 | | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 2 | 2 | 2 | 2 | | |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | 1 | 1 | | |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vertigo | 5 | 5 | 4 | 4 | 1 | 1 |
| Vision blurred | 2 | 3 | 2 | 3 | | |
| Vomiting | 5 | 6 | 3 | 3 | 2 | 3 |
| Wheezing | 1 | 1 | 1 | 1 | | |
| | 241 | 286 | 124 | 151 | 117 | 135 |

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Country Where Event Occurred

DENMARK

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Acute leukaemia | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Aggression | | 1 | | | | 1 |
| Alanine aminotransferase increased | 1 | 1 | 1 | 1 | | |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Anaemia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 3 | | | 2 | 3 |
| Angioedema | | 3 | | | | 3 |
| Arthralgia | 3 | 3 | 2 | 2 | 1 | 1 |
| Aspiration | | 1 | | | | 1 |
| Asthenia | 2 | 3 | | 1 | 2 | 2 |
| Atrial fibrillation | 1 | 1 | | | 1 | 1 |
| Atrial flutter | | 1 | | | | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bacteraemia | | 1 | | | | 1 |
| Blood albumin decreased | 1 | 1 | 1 | 1 | | |
| Blood chloride increased | 1 | 1 | 1 | 1 | | |
| Blood creatine phosphokinase increased | 1 | 1 | | | 1 | 1 |
| Blood creatinine increased | 1 | 1 | | | 1 | 1 |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Blood pressure systolic increased | | 1 | | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bronchospasm | | 1 | | | | 1 |
| Calcium ionised increased | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | | 1 | | | | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiogenic shock | 1 | 1 | | | 1 | 1 |
| Cerebral thrombosis | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 2 | 3 | | | 2 | 3 |
| Chest pain | 5 | 5 | 2 | 2 | 3 | 3 |
| Chills | 5 | 6 | 2 | 2 | 3 | 4 |
| Chorioretinitis | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 2 | 3 | | | 2 | 3 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Coma | | 1 | | | | 1 |
| Condition aggravated | 4 | 6 | | | 4 | 6 |
| Confusional state | 2 | 2 | 1 | 1 | 1 | 1 |
| Coordination abnormal | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 4 | | 1 | 1 | 3 |
| COVID-19 | 4 | 4 | | | 4 | 4 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Crying | 1 | 1 | | | 1 | 1 |
| Death | 2 | 3 | | | 2 | 3 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Delusion | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 2 | | | 1 | 2 |
| Dermatitis allergic | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Discomfort | | 2 | | | | 2 |
| Disturbance in attention | | 1 | | | | 1 |
| Dizziness | 12 | 15 | 5 | 6 | 7 | 9 |
| Drug ineffective | 3 | 3 | | | 3 | 3 |
| Dry eye | | 1 | | 1 | | |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 13 | 20 | 2 | 3 | 11 | 17 |
| Dyspnoea at rest | | 1 | | | | 1 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Erysipelas | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Erythema | 3 | 4 | 2 | 3 | 1 | 1 |
| Eye pain | | 1 | | 1 | | |
| Eye pruritus | | 2 | | 2 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 15 | 19 | 9 | 9 | 6 | 10 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling cold | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | 1 | 1 | | |
| Fluid intake reduced | | 1 | | 1 | | |
| Flushing | | 1 | | | | 1 |
| Foaming at mouth | 1 | 2 | | 1 | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 4 | 7 | | | 4 | 7 |
| Glomerular filtration rate decreased | 1 | 1 | | | 1 | 1 |
| Haemorrhage intracranial | 1 | 1 | | | 1 | 1 |
| Hallucination, visual | 1 | 1 | | | 1 | 1 |
| Headache | 20 | 25 | 10 | 12 | 10 | 13 |
| Head discomfort | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 2 | | | 1 | 2 |
| Hemiparesis | | 1 | | | | 1 |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Hyperacusis | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 2 | | 1 | 1 | 1 |
| Hypersensitivity | 2 | 3 | 1 | 1 | 1 | 2 |
| Hypersomnia | 1 | 1 | 1 | 1 | | |
| Hypertension | 3 | 3 | 1 | 1 | 2 | 2 |
| Hypoglycaemia | 1 | 1 | 1 | 1 | | |
| Hypophagia | 1 | 2 | 1 | 2 | | |
| Hypotension | 2 | 4 | 1 | 1 | 1 | 3 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | | 1 | | 1 | | |
| Infection | | 1 | | | | 1 |
| Influenza | 2 | 2 | 1 | 1 | 1 | 1 |

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|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Injection site pain | | 1 | | 1 | | |
| Joint stiffness | 1 | 1 | | | 1 | 1 |
| Joint swelling | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 3 | 3 | 1 | 1 | 2 | 2 |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 15 | 19 | 7 | 9 | 8 | 10 |
| Micturition urgency | 1 | 1 | | | 1 | 1 |
| Mobility decreased | | 1 | | | | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 9 | 4 | 6 | 2 | 3 |
| Myelitis | 1 | 1 | | | 1 | 1 |
| Nasal congestion | | 1 | | 1 | | |
| Nausea | 16 | 19 | 9 | 12 | 7 | 7 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| Obliterative bronchiolitis | 1 | 1 | | | 1 | 1 |
| Obstructive airways disorder | | 1 | | | | 1 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Off label use | 5 | 5 | 5 | 5 | | |
| Oral mucosal eruption | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 1 | 2 | | | 1 | 2 |
| Pain | 1 | 2 | 1 | 1 | | 1 |
| Painful respiration | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 2 | 1 | 1 | 1 | 1 |
| Pallor | 2 | 3 | | 1 | 2 | 2 |
| Palpitations | 1 | 2 | 1 | 1 | | 1 |
| Paraesthesia | 4 | 4 | 2 | 2 | 2 | 2 |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Periarthritis | 1 | 1 | 1 | 1 | | |
| Periorbital swelling | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pharyngeal paraesthesia | 1 | 1 | 1 | 1 | | |
| Pharyngeal swelling | 1 | 1 | 1 | 1 | | |
| Photophobia | 1 | 1 | | | 1 | 1 |
| Photopsia | 2 | 2 | | | 2 | 2 |
| Pleural effusion | 1 | 2 | | | 1 | 2 |
| Pneumonia | 5 | 5 | | | 5 | 5 |
| Pneumonia aspiration | | 1 | | | | 1 |
| Pneumonia bacterial | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product use issue | 5 | 5 | 5 | 5 | | |
| Prolonged expiration | | 1 | | | | 1 |
| Pruritus | 3 | 5 | 2 | 4 | 1 | 1 |
| Pulmonary arterial hypertension | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pulmonary fibrosis | | 1 | | | | 1 |
| Pulmonary oedema | 2 | 3 | | | 2 | 3 |
| Pyrexia | 17 | 25 | 6 | 8 | 11 | 17 |
| Rales | | 1 | | | | 1 |
| Rash | 1 | 3 | 1 | 2 | | 1 |
| Rash erythematous | 1 | 2 | 1 | 1 | | 1 |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Respiratory acidosis | 1 | 1 | | | 1 | 1 |
| Respiratory arrest | | 1 | | | | 1 |
| Respiratory failure | 5 | 6 | | | 5 | 6 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Salivary hypersecretion | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 2 | 2 | 1 | 1 | 1 | 1 |
| Sensory disturbance | 1 | 1 | 1 | 1 | | |
| Sepsis | | 1 | | | | 1 |
| Sinus tachycardia | 1 | 1 | 1 | 1 | | |
| Somnolence | | 1 | | | | 1 |
| Stridor | | 1 | | | | 1 |
| Sudden cardiac death | 1 | 1 | | | 1 | 1 |

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|-------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Sudden death | 2 | 3 | | | 2 | 3 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swelling face | 2 | 3 | 1 | 1 | 1 | 2 |
| Swelling of eyelid | | 1 | | 1 | | |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | | 1 | | | | 1 |
| Tachypnoea | 1 | 2 | | | 1 | 2 |
| Tenderness | 2 | 2 | 2 | 2 | | |
| Throat irritation | | 1 | | 1 | | |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Troponin I increased | 1 | 1 | | | 1 | 1 |
| Urticaria | 2 | 3 | 2 | 3 | | |
| Vaccination site erythema | 5 | 6 | 4 | 5 | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site mass | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 12 | 20 | 10 | 16 | 2 | 4 |
| Vaccination site pruritus | 1 | 2 | 1 | 2 | | |
| Vaccination site rash | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | 4 | 5 | 3 | 4 | 1 | 1 |
| Vaccination site warmth | 2 | 2 | 2 | 2 | | |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Vomiting | 6 | 10 | 2 | 3 | 4 | 7 |
| | 350 | 480 | 149 | 194 | 201 | 286 |

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Country Where Event Occurred

ESTONIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 4 | 4 | 2 | 2 | 2 | 2 |
| Bone pain | 1 | 1 | | | 1 | 1 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | 3 | 3 | 1 | 1 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 2 | 2 | 2 | | |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Flushing | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 4 | 3 | 3 | 1 | 1 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Insomnia | 1 | 1 | 1 | 1 | | |
| Intranasal paraesthesia | 1 | 1 | 1 | 1 | | |
| Malaise | 4 | 4 | 2 | 2 | 2 | 2 |
| Migraine with aura | 1 | 1 | 1 | 1 | | |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Nausea | 3 | 3 | 2 | 2 | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oral herpes | 1 | 1 | 1 | 1 | | |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-------------------------|--|--|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pallor | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 3 | 3 | 3 | 3 | | |
| Paraesthesia oral | 2 | 2 | 2 | 2 | | |
| Pharyngeal paraesthesia | 1 | 1 | 1 | 1 | | |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pulmonary embolism | 1 | 1 | | | 1 | 1 |
| Pyrexia | 3 | 3 | 2 | 2 | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| | 67 | 67 | 42 | 42 | 25 | 25 |

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Country Where Event Occurred

FINLAND

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | 1 | 1 | | | 1 | 1 |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anaphylactic shock | | 1 | | | | 1 |
| Ankylosing spondylitis | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Aphonia | 1 | 1 | | | 1 | 1 |
| Apnoea | 1 | 1 | | | 1 | 1 |
| Arthralgia | 5 | 5 | | | 5 | 5 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Arthritis reactive | 1 | 1 | | | 1 | 1 |
| Asthenia | 6 | 6 | | | 6 | 6 |
| Asthenopia | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Axillary pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Back pain | 2 | 2 | | | 2 | 2 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| Burning sensation | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 3 | | | 1 | 3 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 2 | 2 | | | 2 | 2 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Confusional state | 1 | 1 | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Congestive cardiomyopathy | 1 | 1 | | | 1 | 1 |
| Cough | 2 | 3 | | | 2 | 3 |
| C-reactive protein increased | 5 | 5 | | | 5 | 5 |
| Death | 3 | 3 | | | 3 | 3 |
| Dementia Alzheimer's type | 1 | 2 | | | 1 | 2 |
| Derealisation | | 1 | | 1 | | |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Dizziness | 5 | 5 | | | 5 | 5 |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysphagia | 3 | 3 | | | 3 | 3 |
| Dyspnoea | 12 | 14 | | | 12 | 14 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Erythema | 2 | 3 | | | 2 | 3 |
| Erythema multiforme | 1 | 1 | | | 1 | 1 |
| Extensive swelling of vaccinated limb | 1 | 1 | 1 | 1 | | |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Eyelid ptosis | 1 | 1 | | | 1 | 1 |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Facial paralysis | 3 | 3 | | | 3 | 3 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 8 | 9 | 1 | 1 | 7 | 8 |
| Feeling abnormal | 1 | 1 | | | 1 | 1 |
| Feeling cold | 1 | 2 | | 1 | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Flatulence | 1 | 1 | 1 | 1 | | |
| Flushing | 1 | 1 | | | 1 | 1 |
| Foaming at mouth | 1 | 1 | | | 1 | 1 |
| Gastric disorder | 1 | 1 | 1 | 1 | | |
| Gaze palsy | 2 | 2 | | | 2 | 2 |
| General physical health deterioration | 5 | 5 | | | 5 | 5 |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Gingival swelling | 1 | 1 | 1 | 1 | | |
| Headache | 12 | 14 | 1 | 1 | 11 | 13 |
| Head discomfort | 1 | 1 | | | 1 | 1 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 2 | | | 1 | 2 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Hemianaesthesia | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 2 | 2 | | | 2 | 2 |
| Hypersensitivity | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 2 | | 1 | 1 | 1 |
| Hypoaesthesia oral | 2 | 2 | | | 2 | 2 |
| Hypokalaemia | 2 | 4 | | | 2 | 4 |
| Hypotonia | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | 2 | 2 | 2 | 2 | | |
| Increased upper airway secretion | 3 | 3 | | | 3 | 3 |
| Inflammatory marker increased | 1 | 1 | | | 1 | 1 |
| Insomnia | 1 | 1 | | | 1 | 1 |
| Lip pain | 2 | 2 | 2 | 2 | | |
| Lip swelling | 1 | 1 | 1 | 1 | | |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Loss of control of legs | 1 | 1 | | | 1 | 1 |
| Loss of personal independence in daily activities | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | | | 1 | 1 |
| Malaise | 4 | 7 | | 2 | 4 | 5 |
| Middle insomnia | 2 | 2 | 1 | 1 | 1 | 1 |
| Migraine | 1 | 2 | | | 1 | 2 |
| Mobility decreased | 1 | 1 | | | 1 | 1 |
| Muscle spasticity | 1 | 1 | | | 1 | 1 |
| Muscle twitching | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscular weakness | 2 | 2 | | | 2 | 2 |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal pain | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 6 | 7 | | 1 | 6 | 6 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Nausea | 9 | 10 | | | 9 | 10 |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Neurological symptom | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Opisthotonus | 1 | 1 | | | 1 | 1 |
| Oral discomfort | 1 | 1 | 1 | 1 | | |
| Oral disorder | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | | | 1 | 1 |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 4 | 5 | | 1 | 4 | 4 |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pallor | 2 | 2 | | | 2 | 2 |
| Palpitations | 3 | 3 | | | 3 | 3 |
| Papule | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 4 | 5 | 1 | 1 | 3 | 4 |
| Paraesthesia oral | 2 | 2 | | | 2 | 2 |
| Pharyngeal oedema | | 1 | | | | 1 |
| Pharyngeal swelling | 2 | 3 | | | 2 | 3 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Presyncope | | 1 | | 1 | | |
| Productive cough | 1 | 1 | | | 1 | 1 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pruritus | 2 | 2 | 1 | 1 | 1 | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pyrexia | 18 | 19 | | 1 | 18 | 18 |
| Rash | | 1 | | | | 1 |
| Rash erythematous | 1 | 2 | | 1 | 1 | 1 |

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|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Rhinitis | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | | | 1 | 1 |
| Rhonchi | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 2 | | | 1 | 2 |
| Sensation of foreign body | 2 | 2 | | | 2 | 2 |
| Sinus tachycardia | 1 | 1 | | | 1 | 1 |
| Slow speech | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Stiff tongue | 1 | 1 | | | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Subcutaneous abscess | 1 | 1 | | | 1 | 1 |
| Sudden death | 2 | 2 | | | 2 | 2 |
| Swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Swelling face | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 2 | | | 1 | 2 |
| Synovial fluid white blood cells positive | 1 | 1 | | | 1 | 1 |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis superficial | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Toothache | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 2 | | | 1 | 2 |
| Urticaria | 2 | 3 | 2 | 2 | | 1 |
| Vaccination site erythema | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site haematoma | 1 | 1 | 1 | 1 | | |
| Vaccination site hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site joint movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site movement impairment | 2 | 2 | | | 2 | 2 |
| Vaccination site oedema | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site pain | 8 | 8 | 1 | 1 | 7 | 7 |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |

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|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Viral infection | 2 | 2 | | | 2 | 2 |
| Visual impairment | 2 | 2 | | | 2 | 2 |
| Vomiting | 3 | 4 | | | 3 | 4 |
| Wheezing | 2 | 2 | | | 2 | 2 |
| | 307 | 343 | 36 | 46 | 271 | 297 |

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Country Where Event Occurred

FRANCE

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Abdominal pain | 12 | 13 | 6 | 6 | 6 | 7 |
| Abdominal pain upper | 4 | 4 | 1 | 1 | 3 | 3 |
| Abnormal behaviour | 1 | 1 | | | 1 | 1 |
| Acute abdomen | 1 | 1 | | | 1 | 1 |
| Acute coronary syndrome | 4 | 4 | | | 4 | 4 |
| Acute febrile neutrophilic dermatosis | 1 | 1 | | | 1 | 1 |
| Acute kidney injury | 6 | 6 | | | 6 | 6 |
| Acute myocardial infarction | 1 | 1 | | | 1 | 1 |
| Acute pulmonary oedema | 7 | 7 | | | 7 | 7 |
| Acute respiratory distress syndrome | 4 | 5 | | | 4 | 5 |
| Acute respiratory failure | 4 | 5 | | | 4 | 5 |
| Adult failure to thrive | 1 | 1 | | | 1 | 1 |
| Aerococcus urinae infection | 1 | 1 | | | 1 | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 7 | 7 | 3 | 3 | 4 | 4 |
| Alanine aminotransferase increased | 2 | 2 | 2 | 2 | | |
| Altered state of consciousness | 4 | 4 | | | 4 | 4 |
| Anaemia | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 5 | 5 | | | 5 | 5 |
| Anaphylactic shock | 3 | 4 | | | 3 | 4 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 2 | 2 | | | 2 | 2 |
| Angioedema | 3 | 4 | | | 3 | 4 |
| Ankylosing spondylitis | 2 | 2 | | | 2 | 2 |
| Anuria | 1 | 1 | | | 1 | 1 |
| Anxiety | 2 | 4 | | | 2 | 4 |
| Anxiety disorder | 1 | 1 | 1 | 1 | | |
| Aphasia | 2 | 2 | | | 2 | 2 |
| Aphonia | 1 | 1 | | | 1 | 1 |

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|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aphthous ulcer | 2 | 2 | 1 | 1 | 1 | 1 |
| Arrhythmia | 6 | 8 | | | 6 | 8 |
| Arrhythmia supraventricular | 1 | 2 | | | 1 | 2 |
| Arthralgia | 12 | 12 | 6 | 6 | 6 | 6 |
| Aspartate aminotransferase increased | 2 | 2 | 2 | 2 | | |
| Asthenia | 56 | 56 | 20 | 20 | 36 | 36 |
| Asthma | 4 | 4 | | | 4 | 4 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 2 | 2 | | | 2 | 2 |
| Atrial fibrillation | 7 | 9 | | | 7 | 9 |
| Atrial flutter | 2 | 2 | | | 2 | 2 |
| Atrioventricular block | 1 | 1 | | | 1 | 1 |
| Atrioventricular block complete | 2 | 2 | | | 2 | 2 |
| Axillary pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Back pain | 1 | 1 | | | 1 | 1 |
| Bacterial infection | 1 | 1 | | | 1 | 1 |
| Balance disorder | 3 | 3 | | | 3 | 3 |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Behaviour disorder | 1 | 1 | | | 1 | 1 |
| Benign breast neoplasm | 1 | 1 | 1 | 1 | | |
| Bipolar disorder | 1 | 1 | | | 1 | 1 |
| Blood alkaline phosphatase increased | 2 | 2 | 2 | 2 | | |
| Blood glucose increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Blood pressure decreased | 2 | 2 | | | 2 | 2 |
| Blood pressure increased | 6 | 6 | 1 | 1 | 5 | 5 |
| Blood pressure systolic increased | 1 | 2 | | | 1 | 2 |
| Blood thyroid stimulating hormone increased | 1 | 1 | 1 | 1 | | |
| Blood uric acid increased | | 1 | | 1 | | |
| Body temperature decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| Bradycardia | 4 | 4 | | | 4 | 4 |
| Brain natriuretic peptide increased | 1 | 1 | | | 1 | 1 |
| Breast swelling | 1 | 1 | 1 | 1 | | |
| Bronchial obstruction | | 1 | | | | 1 |

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bronchiolitis | 1 | 1 | | | 1 | 1 |
| Bronchopneumopathy | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 4 | 4 | | | 4 | 4 |
| Bundle branch block | 1 | 1 | | | 1 | 1 |
| Bundle branch block left | 1 | 1 | | | 1 | 1 |
| Bundle branch block right | 2 | 2 | | | 2 | 2 |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Bursal fluid accumulation | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 2 | 3 | | | 2 | 3 |
| Cardiac failure | 18 | 20 | | | 18 | 20 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cardiac failure congestive | 1 | 1 | | | 1 | 1 |
| Cardiac flutter | 1 | 1 | | | 1 | 1 |
| Cardiogenic shock | 3 | 3 | | | 3 | 3 |
| Cardiomegaly | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 |
| Cardio-respiratory arrest | 4 | 5 | | | 4 | 5 |
| Cardiovascular disorder | 1 | 1 | | | 1 | 1 |
| Central nervous system lesion | 1 | 1 | | | 1 | 1 |
| Cerebellar syndrome | 1 | 1 | | | 1 | 1 |
| Cerebral artery stenosis | 1 | 1 | | | 1 | 1 |
| Cerebral haematoma | 2 | 2 | | | 2 | 2 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 6 | 8 | | | 6 | 8 |
| Chest discomfort | 8 | 8 | 3 | 3 | 5 | 5 |
| Chest injury | 1 | 1 | | | 1 | 1 |
| Chest pain | 10 | 11 | 2 | 2 | 8 | 9 |
| Chills | 22 | 23 | 5 | 6 | 17 | 17 |
| Chronic obstructive pulmonary disease | 3 | 3 | | | 3 | 3 |
| Circulatory collapse | 2 | 2 | | | 2 | 2 |
| Cognitive disorder | 1 | 2 | 1 | 1 | | 1 |
| Coma | 3 | 3 | | | 3 | 3 |
| Condition aggravated | 2 | 3 | 1 | 1 | 1 | 2 |

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusional state | 6 | 7 | | | 6 | 7 |
| Conjunctival haemorrhage | 3 | 3 | | | 3 | 3 |
| Conjunctivitis | 1 | 1 | | | 1 | 1 |
| Constipation | 1 | 2 | 1 | 2 | | |
| Coronary artery disease | 1 | 1 | | | 1 | 1 |
| Coronary artery stenosis | 1 | 1 | | | 1 | 1 |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| Cough | 10 | 10 | 3 | 3 | 7 | 7 |
| COVID-19 | 19 | 19 | 1 | 1 | 18 | 18 |
| COVID-19 pneumonia | 2 | 2 | | | 2 | 2 |
| C-reactive protein increased | 7 | 9 | 4 | 5 | 3 | 4 |
| Creatinine renal clearance decreased | 1 | 1 | | | 1 | 1 |
| Crepitations | 1 | 1 | | | 1 | 1 |
| Cyanosis | 4 | 4 | | | 4 | 4 |
| Cystitis klebsiella | 1 | 1 | | | 1 | 1 |
| Deafness unilateral | 1 | 1 | | | 1 | 1 |
| Death | 34 | 38 | | | 34 | 38 |
| Decreased appetite | 5 | 6 | 3 | 4 | 2 | 2 |
| Deep vein thrombosis | 2 | 2 | | | 2 | 2 |
| Dehydration | 5 | 5 | 1 | 1 | 4 | 4 |
| Delirium | 1 | 1 | | | 1 | 1 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 5 | 6 | | | 5 | 6 |
| Depression | 1 | 1 | 1 | 1 | | |
| Dermo-hypodermatitis | 1 | 1 | | | 1 | 1 |
| Diabetes mellitus | 2 | 2 | | | 2 | 2 |
| Diabetic ketoacidosis | 3 | 3 | | | 3 | 3 |
| Diabetic ketosis | 1 | 1 | | | 1 | 1 |
| Diabetic metabolic decompensation | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 18 | 20 | 6 | 6 | 12 | 14 |
| Diarrhoea haemorrhagic | 1 | 1 | | | 1 | 1 |
| Discomfort | 9 | 9 | | | 9 | 9 |
| Disease progression | 1 | 1 | | | 1 | 1 |

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|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disease recurrence | 13 | 13 | 1 | 1 | 12 | 12 |
| Disorientation | 3 | 3 | 1 | 1 | 2 | 2 |
| Disturbance in attention | 3 | 3 | 1 | 1 | 2 | 2 |
| Dizziness | 16 | 16 | 6 | 6 | 10 | 10 |
| Dizziness postural | 1 | 1 | | | 1 | 1 |
| Drug hypersensitivity | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 14 | 14 | | | 14 | 14 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dysaesthesia | 1 | 1 | 1 | 1 | | |
| Dysarthria | 2 | 3 | | | 2 | 3 |
| Dysgeusia | 6 | 6 | 2 | 2 | 4 | 4 |
| Dyslipidaemia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 5 | 6 | 1 | 1 | 4 | 5 |
| Dysphemia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 36 | 38 | 3 | 3 | 33 | 35 |
| Dyspnoea exertional | 2 | 2 | 1 | 1 | 1 | 1 |
| Eating disorder | 1 | 1 | | | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | 1 | | | 1 | 1 |
| Electrocardiogram T wave inversion | 1 | 1 | | | 1 | 1 |
| Encephalitis | 1 | 1 | | | 1 | 1 |
| Eosinophil count increased | 1 | 1 | 1 | 1 | | |
| Epilepsy | 4 | 4 | | | 4 | 4 |
| Epstein-Barr virus test positive | 1 | 1 | 1 | 1 | | |
| Eructation | 1 | 1 | | | 1 | 1 |
| Erysipelas | 2 | 2 | | | 2 | 2 |
| Erythema | 16 | 16 | 6 | 6 | 10 | 10 |
| Erythema of eyelid | 1 | 1 | | | 1 | 1 |
| Escherichia urinary tract infection | 1 | 1 | | | 1 | 1 |
| Extensor plantar response | 1 | 1 | | | 1 | 1 |
| Eye disorder | 1 | 1 | | | 1 | 1 |
| Eyelid haematoma | 1 | 1 | 1 | 1 | | |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid ptosis | 1 | 1 | | | 1 | 1 |
| Face oedema | 6 | 6 | | | 6 | 6 |
| Facial paralysis | 12 | 12 | | | 12 | 12 |
| Facial paresis | 2 | 2 | | | 2 | 2 |
| Faecal vomiting | 2 | 2 | | | 2 | 2 |
| Fall | 12 | 13 | 4 | 4 | 8 | 9 |
| Fatigue | 33 | 34 | 15 | 16 | 18 | 18 |
| Fat tissue increased | 1 | 1 | 1 | 1 | | |
| Fear | | 1 | | | | 1 |
| Feeling abnormal | 2 | 2 | 2 | 2 | | |
| Feeling cold | 4 | 4 | 2 | 2 | 2 | 2 |
| Feeling hot | 4 | 4 | 1 | 1 | 3 | 3 |
| Flushing | 5 | 5 | 2 | 2 | 3 | 3 |
| Foaming at mouth | 1 | 1 | | | 1 | 1 |
| Frostbite | 1 | 1 | 1 | 1 | | |
| Gait disturbance | 4 | 4 | 2 | 2 | 2 | 2 |
| Gamma-glutamyltransferase increased | 2 | 2 | 2 | 2 | | |
| Gastric volvulus | 1 | 1 | | | 1 | 1 |
| Gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Gaze palsy | 1 | 1 | | | 1 | 1 |
| Generalised oedema | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 8 | 8 | | | 8 | 8 |
| Glomerular filtration rate decreased | 1 | 1 | | | 1 | 1 |
| Glycosylated haemoglobin increased | | 1 | | 1 | | |
| Gout | 1 | 1 | | | 1 | 1 |
| Haemarthrosis | 1 | 1 | | | 1 | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haematochezia | 1 | 1 | | | 1 | 1 |
| Haematoma | 2 | 2 | | | 2 | 2 |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Haemodynamic instability | 1 | 1 | 1 | 1 | | |
| Haemoglobin decreased | 1 | 1 | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haemorrhagic stroke | 1 | 2 | | | 1 | 2 |
| Hallucinations, mixed | 1 | 1 | | | 1 | 1 |
| Headache | 50 | 53 | 16 | 19 | 34 | 34 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Head injury | 2 | 2 | | | 2 | 2 |
| Heart rate increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Heart sounds abnormal | 1 | 1 | | | 1 | 1 |
| Hemianopia homonymous | 1 | 1 | | | 1 | 1 |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hemiplegia | 5 | 5 | | | 5 | 5 |
| Hepatic function abnormal | 1 | 1 | 1 | 1 | | |
| Herpes zoster | 5 | 5 | 1 | 1 | 4 | 4 |
| High-pitched crying | 1 | 1 | 1 | 1 | | |
| Hoffmann's sign | 1 | 1 | 1 | 1 | | |
| Horner's syndrome | 1 | 1 | | | 1 | 1 |
| Hot flush | 4 | 4 | 1 | 1 | 3 | 3 |
| Hyperglycaemia | 2 | 2 | 1 | 1 | 1 | 1 |
| Hyperglycinaemia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 8 | 8 | 1 | 1 | 7 | 7 |
| Hyperkalaemia | 3 | 3 | | | 3 | 3 |
| Hyperleukocytosis | 3 | 4 | | | 3 | 4 |
| Hypernatraemia | 2 | 2 | 2 | 2 | | |
| Hypersensitivity | 15 | 16 | 3 | 3 | 12 | 13 |
| Hypersensitivity vasculitis | 1 | 1 | | | 1 | 1 |
| Hypersomnia | 2 | 2 | | | 2 | 2 |
| Hypertension | 42 | 43 | 4 | 5 | 38 | 38 |
| Hypertensive crisis | 1 | 2 | | | 1 | 2 |
| Hyperthermia | 6 | 6 | 2 | 2 | 4 | 4 |
| Hyperthyroidism | 1 | 1 | | | 1 | 1 |
| Hypertonia | | 1 | | | | 1 |
| Hyperventilation | 1 | 1 | 1 | 1 | | |
| Hypoacusis | 1 | 1 | | | 1 | 1 |

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|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 2 | 2 | | | 2 | 2 |
| Hypocalcaemia | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 2 | 2 | | | 2 | 2 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 24 | 25 | 5 | 5 | 19 | 20 |
| Hypothermia | 4 | 4 | | | 4 | 4 |
| Hypotonia | 1 | 1 | 1 | 1 | | |
| Hypoxia | 6 | 6 | | | 6 | 6 |
| Illrd nerve paralysis | 1 | 1 | | | 1 | 1 |
| Ill-defined disorder | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | 2 | 2 | 1 | 1 | 1 | 1 |
| Incorrect route of product administration | 2 | 3 | 2 | 3 | | |
| Increased bronchial secretion | 1 | 2 | | | 1 | 2 |
| Infarction | 1 | 1 | | | 1 | 1 |
| Inflammation | 2 | 2 | | | 2 | 2 |
| Inflammatory pain | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 7 | 7 | 1 | 1 | 6 | 6 |
| Initial insomnia | 1 | 1 | | | 1 | 1 |
| Injected limb mobility decreased | 1 | 1 | | | 1 | 1 |
| Injection site rash | 1 | 1 | | | 1 | 1 |
| Insomnia | 4 | 4 | 2 | 2 | 2 | 2 |
| Insulin-requiring type 2 diabetes mellitus | 1 | 1 | | | 1 | 1 |
| International normalised ratio abnormal | | 1 | | | | 1 |
| Interstitial lung disease | 1 | 1 | | | 1 | 1 |
| Intracardiac thrombus | 1 | 1 | | | 1 | 1 |
| Intracranial haematoma | 1 | 1 | | | 1 | 1 |
| Iron deficiency anaemia | 1 | 1 | | | 1 | 1 |
| Ischaemic stroke | 10 | 11 | | | 10 | 11 |
| Jaundice | 2 | 2 | | | 2 | 2 |
| Joint stiffness | 1 | 1 | | | 1 | 1 |

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| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Lacrimation increased | 2 | 2 | | | 2 | 2 |
| Language disorder | 1 | 1 | | | 1 | 1 |
| Laryngeal discomfort | 1 | 1 | 1 | 1 | | |
| Laryngeal dyspnoea | 2 | 2 | | | 2 | 2 |
| Laryngeal oedema | 2 | 2 | | | 2 | 2 |
| Laryngitis | 1 | 1 | | | 1 | 1 |
| Left ventricular hypertrophy | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Lichen planus | 1 | 1 | | | 1 | 1 |
| Lip oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Lip pruritus | 1 | 1 | | | 1 | 1 |
| Listless | 1 | 1 | | | 1 | 1 |
| Livedo reticularis | 3 | 3 | 1 | 1 | 2 | 2 |
| Lividity | 1 | 1 | | | 1 | 1 |
| Localised oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Loss of consciousness | 11 | 12 | | | 11 | 12 |
| Lower respiratory tract congestion | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Lung abscess | 1 | 1 | | | 1 | 1 |
| Lung disorder | 5 | 5 | 1 | 1 | 4 | 4 |
| Lymphadenopathy | 9 | 9 | 4 | 4 | 5 | 5 |
| Lymphocyte count decreased | 1 | 1 | | | 1 | 1 |
| Lymphopenia | 3 | 4 | | 1 | 3 | 3 |
| Malaise | 43 | 46 | 8 | 8 | 35 | 38 |
| Malnutrition | 1 | 1 | 1 | 1 | | |
| Mass | 1 | 1 | | | 1 | 1 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Metastases to peritoneum | 1 | 1 | | | 1 | 1 |
| Migraine | 4 | 4 | 1 | 1 | 3 | 3 |
| Migraine with aura | 1 | 1 | 1 | 1 | | |
| Miosis | 1 | 1 | | | 1 | 1 |
| Mitral valve disease | 1 | 1 | | | 1 | 1 |

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| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Mobility decreased | 1 | 1 | | | 1 | 1 |
| Monoparesis | 1 | 1 | | | 1 | 1 |
| Motor dysfunction | 2 | 2 | | | 2 | 2 |
| Muscle contracture | 1 | 1 | | | 1 | 1 |
| Muscle rigidity | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 1 | 1 | 1 | 1 | | |
| Muscle tightness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal stiffness | 6 | 6 | 2 | 2 | 4 | 4 |
| Myalgia | 22 | 22 | 10 | 10 | 12 | 12 |
| Mydriasis | 2 | 2 | | | 2 | 2 |
| Myocardial infarction | 9 | 9 | | | 9 | 9 |
| Myocardial necrosis marker increased | 1 | 1 | | | 1 | 1 |
| Myoclonus | 2 | 2 | | | 2 | 2 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 1 | 1 | 1 | 1 | | |
| Nausea | 28 | 31 | 9 | 10 | 19 | 21 |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Neuralgia | 5 | 5 | 2 | 2 | 3 | 3 |
| Neuromuscular pain | 1 | 1 | 1 | 1 | | |
| Neutropenia | 1 | 1 | | | 1 | 1 |
| Neutrophil count abnormal | 1 | 1 | | | 1 | 1 |
| Neutrophil count decreased | 1 | 1 | | | 1 | 1 |
| Neutrophil count increased | 1 | 1 | 1 | 1 | | |
| N-terminal prohormone brain natriuretic peptide increased | 1 | 1 | | | 1 | 1 |
| Obstructive airways disorder | 1 | 1 | 1 | 1 | | |
| Ocular discomfort | 1 | 1 | 1 | 1 | | |
| Oedema | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 4 | 5 | | | 4 | 5 |
| Off label use | 7 | 7 | 7 | 7 | | |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Optic ischaemic neuropathy | 1 | 1 | | | 1 | 1 |
| Oral pain | 1 | 1 | 1 | 1 | | |

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| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oral pruritus | 2 | 2 | | | 2 | 2 |
| Oropharyngeal discomfort | | 1 | | | | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 36 | 37 | 3 | 3 | 33 | 34 |
| Pain | 17 | 17 | 9 | 9 | 8 | 8 |
| Pain in extremity | 8 | 8 | 3 | 3 | 5 | 5 |
| Palatal oedema | 1 | 1 | | | 1 | 1 |
| Pallor | 4 | 4 | | | 4 | 4 |
| Palpitations | 2 | 3 | | 1 | 2 | 2 |
| Pancreatitis acute | 2 | 2 | | | 2 | 2 |
| Pancytopenia | 2 | 2 | | | 2 | 2 |
| Paraesthesia | 11 | 11 | 5 | 5 | 6 | 6 |
| Paraesthesia oral | 3 | 3 | 1 | 1 | 2 | 2 |
| Paralysis | 2 | 2 | | | 2 | 2 |
| Paresis | 1 | 1 | | | 1 | 1 |
| Peau d'orange | 1 | 1 | 1 | 1 | | |
| Pericardial effusion | 1 | 1 | | | 1 | 1 |
| Pericarditis | 4 | 4 | | | 4 | 4 |
| Peripheral coldness | 2 | 2 | 1 | 1 | 1 | 1 |
| Peripheral swelling | 2 | 2 | 1 | 1 | 1 | 1 |
| Pernio-like erythema | 1 | 1 | 1 | 1 | | |
| Petechiae | 1 | 1 | 1 | 1 | | |
| Petit mal epilepsy | | 1 | | | | 1 |
| Pharyngeal disorder | 1 | 1 | | | 1 | 1 |
| Phonophobia | 1 | 1 | | | 1 | 1 |
| Photophobia | 2 | 2 | | | 2 | 2 |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 6 | 6 | | | 6 | 6 |
| Pneumonia aspiration | 8 | 8 | | | 8 | 8 |
| Pneumonitis | 1 | 1 | | | 1 | 1 |
| Pneumoperitoneum | 1 | 1 | | | 1 | 1 |
| Polyarthrits | 1 | 1 | | | 1 | 1 |
| Polydipsia | 2 | 2 | 1 | 1 | 1 | 1 |

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|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Presyncope | 5 | 5 | 3 | 3 | 2 | 2 |
| Product administration error | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 2 | | | 1 | 2 |
| Product use issue | 6 | 6 | 6 | 6 | | |
| Pruritus | 8 | 9 | 3 | 4 | 5 | 5 |
| Pulmonary arterial hypertension | 1 | 1 | | | 1 | 1 |
| Pulmonary congestion | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 10 | 10 | | | 10 | 10 |
| Pulmonary infarction | 1 | 1 | | | 1 | 1 |
| Pulmonary oedema | 2 | 2 | | | 2 | 2 |
| Purpura | 1 | 1 | | | 1 | 1 |
| Pyrexia | 66 | 69 | 17 | 19 | 49 | 50 |
| Rales | 2 | 3 | | | 2 | 3 |
| Rash | 4 | 4 | 4 | 4 | | |
| Rash erythematous | 2 | 2 | | | 2 | 2 |
| Rash macular | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 1 | 1 | | | 1 | 1 |
| Red blood cell sedimentation rate increased | 1 | 1 | 1 | 1 | | |
| Renal failure | 4 | 5 | | | 4 | 5 |
| Renal impairment | 2 | 2 | | | 2 | 2 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Respiratory alkalosis | 2 | 2 | | | 2 | 2 |
| Respiratory arrest | 1 | 1 | | | 1 | 1 |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory disorder | 3 | 3 | | | 3 | 3 |
| Respiratory distress | 8 | 8 | | | 8 | 8 |
| Respiratory failure | 3 | 3 | | | 3 | 3 |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Respiratory tract oedema | 1 | 1 | | | 1 | 1 |
| Restlessness | 4 | 4 | 2 | 2 | 2 | 2 |
| Rhabdomyolysis | 1 | 1 | | | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Rhinitis | 2 | 2 | | | 2 | 2 |
| Rhinorrhoea | 3 | 3 | 1 | 1 | 2 | 2 |
| Rhonchi | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 test positive | 4 | 4 | 1 | 1 | 3 | 3 |
| Seizure | 5 | 5 | | | 5 | 5 |
| Sensory loss | 1 | 1 | | | 1 | 1 |
| Septic shock | 3 | 3 | | | 3 | 3 |
| Sinus bradycardia | 1 | 1 | | | 1 | 1 |
| Sinus tachycardia | 3 | 3 | 1 | 1 | 2 | 2 |
| Skin discolouration | 1 | 1 | 1 | 1 | | |
| Skin mass | 1 | 1 | | | 1 | 1 |
| Skin plaque | 1 | 1 | 1 | 1 | | |
| Skin warm | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 1 | 1 | | | 1 | 1 |
| Sleep talking | 1 | 1 | 1 | 1 | | |
| Somnolence | 9 | 9 | 3 | 3 | 6 | 6 |
| Spinal osteoarthritis | 1 | 1 | 1 | 1 | | |
| Spinal pain | 1 | 1 | | | 1 | 1 |
| Spondylitis | 1 | 1 | | | 1 | 1 |
| Staring | 1 | 1 | | | 1 | 1 |
| Status epilepticus | 2 | 2 | | | 2 | 2 |
| Subileus | 2 | 2 | | | 2 | 2 |
| Sudden death | 18 | 24 | | | 18 | 24 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 |
| Suicidal ideation | 1 | 1 | | | 1 | 1 |
| Supraventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Suspected COVID-19 | 2 | 2 | | | 2 | 2 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 3 | 3 | 1 | 1 | 2 | 2 |
| Syncope | 5 | 5 | | | 5 | 5 |
| Systemic lupus erythematosus | 1 | 1 | | | 1 | 1 |
| Tachyarrhythmia | 2 | 2 | 1 | 1 | 1 | 1 |

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | 39 | 40 | 6 | 6 | 33 | 34 |
| Tachypnoea | 5 | 5 | | | 5 | 5 |
| Tension | 1 | 1 | 1 | 1 | | |
| Thirst | 1 | 1 | 1 | 1 | | |
| Thrombocytopenia | 2 | 3 | | | 2 | 3 |
| Thrombocytopenic purpura | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis superficial | 3 | 3 | 1 | 1 | 2 | 2 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Thyroid mass | 1 | 1 | 1 | 1 | | |
| Tongue biting | 1 | 1 | | | 1 | 1 |
| Tongue coated | 1 | 1 | | | 1 | 1 |
| Tongue discolouration | 1 | 1 | | | 1 | 1 |
| Tongue disorder | 1 | 1 | | | 1 | 1 |
| Tongue dry | 1 | 1 | | | 1 | 1 |
| Tongue movement disturbance | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Tonic clonic movements | 3 | 3 | | | 3 | 3 |
| Transaminases increased | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 4 | 4 | | | 4 | 4 |
| Tremor | 7 | 8 | 1 | 2 | 6 | 6 |
| Tumour perforation | 1 | 1 | | | 1 | 1 |
| Type I hypersensitivity | 2 | 2 | | | 2 | 2 |
| Type II hypersensitivity | 1 | 1 | | | 1 | 1 |
| Unresponsive to stimuli | 2 | 2 | | | 2 | 2 |
| Urinary tract candidiasis | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Urosepsis | 1 | 1 | | | 1 | 1 |
| Urticaria | 10 | 12 | 3 | 3 | 7 | 9 |
| Vaccination site erythema | 7 | 7 | 6 | 6 | 1 | 1 |
| Vaccination site exfoliation | 1 | 1 | | | 1 | 1 |
| Vaccination site haematoma | 2 | 2 | | | 2 | 2 |
| Vaccination site hypersensitivity | 3 | 3 | 3 | 3 | | |

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site movement impairment | 2 | 2 | 2 | 2 | | |
| Vaccination site oedema | 3 | 3 | 1 | 1 | 2 | 2 |
| Vaccination site pain | 31 | 33 | 15 | 17 | 16 | 16 |
| Vaccination site paraesthesia | 1 | 1 | 1 | 1 | | |
| Vaccination site pruritus | 3 | 3 | | | 3 | 3 |
| Vaccination site swelling | 4 | 4 | 3 | 3 | 1 | 1 |
| Ventricular fibrillation | 1 | 1 | | | 1 | 1 |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vertigo | 10 | 10 | 4 | 4 | 6 | 6 |
| Vertigo positional | 2 | 2 | | | 2 | 2 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 1 | | | 1 | 1 |
| Vomiting | 28 | 30 | 7 | 7 | 21 | 23 |
| Wheezing | 2 | 2 | | | 2 | 2 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| | 1,776 | 1,870 | 397 | 418 | 1379 | 1452 |

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Country Where Event Occurred

FRENCH POLYNESIA

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------|--|--|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dermatitis bullous | 1 | 1 | 1 | 1 |
| Dermatosis | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

GERMANY

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | | | 2 | 2 |
| Abdominal pain lower | | 2 | | 2 | | |
| Abdominal pain upper | 3 | 4 | 3 | 4 | | |
| Abnormal faeces | 1 | 1 | 1 | 1 | | |
| Abortion missed | 1 | 1 | | | 1 | 1 |
| Accidental overdose | | 1 | | 1 | | |
| Acute abdomen | 1 | 1 | | | 1 | 1 |
| Acute kidney injury | 3 | 7 | | | 3 | 7 |
| Acute myocardial infarction | 1 | 3 | | | 1 | 3 |
| Acute respiratory distress syndrome | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Ageusia | 1 | 1 | 1 | 1 | | |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 2 | | | 1 | 2 |
| Amnesia | 2 | 2 | | | 2 | 2 |
| Anaphylactic reaction | 8 | 8 | | | 8 | 8 |
| Anaphylactic shock | | 3 | | | | 3 |
| Angina pectoris | 1 | 2 | | | 1 | 2 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Aortic aneurysm | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arrhythmia | 3 | 4 | | | 3 | 4 |
| Arterial occlusive disease | 1 | 1 | | | 1 | 1 |
| Arteriosclerosis | 1 | 1 | | | 1 | 1 |
| Arthralgia | 4 | 8 | 4 | 8 | | |
| Asthenia | 9 | 16 | 6 | 11 | 3 | 5 |
| Asthma | 2 | 2 | 1 | 1 | 1 | 1 |
| Ataxia | 2 | 2 | | | 2 | 2 |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Atrial fibrillation | 1 | 3 | | | 1 | 3 |
| Atrioventricular block complete | 1 | 1 | | | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 | 1 | 1 | | |
| Back pain | 2 | 3 | 2 | 3 | | |
| Bedridden | | 1 | | | | 1 |
| Blister | | 1 | | 1 | | |
| Blood calcium decreased | | 1 | | 1 | | |
| Blood creatine phosphokinase increased | | 1 | | 1 | | |
| Blood creatine phosphokinase MB increased | | 1 | | 1 | | |
| Blood creatinine increased | | 1 | | 1 | | |
| Blood glucose fluctuation | | 1 | | 1 | | |
| Blood potassium decreased | | 1 | | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure immeasurable | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Blood urine present | | 1 | | | | 1 |
| Body temperature increased | 5 | 8 | 4 | 5 | 1 | 3 |
| Bone pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bronchitis | 1 | 1 | 1 | 1 | | |
| Burning sensation | 1 | 1 | 1 | 1 | | |
| Capillary nail refill test abnormal | 1 | 1 | 1 | 1 | | |
| Cardiac aneurysm | 1 | 1 | | | 1 | 1 |
| Cardiac arrest | 4 | 5 | | | 4 | 5 |
| Cardiac failure | 3 | 9 | | | 3 | 9 |
| Cardiac fibrillation | | 1 | | | | 1 |
| Cardiogenic shock | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | | 1 | | | | 1 |
| Cardio-respiratory arrest | 1 | 1 | | | 1 | 1 |
| Cardiovascular disorder | 1 | 2 | | | 1 | 2 |
| Cerebellar syndrome | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 3 | 4 | | | 3 | 4 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |

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|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chest pain | 2 | 2 | 2 | 2 | | |
| Chest X-ray abnormal | 1 | 1 | | | 1 | 1 |
| Chills | 6 | 13 | 4 | 10 | 2 | 3 |
| Chronic kidney disease | | 1 | | | | 1 |
| Chronic obstructive pulmonary disease | 2 | 2 | | | 2 | 2 |
| Circulatory collapse | 7 | 10 | | | 7 | 10 |
| Condition aggravated | 2 | 2 | 2 | 2 | | |
| Contusion | 1 | 1 | | | 1 | 1 |
| Coronavirus infection | 1 | 1 | | | 1 | 1 |
| Coronavirus test positive | 1 | 1 | | | 1 | 1 |
| Cough | 11 | 16 | 6 | 10 | 5 | 6 |
| COVID-19 | 9 | 23 | 2 | 2 | 7 | 21 |
| COVID-19 pneumonia | 6 | 9 | | | 6 | 9 |
| Cranial nerve disorder | 1 | 1 | 1 | 1 | | |
| Crepitations | | 1 | | | | 1 |
| Cyanosis | 1 | 2 | | | 1 | 2 |
| Death | 11 | 28 | | | 11 | 28 |
| Decreased appetite | 2 | 3 | 1 | 1 | 1 | 2 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |
| Dehydration | 1 | 1 | | | 1 | 1 |
| Delirium | 1 | 1 | | | 1 | 1 |
| Dementia | | 1 | | | | 1 |
| Dementia of the Alzheimer's type, with delirium | | 1 | | | | 1 |
| Depressed level of consciousness | 2 | 3 | 1 | 1 | 1 | 2 |
| Depression | 1 | 1 | 1 | 1 | | |
| Dermatitis allergic | | 1 | | 1 | | |
| Diabetes mellitus | | 1 | | | | 1 |
| Diaphragmalgia | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 6 | 10 | 4 | 7 | 2 | 3 |
| Diet refusal | 2 | 4 | | | 2 | 4 |
| Disease recurrence | 1 | 2 | | | 1 | 2 |
| Disorientation | | 1 | | 1 | | |
| Disturbance in attention | 6 | 6 | 4 | 4 | 2 | 2 |

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|-----------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | 19 | 27 | 10 | 16 | 9 | 11 |
| Dizziness postural | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 13 | 28 | | | 13 | 28 |
| Dry mouth | 1 | 1 | 1 | 1 | | |
| Dry skin | | 1 | | 1 | | |
| Dysaesthesia | 1 | 1 | | | 1 | 1 |
| Dysarthria | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dyspepsia | | 1 | | 1 | | |
| Dysphagia | 3 | 3 | 2 | 2 | 1 | 1 |
| Dysphonia | 2 | 4 | 2 | 4 | | |
| Dyspnoea | 18 | 22 | 7 | 10 | 11 | 12 |
| Dyspnoea exertional | 2 | 2 | 1 | 1 | 1 | 1 |
| Enteritis | 1 | 1 | | | 1 | 1 |
| Epilepsy | 4 | 5 | | | 4 | 5 |
| Erythema | 4 | 5 | 4 | 5 | | |
| Eye haemorrhage | 1 | 1 | | | 1 | 1 |
| Eye irritation | | 1 | | 1 | | |
| Eye pain | 1 | 1 | 1 | 1 | | |
| Eye pruritus | 2 | 4 | | 1 | 2 | 3 |
| Eye swelling | 1 | 2 | 1 | 1 | | 1 |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Facial paresis | 2 | 2 | 1 | 1 | 1 | 1 |
| Fall | 2 | 3 | | | 2 | 3 |
| Fatigue | 13 | 29 | 12 | 25 | 1 | 4 |
| Feeling cold | 1 | 2 | | 1 | 1 | 1 |
| Feeling hot | 3 | 4 | 2 | 3 | 1 | 1 |
| Femoral neck fracture | | 1 | | | | 1 |
| Femur fracture | 1 | 1 | | | 1 | 1 |
| Flushing | 2 | 2 | 2 | 2 | | |
| Food refusal | | 2 | | | | 2 |
| Fracture | 1 | 1 | | | 1 | 1 |
| Gait disturbance | 1 | 1 | | | 1 | 1 |

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|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| General physical condition abnormal | 3 | 4 | | | 3 | 4 |
| General physical health deterioration | 10 | 14 | 1 | 2 | 9 | 12 |
| Glomerulonephritis minimal lesion | 1 | 1 | | | 1 | 1 |
| Gout | 1 | 1 | 1 | 1 | | |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haematocrit decreased | | 1 | | 1 | | |
| Haematoma | 2 | 3 | | 1 | 2 | 2 |
| Haemoglobin decreased | | 1 | | 1 | | |
| Headache | 18 | 30 | 16 | 25 | 2 | 5 |
| Heart rate decreased | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 3 | 3 | 2 | 2 | 1 | 1 |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Herpes simplex | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 1 | 1 | 1 | 1 | | |
| Herpes zoster meningitis | 1 | 1 | | | 1 | 1 |
| Hot flush | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | | 1 | | 1 | | |
| Hypersensitivity | 5 | 6 | | | 5 | 6 |
| Hypersomnia | 1 | 2 | | | 1 | 2 |
| Hypertension | 3 | 6 | | | 3 | 6 |
| Hypertensive crisis | 4 | 4 | | | 4 | 4 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 | | |
| Hyponatraemia | 1 | 1 | | | 1 | 1 |
| Hyporesponsive to stimuli | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 5 | | 1 | 3 | 4 |
| Hypotonia | 1 | 2 | 1 | 1 | | 1 |
| Hypoxia | 1 | 1 | 1 | 1 | | |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | 4 | 6 | 4 | 6 | | |
| Infarction | 1 | 1 | | | 1 | 1 |
| Infection | 1 | 1 | | | 1 | 1 |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Infective exacerbation of chronic obstructive airways disease | | 1 | | | | 1 | |
| Influenza like illness | 5 | 10 | 4 | 9 | 1 | 1 | |
| Intestinal ischaemia | 1 | 1 | | | 1 | 1 | |
| Irregular breathing | | 1 | | | | 1 | |
| Ischaemic cerebral infarction | 1 | 1 | | | 1 | 1 | |
| Jaundice | | 1 | | 1 | | | |
| Jaw clicking | | 1 | | | | 1 | |
| Joint range of motion decreased | 2 | 2 | 2 | 2 | | | |
| Lacrimation increased | 3 | 3 | 1 | 1 | 2 | 2 | |
| Language disorder | 1 | 1 | | | 1 | 1 | |
| Laryngeal oedema | 1 | 2 | | | 1 | 2 | |
| Leukocytosis | 1 | 1 | | | 1 | 1 | |
| Limb discomfort | | 1 | | 1 | | | |
| Lipase increased | 1 | 1 | | | 1 | 1 | |
| Lip oedema | 1 | 1 | | | 1 | 1 | |
| Lip swelling | | 1 | | | | 1 | |
| Livedo reticularis | | 1 | | 1 | | | |
| Liver function test increased | 1 | 1 | | | 1 | 1 | |
| Local reaction | | 1 | | 1 | | | |
| Loss of consciousness | 1 | 2 | | | 1 | 2 | |
| Lower respiratory tract congestion | 1 | 1 | 1 | 1 | | | |
| Lung disorder | 1 | 1 | 1 | 1 | | | |
| Lymphadenopathy | 1 | 5 | 1 | 5 | | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | | |
| Lymphopenia | 1 | 1 | | | 1 | 1 | |
| Malaise | 3 | 8 | 2 | 3 | 1 | 5 | |
| Maternal exposure during pregnancy | 1 | 1 | | | 1 | 1 | |
| Memory impairment | 1 | 1 | 1 | 1 | | | |
| Mobility decreased | 2 | 3 | 1 | 2 | 1 | 1 | |
| Multiple organ dysfunction syndrome | 2 | 2 | | | 2 | 2 | |
| Multiple sclerosis | 1 | 1 | | | 1 | 1 | |
| Muscle discomfort | 1 | 1 | 1 | 1 | | | |

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|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle spasticity | 1 | 1 | | | 1 | 1 |
| Muscle swelling | | 1 | | 1 | | |
| Muscular weakness | 1 | 2 | | 1 | 1 | 1 |
| Myalgia | 6 | 12 | 5 | 11 | 1 | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Myocarditis | 2 | 2 | | | 2 | 2 |
| Myocarditis infectious | 1 | 1 | | | 1 | 1 |
| Nasal congestion | | 1 | | 1 | | |
| Nasopharyngitis | 2 | 2 | 2 | 2 | | |
| Nausea | 10 | 14 | 7 | 9 | 3 | 5 |
| Neck pain | | 1 | | 1 | | |
| Nephrotic syndrome | 1 | 1 | | | 1 | 1 |
| Nervous system disorder | 1 | 1 | | | 1 | 1 |
| Neuralgia | 1 | 1 | 1 | 1 | | |
| Occipital neuralgia | 1 | 1 | 1 | 1 | | |
| Ocular hyperaemia | 1 | 2 | | 1 | 1 | 1 |
| Oedema | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 1 | 1 | 1 | 1 | | |
| Off label use | 4 | 7 | 4 | 7 | | |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 2 | 2 | 2 | 2 | | |
| Otitis media | | 1 | | 1 | | |
| Oxygen saturation decreased | 2 | 5 | | | 2 | 5 |
| Pain | 2 | 2 | | | 2 | 2 |
| Pain in extremity | 6 | 13 | 6 | 12 | | 1 |
| Palpitations | 3 | 4 | 2 | 3 | 1 | 1 |
| Pancreatitis acute | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 5 | 7 | 2 | 3 | 3 | 4 |
| Paraesthesia oral | | 2 | | 1 | | 1 |
| Pathogen resistance | | 1 | | | | 1 |
| Pelvic pain | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |

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|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral vascular disorder | 3 | 5 | | 1 | 3 | 4 |
| Personality change | 5 | 6 | | | 5 | 6 |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Pharyngeal hypoesthesia | 1 | 1 | 1 | 1 | | |
| Pharyngeal inflammation | | 1 | | 1 | | |
| Pharyngeal swelling | | 1 | | | | 1 |
| Pleurisy | 1 | 1 | | | 1 | 1 |
| Pneumonia | 8 | 12 | | | 8 | 12 |
| Poor quality product administered | 3 | 3 | 3 | 3 | | |
| Poor quality sleep | | 1 | | | | 1 |
| Product preparation issue | | 1 | | 1 | | |
| Product temperature excursion issue | 3 | 3 | 3 | 3 | | |
| Product use issue | 4 | 7 | 4 | 7 | | |
| Proteinuria | 1 | 1 | | | 1 | 1 |
| Pruritus | 7 | 8 | 4 | 5 | 3 | 3 |
| Pruritus allergic | 1 | 1 | | | 1 | 1 |
| Psoriasis | | 1 | | 1 | | |
| Pulmonary embolism | 1 | 2 | | | 1 | 2 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pulmonary sepsis | 1 | 1 | | | 1 | 1 |
| Pulse waveform abnormal | 1 | 1 | 1 | 1 | | |
| Pyrexia | 21 | 38 | 11 | 23 | 10 | 15 |
| Quadripareisis | 1 | 1 | | | 1 | 1 |
| Rash | 5 | 7 | 2 | 3 | 3 | 4 |
| Rash macular | 1 | 1 | 1 | 1 | | |
| Rash maculo-papular | 2 | 2 | 2 | 2 | | |
| Red blood cell count decreased | | 1 | | 1 | | |
| Renal failure | 2 | 4 | | | 2 | 4 |
| Respiratory distress | 10 | 13 | | | 10 | 13 |
| Respiratory failure | 6 | 7 | | | 6 | 7 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Restlessness | 2 | 2 | 1 | 1 | 1 | 1 |
| Retching | | 1 | | 1 | | |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Retinal tear | 1 | 1 | | | 1 | 1 |
| Retrograde amnesia | 1 | 1 | | | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 | | | 1 | 1 |
| Rhinalgia | | 1 | | 1 | | |
| Rhinorrhoea | 3 | 4 | 3 | 3 | | 1 |
| Rhonchi | | 1 | | | | 1 |
| Rosacea | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test positive | 3 | 3 | 3 | 3 | | |
| SARS-CoV-2 sepsis | 1 | 1 | | | 1 | 1 |
| SARS-CoV-2 test positive | 3 | 6 | 1 | 1 | 2 | 5 |
| Seizure | 6 | 8 | | | 6 | 8 |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Sensory disturbance | 1 | 1 | | | 1 | 1 |
| Septic shock | 1 | 1 | | | 1 | 1 |
| Shock | 1 | 1 | | | 1 | 1 |
| Sinusitis | 1 | 1 | 1 | 1 | | |
| Sleep disorder | 1 | 1 | 1 | 1 | | |
| Sneezing | 1 | 1 | 1 | 1 | | |
| Somnolence | 4 | 6 | 2 | 4 | 2 | 2 |
| Staphylococcal sepsis | | 1 | | | | 1 |
| Status epilepticus | 2 | 2 | | | 2 | 2 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Stupor | 1 | 1 | | | 1 | 1 |
| Sudden death | 9 | 15 | | | 9 | 15 |
| Superinfection bacterial | 1 | 1 | | | 1 | 1 |
| Swelling | | 1 | | 1 | | |
| Swelling face | 3 | 4 | 2 | 2 | 1 | 2 |
| Swollen tongue | 1 | 2 | | | 1 | 2 |
| Syncope | 5 | 6 | | | 5 | 6 |
| Systemic inflammatory response syndrome | 1 | 1 | | | 1 | 1 |
| Tachyarrhythmia | | 2 | | | | 2 |
| Tachycardia | 6 | 12 | 4 | 6 | 2 | 6 |

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| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | 2 | 2 | 2 | 2 | | |
| Throat irritation | 2 | 3 | 2 | 3 | | |
| Throat tightness | 1 | 2 | | | 1 | 2 |
| Thrombocytopenia | 2 | 2 | | | 2 | 2 |
| Toxicity to various agents | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | | 1 | | | | 1 |
| Tremor | 3 | 4 | 2 | 3 | 1 | 1 |
| Unresponsive to stimuli | 2 | 4 | | | 2 | 4 |
| Upper gastrointestinal haemorrhage | 2 | 2 | | | 2 | 2 |
| Upper respiratory tract infection | 2 | 2 | | | 2 | 2 |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urticaria | 5 | 5 | 3 | 3 | 2 | 2 |
| Vaccination site dermatitis | | 1 | | 1 | | |
| Vaccination site erythema | 3 | 5 | 2 | 4 | 1 | 1 |
| Vaccination site haemorrhage | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |
| Vaccination site pain | 8 | 24 | 8 | 23 | | 1 |
| Vaccination site paraesthesia | | 1 | | 1 | | |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site rash | | 1 | | 1 | | |
| Vaccination site reaction | | 2 | | 2 | | |
| Vaccination site swelling | 4 | 7 | 2 | 5 | 2 | 2 |
| Vaccination site warmth | 4 | 6 | 3 | 5 | 1 | 1 |
| Ventricular fibrillation | 1 | 2 | | | 1 | 2 |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Visual impairment | 1 | 2 | 1 | 1 | | 1 |
| Vitreous disorder | 1 | 1 | | | 1 | 1 |
| Vomiting | 10 | 15 | 4 | 5 | 6 | 10 |
| Wheezing | 1 | 1 | 1 | 1 | | |
| White blood cell count increased | 2 | 2 | | | 2 | 2 |
| | 666 | 1,052 | 270 | 457 | 396 | 595 |

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Country Where Event Occurred

GREECE

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|--|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Acute myocardial infarction | | 1 | | | | 1 | |
| Acute respiratory distress syndrome | | 1 | | | | 1 | |
| Acute respiratory failure | | 1 | | | | 1 | |
| Aggression | 1 | 1 | | | 1 | 1 | |
| Agitation | 1 | 1 | | | 1 | 1 | |
| Allergy to vaccine | | 1 | | | | 1 | |
| Anaphylactic shock | | 1 | | | | 1 | |
| Arthralgia | 5 | 5 | 4 | 4 | 1 | 1 | |
| Arthritis enteropathic | 1 | 1 | | | 1 | 1 | |
| Asthenia | 2 | 3 | 1 | 2 | 1 | 1 | |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 | |
| Asymptomatic COVID-19 | 1 | 1 | | | 1 | 1 | |
| Atrial fibrillation | | 1 | | | | 1 | |
| Auscultation | | 1 | | 1 | | | |
| Blood glucose abnormal | 1 | 1 | 1 | 1 | | | |
| Blood pressure fluctuation | 1 | 1 | 1 | 1 | | | |
| Blood pressure inadequately controlled | | 1 | | 1 | | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | | |
| Bone pain | 1 | 1 | 1 | 1 | | | |
| Bronchospasm | 2 | 2 | | | 2 | 2 | |
| Cardiac arrest | | 2 | | | | 2 | |
| Cardiac valve disease | | 1 | | | | 1 | |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 | |
| Chest pain | | 2 | | 1 | | 1 | |
| Chills | 2 | 3 | 1 | 2 | 1 | 1 | |
| Complex regional pain syndrome | 1 | 1 | | | 1 | 1 | |
| Condition aggravated | 1 | 2 | | | 1 | 2 | |
| Cough | 1 | 1 | | | 1 | 1 | |
| COVID-19 | 1 | 1 | | | 1 | 1 | |
| Death | 1 | 1 | | | 1 | 1 | |

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Diabetes mellitus inadequate control | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Diastolic hypertension | | 1 | | | | 1 |
| Discomfort | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Dizziness | 5 | 9 | 3 | 5 | 2 | 4 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Drug interaction | | 1 | | | | 1 |
| Dysphagia | 2 | 3 | 1 | 1 | 1 | 2 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 3 | 5 | | 1 | 3 | 4 |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Erythema | 3 | 3 | 2 | 2 | 1 | 1 |
| Eye pruritus | | 1 | | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Fall | | 1 | | | | 1 |
| Fatigue | 4 | 6 | 3 | 4 | 1 | 2 |
| Feeling cold | | 1 | | 1 | | |
| Flushing | 1 | 1 | | | 1 | 1 |
| Gait disturbance | | 1 | | 1 | | |
| Gastrointestinal disorder | 1 | 1 | 1 | 1 | | |
| Haematuria | 1 | 1 | | | 1 | 1 |
| Headache | 5 | 7 | 4 | 6 | 1 | 1 |
| Head discomfort | 1 | 1 | 1 | 1 | | |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypertension | 2 | 3 | | 1 | 2 | 2 |
| Hypoesthesia | 6 | 7 | 4 | 4 | 2 | 3 |
| Illness | 1 | 1 | | | 1 | 1 |
| Insulin resistance | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Leukocytosis | | 1 | | | | | 1 |
| Lip oedema | 1 | 1 | | | 1 | | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | | 1 |
| Lymphadenopathy | 1 | 1 | | | 1 | | 1 |
| Lymphoedema | 1 | 1 | | | 1 | | 1 |
| Malaise | 3 | 3 | 3 | 3 | | | |
| Migraine | 1 | 1 | 1 | 1 | | | |
| Myalgia | 6 | 7 | 5 | 6 | 1 | | 1 |
| Myocardial infarction | | 1 | | | | | 1 |
| Nasal pruritus | | 1 | | 1 | | | |
| Nausea | 2 | 2 | 2 | 2 | | | |
| Off label use | 3 | 3 | 3 | 3 | | | |
| Oral herpes | 1 | 1 | | | 1 | | 1 |
| Pain | 1 | 1 | 1 | 1 | | | |
| Pneumonia | | 1 | | | | | 1 |
| Polydipsia | 1 | 1 | 1 | 1 | | | |
| Polyuria | 1 | 1 | 1 | 1 | | | |
| Post herpetic neuralgia | 1 | 1 | | | 1 | | 1 |
| Presyncope | 1 | 2 | 1 | 1 | | | 1 |
| Product use issue | 3 | 3 | 3 | 3 | | | |
| Pruritus | 2 | 3 | 2 | 2 | | | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | | 1 |
| Pyrexia | 1 | 2 | 1 | 1 | | | 1 |
| Rash | 1 | 3 | 1 | 2 | | | 1 |
| Rash erythematous | 1 | 1 | 1 | 1 | | | |
| Respiratory tract infection | | 1 | | | | | 1 |
| Rheumatoid arthritis | 1 | 1 | | | 1 | | 1 |
| Seizure | | 1 | | | | | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | | |
| Sudden death | 1 | 2 | | | 1 | | 2 |
| Suspected COVID-19 | 1 | 1 | 1 | 1 | | | |
| Syncope | 1 | 1 | | | 1 | | 1 |
| Tachycardia | 1 | 2 | | | 1 | | 2 |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|--------------------------------------|--|--|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Throat irritation | | 1 | | 1 | | |
| Tremor | | 1 | | | | 1 |
| Trigeminal neuralgia | 1 | 1 | | | 1 | 1 |
| Vaccination site movement impairment | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 3 | 3 | 3 | 3 | | |
| Vertigo | 2 | 2 | 2 | 2 | | |
| Vomiting | | 1 | | 1 | | |
| | 124 | 176 | 69 | 89 | 55 | 87 |

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Country Where Event Occurred

HUNGARY

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | 1 | 1 | | |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Ageusia | | 2 | | 2 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anosmia | | 1 | | 1 | | |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthenia | 5 | 8 | 3 | 6 | 2 | 2 |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Blood glucose increased | | 1 | | 1 | | |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 2 | | | 1 | 2 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 2 | 1 | 2 | | |
| Chills | 1 | 2 | 1 | 2 | | |
| Chronic obstructive pulmonary disease | 1 | 1 | 1 | 1 | | |
| Cold sweat | 1 | 1 | 1 | 1 | | |
| COVID-19 | | 1 | | | | 1 |
| Craniofacial fracture | 1 | 1 | | | 1 | 1 |
| Depressed mood | 1 | 1 | 1 | 1 | | |
| Diarrhoea | 2 | 2 | 2 | 2 | | |
| Dizziness | 3 | 5 | 1 | 3 | 2 | 2 |
| Drug hypersensitivity | 1 | 1 | 1 | 1 | | |
| Drug ineffective | | 1 | | | | 1 |
| Dry mouth | | 1 | | | | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 3 | 3 | 1 | 1 | 2 | 2 |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Extrasystoles | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 3 | | 2 | 1 | 1 |
| Feeding disorder | 1 | 1 | | | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Feeling hot | | 2 | | 1 | | 1 |
| Flushing | 1 | 1 | 1 | 1 | | |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Haemorrhage | | 1 | | | | 1 |
| Headache | 4 | 8 | 3 | 7 | 1 | 1 |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | | 2 | | 2 | | |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Incorrect route of product administration | | 1 | | 1 | | |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Localised oedema | 1 | 1 | 1 | 1 | | |
| Lymphadenopathy | 4 | 4 | 4 | 4 | | |
| Lymph node pain | 2 | 2 | 2 | 2 | | |
| Malaise | 1 | 3 | 1 | 3 | | |
| Micturition urgency | | 1 | | 1 | | |
| Musculoskeletal stiffness | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 3 | 5 | 3 | 5 | | |
| Nasopharyngitis | | 1 | | 1 | | |
| Nausea | 3 | 3 | 2 | 2 | 1 | 1 |
| Neoplasm progression | 1 | 1 | | | 1 | 1 |
| Odynophagia | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 1 | 2 | 1 | 2 | | |
| Oxygen saturation decreased | | 1 | | 1 | | |
| Pain in extremity | 1 | 2 | 1 | 2 | | |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Paraesthesia | | 1 | | | | 1 |

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|---------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral swelling | | 1 | | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pulpitis dental | 1 | 1 | 1 | 1 | | |
| Pyrexia | 5 | 7 | 4 | 6 | 1 | 1 |
| Rash | 2 | 2 | 2 | 2 | | |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Sensation of foreign body | 1 | 1 | | | 1 | 1 |
| Somnolence | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Tachycardia | 2 | 2 | 1 | 1 | 1 | 1 |
| Thirst | | 1 | | | | 1 |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site nodule | | 2 | | 2 | | |
| Vaccination site pain | 2 | 5 | 2 | 5 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 90 | 139 | 61 | 101 | 29 | 38 |

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Country Where Event Occurred

ICELAND

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anal incontinence | 1 | 1 | 1 | 1 | | |
| Aortic aneurysm | | 1 | | | | 1 |
| Aphasia | 1 | 1 | 1 | 1 | | |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthenia | 1 | 3 | 1 | 3 | | |
| Asthma | 1 | 1 | | | 1 | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Cardiac failure | | 2 | | | | 2 |
| Chills | 1 | 1 | 1 | 1 | | |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 3 | 1 | 2 | | 1 |
| Death | | 2 | | | | 2 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Disease progression | | 1 | | | | 1 |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling abnormal | 1 | 1 | 1 | 1 | | |
| Headache | 2 | 3 | 2 | 3 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Joint stiffness | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 4 | 2 | 2 | | 2 |
| Migraine | | 1 | | 1 | | |
| Myocardial infarction | | 1 | | | | 1 |
| Nasopharyngitis | | 3 | | 3 | | |
| Nausea | | 1 | | 1 | | |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|------------------------------|--|--|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Oxygen saturation decreased | 2 | 2 | | | 2 | 2 |
| Peripheral artery thrombosis | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 3 | | | 1 | 3 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 8 | 1 | 5 | 1 | 3 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | | 1 | | 1 | | |
| Sepsis | | 1 | | | | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Urinary incontinence | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 34 | 65 | 21 | 37 | 13 | 28 |

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Country Where Event Occurred

IRELAND

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Acute cardiac event | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | | | 1 | 1 |
| Arthralgia | 3 | 3 | 1 | 1 | 2 | 2 |
| Asthenia | 4 | 4 | | | 4 | 4 |
| Asthma | 2 | 2 | | | 2 | 2 |
| Back pain | 2 | 2 | | | 2 | 2 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Body temperature decreased | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | | | 1 | 1 |
| Chills | 4 | 4 | | | 4 | 4 |
| Cold sweat | 1 | 1 | | | 1 | 1 |
| Confusional state | 2 | 2 | | | 2 | 2 |
| Cough | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | 1 | 1 | | | 1 | 1 |
| Cyanosis | | 1 | | 1 | | |
| Death | 2 | 3 | | | 2 | 3 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | | 1 | | | | 1 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Disease recurrence | 2 | 2 | | | 2 | 2 |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Dizziness | 10 | 10 | 1 | 1 | 9 | 9 |
| Dry throat | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dyspnoea | 5 | 5 | | | 5 | 5 |
| Dyspnoea at rest | 1 | 1 | | | 1 | 1 |
| Dysstasia | 1 | 1 | | | 1 | 1 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Emotional distress | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Facial pain | 1 | 1 | 1 | 1 | | |
| Faeces discoloured | 1 | 1 | | | 1 | 1 |
| Fatigue | 10 | 10 | | | 10 | 10 |
| Feeling cold | 1 | 1 | | | 1 | 1 |
| Feeling hot | 2 | 2 | | | 2 | 2 |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Flushing | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Headache | 12 | 12 | 2 | 2 | 10 | 10 |
| Hyperhidrosis | 4 | 4 | | | 4 | 4 |
| Hypertension | 3 | 3 | | | 3 | 3 |
| Hypoaesthesia | 2 | 2 | | | 2 | 2 |
| Hypoaesthesia oral | 3 | 3 | | | 3 | 3 |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 3 | | | 3 | 3 |
| Insomnia | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | 1 | 1 | | |
| Lip swelling | 3 | 3 | | | 3 | 3 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 2 | 2 | | | 2 | 2 |
| Lymph node pain | 2 | 2 | | | 2 | 2 |
| Malaise | 7 | 7 | | | 7 | 7 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 1 | 1 | | | 1 | 1 |

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|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myalgia | 2 | 2 | | | 2 | 2 |
| Myelitis transverse | 1 | 1 | | | 1 | 1 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Nausea | 10 | 10 | 1 | 1 | 9 | 9 |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 4 | 4 | 1 | 1 | 3 | 3 |
| Oxygen saturation decreased | 5 | 5 | | | 5 | 5 |
| Pain | 3 | 3 | 1 | 1 | 2 | 2 |
| Pain in extremity | 4 | 4 | 1 | 1 | 3 | 3 |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Palpitations | 2 | 2 | | | 2 | 2 |
| Pancreatitis relapsing | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 4 | 4 | | | 4 | 4 |
| Paraesthesia oral | 2 | 2 | | | 2 | 2 |
| Periorbital oedema | 1 | 1 | 1 | 1 | | |
| Peripheral swelling | 1 | 1 | | | 1 | 1 |
| Pharyngeal paraesthesia | 1 | 1 | | | 1 | 1 |
| Pharyngeal swelling | 1 | 1 | | | 1 | 1 |
| Platelet count decreased | 1 | 1 | | | 1 | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Poor quality sleep | 1 | 1 | 1 | 1 | | |
| Presyncope | 2 | 2 | | | 2 | 2 |
| Pruritus | 3 | 3 | | | 3 | 3 |
| Pyrexia | 7 | 7 | 1 | 1 | 6 | 6 |
| Rales | 1 | 1 | | | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash erythematous | 2 | 2 | | | 2 | 2 |
| Respiratory rate increased | 1 | 1 | | | 1 | 1 |
| Respiratory tract infection | 1 | 1 | | | 1 | 1 |
| Retching | 1 | 1 | | | 1 | 1 |
| Sinusitis | 1 | 1 | | | 1 | 1 |
| Skin discolouration | 1 | 1 | 1 | 1 | | |

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|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Stridor | 1 | 1 | | | 1 | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Swelling face | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 4 | 4 | | | 4 | 4 |
| Tachycardia | 5 | 5 | | | 5 | 5 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Tinnitus | 1 | 1 | | | 1 | 1 |
| Upper gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Urticaria | 2 | 2 | | | 2 | 2 |
| Vaccination site pain | 2 | 2 | | | 2 | 2 |
| Vaccination site pruritus | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Vomiting | 5 | 5 | | | 5 | 5 |
| Wheezing | 4 | 4 | | | 4 | 4 |
| | 234 | 237 | 19 | 20 | 215 | 217 |

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Country Where Event Occurred

ISRAEL

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Acute myocardial infarction | | 1 | | | | 1 | |
| Allergy to vaccine | | 2 | | | | | 2 |
| Anaphylactic reaction | | 1 | | | | | 1 |
| Angina pectoris | 1 | 2 | | | 1 | | 2 |
| Arthralgia | 1 | 2 | 1 | 2 | | | |
| Aspiration | 1 | 1 | | | 1 | | 1 |
| Asthenia | 4 | 12 | 3 | 11 | 1 | | 1 |
| Asthma | 1 | 2 | | 1 | 1 | | 1 |
| Atelectasis | 1 | 1 | | | 1 | | 1 |
| Atrial f brillation | | 2 | | | | | 2 |
| Back pain | 1 | 1 | 1 | 1 | | | |
| Balance disorder | | 1 | | 1 | | | |
| Blood chloride increased | | 2 | | 1 | | | 1 |
| Blood glucose increased | | 2 | | 1 | | | 1 |
| Blood pressure increased | | 2 | | 1 | | | 1 |
| Brain injury | 1 | 1 | | | 1 | | 1 |
| Breast inflammation | 1 | 1 | 1 | 1 | | | |
| Cardiac arrest | 1 | 5 | | | 1 | | 5 |
| Cardiac failure | | 1 | | | | | 1 |
| Cardiac flutter | 1 | 1 | | | 1 | | 1 |
| Chest discomfort | | 1 | | 1 | | | |
| Chest pain | 1 | 1 | 1 | 1 | | | |
| Chills | | 2 | | 2 | | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 1 | 1 | | | 1 | | 1 |
| Circulatory collapse | | 1 | | | | | 1 |
| Condition aggravated | 1 | 1 | | | 1 | | 1 |
| Contusion | | 1 | | | | | 1 |
| Cough | | 1 | | 1 | | | |
| COVID-19 | 1 | 2 | | | 1 | | 2 |

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| C-reactive protein increased | | 1 | | 1 | | | |
| Crying | | 1 | | 1 | | | |
| Death | 1 | 5 | | | 1 | | 5 |
| Disease recurrence | 1 | 3 | 1 | 2 | | | 1 |
| Dizziness | 2 | 7 | 1 | 6 | 1 | | 1 |
| Drug ineffective | 1 | 2 | | | 1 | | 2 |
| Dysgeusia | | 1 | | 1 | | | |
| Dysphagia | | 2 | | 1 | | | 1 |
| Dyspnoea | 4 | 11 | 1 | 5 | 3 | | 6 |
| Dyspnoea exertional | | 1 | | 1 | | | |
| Dysstasia | 1 | 1 | 1 | 1 | | | |
| Ear discomfort | | 1 | | 1 | | | |
| Ear pain | 1 | 1 | 1 | 1 | | | |
| Eosinophilic oesophagitis | | 1 | | 1 | | | |
| Erythema | | 4 | | 4 | | | |
| Eye irritation | | 2 | | 1 | | | 1 |
| Facial paralysis | 1 | 2 | | | 1 | | 2 |
| Fall | | 1 | | | | | 1 |
| Fatigue | 2 | 4 | 2 | 4 | | | |
| Feeling abnormal | 1 | 3 | 1 | 1 | | | 2 |
| Feeling hot | | 3 | | 3 | | | |
| Gastric haemorrhage | 1 | 1 | | | 1 | | 1 |
| Gastrointestinal necrosis | 1 | 1 | | | 1 | | 1 |
| Glomerular filtration rate decreased | | 1 | | | | | 1 |
| Haemolytic anaemia | | 1 | | | | | 1 |
| Headache | 5 | 12 | 5 | 11 | | | 1 |
| Heart rate increased | | 2 | | 2 | | | |
| Herpes zoster | 5 | 5 | 5 | 5 | | | |
| Hypoesthesia | | 2 | | 2 | | | |
| Hypoesthesia oral | | 2 | | 1 | | | 1 |
| Hypotension | | 1 | | 1 | | | |
| Hypoventilation | | 1 | | | | | 1 |
| Illness | 1 | 1 | 1 | 1 | | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|---|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Inflammatory marker increased | | 1 | | | | 1 | |
| Influenza like illness | | 1 | | 1 | | | |
| Injection site pain | 1 | 1 | 1 | 1 | | | |
| Insomnia | 2 | 2 | 2 | 2 | | | |
| Jaundice | | 1 | | 1 | | | |
| Lacrimation increased | | 2 | | 1 | | | 1 |
| Leukocytosis | 1 | 2 | | | 1 | | 2 |
| Lip swelling | | 1 | | 1 | | | |
| Loss of consciousness | 1 | 2 | | | 1 | | 2 |
| Loss of libido | 1 | 1 | 1 | 1 | | | |
| Lymphocyte count increased | | 1 | | 1 | | | |
| Lymphocytosis | | 1 | | 1 | | | |
| Lymphopenia | | 1 | | | | | 1 |
| Malaise | | 1 | | 1 | | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | | |
| Mean cell haemoglobin concentration decreased | | 1 | | 1 | | | |
| Mean cell haemoglobin decreased | | 2 | | 1 | | | 1 |
| Mean cell volume decreased | | 1 | | 1 | | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | | |
| Multiple sclerosis relapse | | 3 | | | | | 3 |
| Muscular weakness | 1 | 1 | 1 | 1 | | | |
| Myalgia | | 4 | | 4 | | | |
| Myasthenia gravis | 1 | 1 | | | 1 | | 1 |
| Nausea | 1 | 3 | 1 | 3 | | | |
| Neutrophil count increased | | 1 | | | | | 1 |
| Off label use | 2 | 3 | 2 | 3 | | | |
| Oropharyngeal discomfort | | 1 | | 1 | | | |
| Oropharyngeal pain | | 1 | | 1 | | | |
| Oxygen saturation decreased | | 1 | | | | | 1 |
| Pain | 2 | 3 | 2 | 3 | | | |
| Pain in extremity | 2 | 4 | 2 | 4 | | | |
| Palpitations | 1 | 3 | 1 | 3 | | | |
| Paraesthesia | | 4 | | 3 | | | 1 |

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Paraesthesia oral | | 3 | | 3 | | |
| Pericarditis | | 1 | | | | 1 |
| Personality change | | 1 | | 1 | | |
| Pharyngeal swelling | | 1 | | 1 | | |
| Pleural effusion | | 1 | | | | 1 |
| Pleuritic pain | | 1 | | | | 1 |
| Pneumonia | 1 | 1 | | | 1 | 1 |
| Product use issue | 2 | 3 | 2 | 3 | | |
| Pruritus | | 1 | | | | 1 |
| Pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Pulse abnormal | | 1 | | | | 1 |
| Pyrexia | 3 | 7 | 2 | 5 | 1 | 2 |
| Rash | | 1 | | | | 1 |
| Red blood cell count increased | | 1 | | 1 | | |
| Respiratory arrest | | 1 | | | | 1 |
| Respiratory distress | | 1 | | | | 1 |
| SARS-CoV-2 ant body test negative | 1 | 1 | 1 | 1 | | |
| Sepsis | | 1 | | | | 1 |
| Sudden death | 1 | 1 | | | 1 | 1 |
| Suffocation feeling | | 1 | | 1 | | |
| Swollen tongue | | 2 | | | | 2 |
| Tachycardia | | 1 | | 1 | | |
| Therapeutic response unexpected | | 1 | | 1 | | |
| Throat tightness | | 1 | | | | 1 |
| Tinnitus | | 1 | | 1 | | |
| Tremor | | 1 | | 1 | | |
| Urticaria | | 1 | | | | 1 |
| Vaccination site movement impairment | | 1 | | 1 | | |
| Vaccination site pain | 1 | 6 | 1 | 6 | | |
| Vaccination site swelling | | 1 | | 1 | | |
| Vision blurred | | 1 | | 1 | | |
| Vomiting | | 1 | | 1 | | |
| | 74 | 246 | 47 | 155 | 27 | 91 |

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Country Where Event Occurred

ITALY

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|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal distension | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Abdominal pain | 10 | 12 | | | 7 | 9 | 3 | 3 |
| Abdominal pain upper | 2 | 4 | | | 1 | 3 | 1 | 1 |
| Acute coronary syndrome | | 1 | | | | | | 1 |
| Acute myocardial infarction | | 1 | | | | | | 1 |
| Acute respiratory failure | 2 | 2 | | | | | 2 | 2 |
| Administration site movement impairment | 1 | 1 | | | | | 1 | 1 |
| Ageusia | 1 | 1 | | | | | 1 | 1 |
| Agitation | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Allergic respiratory symptom | | 1 | | | | | | 1 |
| Allergy to vaccine | 1 | 2 | | | | | 1 | 2 |
| Altered state of consciousness | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic reaction | 2 | 3 | | | | | 2 | 3 |
| Angioedema | | 1 | | | | | | 1 |
| Anosmia | 1 | 1 | | | | | 1 | 1 |
| Anxiety | 1 | 1 | | | | | 1 | 1 |
| Arteriosclerosis | | 1 | | | | | | 1 |
| Arthralgia | 23 | 28 | 1 | 1 | 13 | 18 | 10 | 10 |
| Asphyxia | | 1 | | | | | | 1 |
| Asthenia | 18 | 23 | 1 | 1 | 7 | 11 | 11 | 12 |
| Asthma | 3 | 3 | | | | | 3 | 3 |
| Asthmatic crisis | 2 | 2 | | | | | 2 | 2 |
| Atrioventricular block complete | | 1 | | | | | | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 | | |
| Back pain | 4 | 6 | 1 | 1 | 1 | 2 | 3 | 4 |
| Balance disorder | 1 | 2 | | | | 1 | 1 | 1 |
| Basedow's disease | 1 | 1 | | | | | 1 | 1 |
| Blepharospasm | 1 | 1 | | | | | 1 | 1 |
| Blindness | 1 | 1 | | | | | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 | | |

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|-----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 | | |
| Blood pressure increased | 4 | 5 | | | | | 4 | 5 |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 | | |
| Body temperature increased | 2 | 3 | | | 2 | 3 | | |
| Bone pain | 5 | 5 | | | 2 | 2 | 3 | 3 |
| Bradycardia | 2 | 3 | | | | | 2 | 3 |
| Bronchospasm | 4 | 4 | | | | | 4 | 4 |
| Burning sensation | 2 | 3 | | | | 1 | 2 | 2 |
| Cardiac arrest | 3 | 3 | | | | | 3 | 3 |
| Cardiac failure | 1 | 1 | | | | | 1 | 1 |
| Catarrh | 2 | 2 | | | | | 2 | 2 |
| Cerebellar haemorrhage | | 1 | | | | | | 1 |
| Cerebrovascular accident | | 1 | | | | | | 1 |
| Chest discomfort | 3 | 3 | 1 | 1 | 1 | 1 | 2 | 2 |
| Chest pain | 3 | 3 | 1 | 1 | 1 | 1 | 2 | 2 |
| Chills | 20 | 23 | 1 | 1 | 8 | 11 | 12 | 12 |
| Circulatory collapse | | 1 | | | | | | 1 |
| Circumoral swelling | 1 | 1 | | | | | 1 | 1 |
| Cold sweat | 1 | 1 | | | | | 1 | 1 |
| Coma | 1 | 1 | | | | | 1 | 1 |
| Coma scale abnormal | | 1 | | | | | | 1 |
| Condition aggravated | 2 | 3 | | | | | 2 | 3 |
| Confusional state | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Conjunctival haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Conjunctivitis | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Coronary artery disease | 1 | 1 | | | | | 1 | 1 |
| Cough | 12 | 14 | | | 3 | 5 | 9 | 9 |
| COVID-19 | 2 | 3 | | | | 1 | 2 | 2 |
| Deafness | 1 | 1 | | | | | 1 | 1 |
| Deafness neurosensory | 1 | 1 | | | | | 1 | 1 |
| Death | 1 | 2 | | | | | 1 | 2 |
| Decreased appetite | 3 | 3 | | | 3 | 3 | | |
| Deep vein thrombosis | 1 | 2 | | | | | 1 | 2 |

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|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Dehydration | | 1 | | | | | | 1 |
| Dermatitis allergic | | 1 | | | | | | 1 |
| Dermatitis atopic | 1 | 1 | | | 1 | 1 | | |
| Dermatitis exfoliative generalised | | 1 | | | | | | 1 |
| Diarrhoea | 7 | 7 | | | 2 | 2 | 5 | 5 |
| Diplopia | 1 | 1 | | | | | 1 | 1 |
| Disease recurrence | 2 | 3 | | | | 1 | 2 | 2 |
| Disorientation | 1 | 1 | | | | | 1 | 1 |
| Dizziness | 13 | 16 | | | 7 | 10 | 6 | 6 |
| Drug hypersensitivity | 1 | 1 | | | | | 1 | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 | | |
| Dry mouth | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Dysaesthesia pharynx | 1 | 1 | | | 1 | 1 | | |
| Dysentery | 10 | 10 | | | | | 10 | 10 |
| Dysgeusia | 3 | 3 | | | | | 3 | 3 |
| Dysmetria | 1 | 1 | | | | | 1 | 1 |
| Dyspepsia | 1 | 1 | | | 1 | 1 | | |
| Dysphagia | 2 | 5 | | | | 1 | 2 | 4 |
| Dysphonia | 4 | 4 | | | | | 4 | 4 |
| Dyspnoea | 16 | 21 | | | 1 | 2 | 15 | 19 |
| Dysuria | 1 | 1 | | | | | 1 | 1 |
| Ear pain | 2 | 2 | | | 2 | 2 | | |
| Eosinophil count increased | 1 | 1 | | | | | 1 | 1 |
| Epistaxis | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Erythema | 8 | 10 | | | 1 | 2 | 7 | 8 |
| Extremity contracture | | 1 | | | | 1 | | |
| Eye disorder | 1 | 1 | | | 1 | 1 | | |
| Eye irritation | 1 | 1 | | | | | 1 | 1 |
| Eyelid oedema | 1 | 1 | | | | | 1 | 1 |
| Eyelid ptosis | 1 | 1 | | | | | 1 | 1 |
| Eye pain | | 1 | | | | 1 | | |
| Eye swelling | 1 | 1 | | | | | 1 | 1 |
| Face oedema | 1 | 1 | | | | | 1 | 1 |

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|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Facial nerve disorder | 1 | 1 | | | | | 1 | 1 |
| Facial paralysis | 5 | 5 | | | | | 5 | 5 |
| Facial spasm | | 1 | | | | | | 1 |
| Fall | | 1 | | | | | | 1 |
| Fatigue | 15 | 17 | | | 6 | 8 | 9 | 9 |
| Feeling cold | 1 | 1 | | | | | 1 | 1 |
| Feeling hot | 5 | 5 | | | | | 5 | 5 |
| Feeling of body temperature change | 2 | 2 | | | | | 2 | 2 |
| Fibrin D dimer increased | 1 | 1 | | | 1 | 1 | | |
| Flushing | 4 | 6 | | | 1 | 3 | 3 | 3 |
| Gait inability | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal disorder | | 1 | | | | 1 | | |
| General physical health deterioration | | 1 | | | | | | 1 |
| Haematochezia | 1 | 1 | | | | | 1 | 1 |
| Haemorrhage subcutaneous | 1 | 1 | | | | | 1 | 1 |
| Hallucinations, mixed | 1 | 1 | | | | | 1 | 1 |
| Headache | 36 | 47 | 1 | 1 | 13 | 24 | 23 | 23 |
| Heart rate increased | 2 | 2 | | | | | 2 | 2 |
| Hemiparaesthesia | 3 | 3 | | | | | 3 | 3 |
| Hemiparesis | 2 | 3 | | | | | 2 | 3 |
| Herpes ophthalmic | 1 | 1 | | | | | 1 | 1 |
| Herpes zoster | 1 | 1 | | | | | 1 | 1 |
| Hot flush | 1 | 2 | | | | 1 | 1 | 1 |
| Hyperaemia | 1 | 1 | | | | | 1 | 1 |
| Hyperglycaemia | 1 | 1 | | | | | 1 | 1 |
| Hyperhidrosis | 5 | 7 | | | | 2 | 5 | 5 |
| Hyperpyrexia | 6 | 6 | | | | | 6 | 6 |
| Hypersensitivity | 5 | 6 | | | 1 | 1 | 4 | 5 |
| Hypersomnia | 1 | 1 | | | 1 | 1 | | |
| Hypertension | 3 | 7 | | | | 1 | 3 | 6 |
| Hypertensive crisis | 5 | 6 | | | | | 5 | 6 |
| Hyperthermia | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Hypertransaminasaemia | 1 | 1 | | | | | 1 | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Hypoaesthesia | 2 | 2 | | | | | 2 | 2 |
| Hypoaesthesia oral | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Hypotension | 4 | 4 | | | | | 4 | 4 |
| Hypotensive crisis | 1 | 1 | | | | | 1 | 1 |
| Hypotonia | 1 | 1 | | | | | 1 | 1 |
| Hypoxia | 1 | 1 | | | | | 1 | 1 |
| Influenza | 1 | 1 | | | 1 | 1 | | |
| Influenza like illness | 2 | 4 | | | 1 | 3 | 1 | 1 |
| Injection site urticaria | 1 | 1 | | | 1 | 1 | | |
| Insomnia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| International normalised ratio increased | 1 | 1 | | | 1 | 1 | | |
| Interstitial lung disease | 1 | 1 | | | | | 1 | 1 |
| Ischaemic stroke | 1 | 1 | | | | | 1 | 1 |
| Joint range of motion decreased | 1 | 1 | | | | | 1 | 1 |
| Labyrinthitis | 2 | 2 | | | | | 2 | 2 |
| Laryngeal oedema | 8 | 11 | | | | | 8 | 11 |
| Laryngospasm | 1 | 2 | | | | | 1 | 2 |
| Limb discomfort | 1 | 2 | | | 1 | 2 | | |
| Lip oedema | 2 | 2 | | | | | 2 | 2 |
| Loss of consciousness | 4 | 4 | | | | | 4 | 4 |
| Lymphadenitis | 1 | 1 | | | 1 | 1 | | |
| Lymphadenopathy | 8 | 10 | | | 4 | 6 | 4 | 4 |
| Lymph node pain | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Lymphocyte count decreased | 1 | 1 | | | 1 | 1 | | |
| Malaise | 9 | 13 | | | 2 | 6 | 7 | 7 |
| Maternal exposure during pregnancy | 1 | 1 | | | 1 | 1 | | |
| Mean cell volume increased | 1 | 1 | | | 1 | 1 | | |
| Mechanical urticaria | 1 | 1 | | | | | 1 | 1 |
| Migraine | 2 | 3 | | | | 1 | 2 | 2 |
| Monocyte count increased | 1 | 1 | | | 1 | 1 | | |
| Monoplegia | 1 | 1 | | | | | 1 | 1 |
| Mood altered | 1 | 1 | | | 1 | 1 | | |
| Mouth swelling | 1 | 1 | | | | | 1 | 1 |

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|-------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Movement disorder | 1 | 1 | | | | | 1 | 1 |
| Mucous stools | 1 | 1 | | | 1 | 1 | | |
| Multiple organ dysfunction syndrome | 2 | 2 | | | | | 2 | 2 |
| Muscle contractions involuntary | | 1 | | | | | | 1 |
| Muscle rigidity | | 1 | | | | | | 1 |
| Muscle spasms | 4 | 5 | | | 2 | 3 | 2 | 2 |
| Muscular weakness | 2 | 2 | | | 2 | 2 | | |
| Musculoskeletal disorder | 1 | 1 | | | | | 1 | 1 |
| Musculoskeletal pain | 4 | 6 | | | 3 | 5 | 1 | 1 |
| Musculoskeletal stiffness | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Myalgia | 16 | 19 | 1 | 1 | 6 | 9 | 10 | 10 |
| Myasthenia gravis crisis | 1 | 1 | | | | | 1 | 1 |
| Myocardial infarction | | 1 | | | | | | 1 |
| Myocardial ischaemia | | 1 | | | | | | 1 |
| Nasopharyngitis | 1 | 1 | | | | | 1 | 1 |
| Nausea | 26 | 31 | | | 10 | 14 | 16 | 17 |
| Neck pain | 2 | 3 | | | 2 | 3 | | |
| Neuralgia | 3 | 3 | | | | | 3 | 3 |
| Neuropathy peripheral | 1 | 1 | | | | | 1 | 1 |
| Nightmare | 1 | 1 | | | 1 | 1 | | |
| Night sweats | 1 | 1 | | | 1 | 1 | | |
| Nuchal rigidity | | 2 | | | | 1 | | 1 |
| Nystagmus | 1 | 1 | | | | | 1 | 1 |
| Obstructive airways disorder | 1 | 1 | | | 1 | 1 | | |
| Oedema mouth | 1 | 1 | | | | | 1 | 1 |
| Off label use | 8 | 9 | | | 7 | 8 | 1 | 1 |
| Optic neuritis | 3 | 3 | | | | | 3 | 3 |
| Oral herpes | | 1 | | | | 1 | | |
| Oral pain | 1 | 1 | | | | | 1 | 1 |
| Oral pruritus | 1 | 1 | | | | | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 | | | | | 1 | 1 |
| Oropharyngeal pain | 6 | 6 | | | 2 | 2 | 4 | 4 |
| Orthostatic hypotension | 1 | 1 | | | 1 | 1 | | |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Overdose | 2 | 2 | | | 2 | 2 | | |
| Oxygen saturation decreased | 4 | 6 | | | | 1 | 4 | 5 |
| Pain | 12 | 12 | | | 3 | 3 | 9 | 9 |
| Pain in extremity | 15 | 16 | | | 7 | 8 | 8 | 8 |
| Palatal oedema | 2 | 2 | | | | | 2 | 2 |
| Palatal swelling | | 1 | | | | 1 | | |
| Pallor | 2 | 2 | | | | | 2 | 2 |
| Panniculitis | 1 | 1 | | | | | 1 | 1 |
| Papilloedema | 1 | 1 | | | | | 1 | 1 |
| Paraesthesia | 15 | 16 | | | 5 | 6 | 10 | 10 |
| Paraesthesia oral | 11 | 13 | | | 5 | 7 | 6 | 6 |
| Pemphigoid | 1 | 1 | | | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 | | |
| Peripheral sensorimotor neuropathy | 1 | 1 | | | | | 1 | 1 |
| Peripheral swelling | 2 | 2 | | | | | 2 | 2 |
| Pharyngeal erythema | 2 | 2 | | | | | 2 | 2 |
| Pharyngeal oedema | 1 | 1 | | | | | 1 | 1 |
| Pharyngeal paraesthesia | 1 | 2 | | | | | 1 | 2 |
| Pharyngitis | 2 | 2 | | | | | 2 | 2 |
| Photophobia | 1 | 1 | | | | | 1 | 1 |
| Photopsia | 1 | 1 | | | | | 1 | 1 |
| Pneumonia bacterial | 1 | 1 | | | | | 1 | 1 |
| Pneumonitis | 1 | 1 | | | | | 1 | 1 |
| Presyncope | 2 | 3 | | | | 1 | 2 | 2 |
| Productive cough | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Product use issue | 8 | 9 | | | 7 | 8 | 1 | 1 |
| Pruritus | 12 | 16 | | | 1 | 5 | 11 | 11 |
| Pulmonary embolism | | 1 | | | | | | 1 |
| Purpura | 1 | 1 | | | | | 1 | 1 |
| Pyrexia | 51 | 59 | 2 | 2 | 21 | 28 | 30 | 31 |
| Rales | 1 | 1 | | | | | 1 | 1 |
| Rash | 8 | 11 | | | | 2 | 8 | 9 |
| Rash pruritic | 1 | 2 | | | 1 | 2 | | |

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|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Red blood cell count decreased | 1 | 1 | | | | | 1 | 1 |
| Red cell distribution width increased | 1 | 1 | | | 1 | 1 | | |
| Reduced facial expression | | 1 | | | | | | 1 |
| Regurgitation | 1 | 1 | | | | | 1 | 1 |
| Renal failure | 1 | 3 | | | | | 1 | 3 |
| Respiratory arrest | 1 | 2 | | | | | 1 | 2 |
| Respiratory disorder | 1 | 2 | | | | 1 | 1 | 1 |
| Respiratory distress | | 1 | | | | | | 1 |
| Respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Restlessness | 1 | 2 | | | | | 1 | 2 |
| Retching | 2 | 2 | | | | | 2 | 2 |
| Retinal degeneration | 1 | 1 | | | | | 1 | 1 |
| Retinal detachment | 1 | 1 | | | | | 1 | 1 |
| Retinal disorder | 1 | 1 | | | | | 1 | 1 |
| Rheumatoid arthritis | 1 | 1 | | | | | 1 | 1 |
| Scleral discolouration | 1 | 1 | | | | | 1 | 1 |
| Seizure | 2 | 2 | | | | | 2 | 2 |
| Sensation of foreign body | 1 | 2 | | | | 1 | 1 | 1 |
| Sensory loss | 1 | 1 | | | | | 1 | 1 |
| Sepsis | 1 | 1 | | | | | 1 | 1 |
| Septic shock | 1 | 1 | | | | | 1 | 1 |
| Severe acute respiratory syndrome | 1 | 1 | | | | | 1 | 1 |
| Sinus headache | 1 | 1 | | | 1 | 1 | | |
| Sinus tachycardia | 1 | 2 | | | | 1 | 1 | 1 |
| Skin reaction | | 1 | | | | 1 | | |
| Somnolence | 6 | 7 | | | 1 | 2 | 5 | 5 |
| Speech disorder | 1 | 1 | | | 1 | 1 | | |
| Spinal pain | | 1 | | | | 1 | | |
| Stertor | 1 | 1 | | | | | 1 | 1 |
| Stupor | 2 | 2 | | | | | 2 | 2 |
| Sudden death | 1 | 1 | | | | | 1 | 1 |
| Swelling face | | 1 | | | | | | 1 |
| Swollen tongue | 1 | 1 | | | | | 1 | 1 |

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|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Syncope | 6 | 6 | 1 | 1 | | | 6 | 6 |
| Systolic hypertension | | 1 | | | | | | 1 |
| Tachycardia | 13 | 16 | | | 3 | 4 | 10 | 12 |
| Tachypnoea | 1 | 2 | | | | 1 | 1 | 1 |
| Throat irritation | 3 | 4 | | | | 1 | 3 | 3 |
| Throat tightness | 4 | 10 | | | | 3 | 4 | 7 |
| Thrombocytopenia | 1 | 1 | | | | | 1 | 1 |
| Thyroid disorder | 1 | 1 | | | 1 | 1 | | |
| Tinnitus | 1 | 1 | | | 1 | 1 | | |
| Tongue oedema | 1 | 2 | | | | | 1 | 2 |
| Transaminases increased | 1 | 1 | | | | | 1 | 1 |
| Tremor | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Trigeminal nerve disorder | 1 | 1 | | | 1 | 1 | | |
| Underdose | | 1 | | | | 1 | | |
| Urticaria | 8 | 12 | | | 1 | 4 | 7 | 8 |
| Vaccination complication | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Vaccination failure | 1 | 1 | | | | | 1 | 1 |
| Vaccination site erythema | 1 | 3 | | | | 2 | 1 | 1 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 | | |
| Vaccination site movement impairment | | 1 | | | | 1 | | |
| Vaccination site oedema | | 1 | | | | 1 | | |
| Vaccination site pain | 17 | 24 | 1 | 1 | 7 | 14 | 10 | 10 |
| Vaccination site paraesthesia | 1 | 2 | | | | 1 | 1 | 1 |
| Vaccination site pruritus | 1 | 1 | | | | | 1 | 1 |
| Vaccination site reaction | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Vaccination site swelling | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Vaccination site warmth | | 1 | | | | 1 | | |
| Vasoconstriction | 1 | 1 | | | | | 1 | 1 |
| Vertigo | 8 | 9 | | | 4 | 5 | 4 | 4 |
| Vertigo positional | 1 | 1 | | | | | 1 | 1 |
| Vision blurred | 1 | 1 | | | | | 1 | 1 |
| Visual impairment | 2 | 2 | | | | | 2 | 2 |
| Vitreous detachment | 1 | 1 | | | | | 1 | 1 |

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 * AE=Adverse Event

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vitreous floaters | 1 | 1 | | | | | 1 | 1 |
| Vomiting | 12 | 14 | | | 3 | 4 | 9 | 10 |
| Weight decreased | | 1 | | | | | | 1 |
| Wheezing | 1 | 1 | | | | | 1 | 1 |
| White blood cell count decreased | 1 | 1 | | | | | 1 | 1 |
| White blood cell count increased | 1 | 1 | | | | | 1 | 1 |
| | 843 | 1,046 | 12 | 12 | 247 | 379 | 596 | 667 |

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Country Where Event Occurred
JAPAN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Dermatitis allergic | 1 | 1 | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 |
| Hypersensitivity | 1 | 1 | 1 | 1 |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 |
| Oral discomfort | 1 | 1 | 1 | 1 |
| Pallor | 1 | 1 | 1 | 1 |
| Pruritus | 1 | 1 | 1 | 1 |
| Respiratory distress | 1 | 1 | 1 | 1 |
| Urticaria | 1 | 1 | 1 | 1 |
| | 10 | 10 | 10 | 10 |

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Country Where Event Occurred
LATVIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 2 | 2 | | | 2 | 2 |
| Arthralgia | 1 | 3 | 1 | 2 | | 1 |
| Asthenia | 1 | 3 | 1 | 3 | | |
| Asthma | | 1 | | 1 | | |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Chest pain | | 1 | | 1 | | |
| Condition aggravated | | 1 | | 1 | | |
| Cough | 1 | 2 | 1 | 2 | | |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Depressed mood | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Dizziness | 4 | 4 | 1 | 1 | 3 | 3 |
| Dyspnoea | 1 | 2 | | 1 | 1 | 1 |
| Ear discomfort | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Fatigue | 3 | 5 | 1 | 3 | 2 | 2 |
| Headache | 1 | 2 | 1 | 1 | | 1 |
| Hot flush | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Insomnia | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 1 | 1 | 1 | | |
| Neuralgia | | 1 | | | | 1 |
| Pain in extremity | | 1 | | | | 1 |
| Palpitations | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 1 | 2 | | | 1 | 2 |
| Pyrexia | 2 | 3 | 1 | 2 | 1 | 1 |
| Skin burning sensation | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Somnolence | 2 | 2 | | | 2 | 2 |
| Tachycardia | 2 | 2 | | | 2 | 2 |
| Thirst | 1 | 1 | | | 1 | 1 |
| Throat irritation | 1 | 2 | 1 | 2 | | |
| Vaccination site erythema | 3 | 3 | 2 | 2 | 1 | 1 |
| Vaccination site mass | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 4 | 6 | 3 | 5 | 1 | 1 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| | 47 | 66 | 20 | 34 | 27 | 32 |

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Country Where Event Occurred
LITHUANIA

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-----------------------|--|--|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Death | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 2 | 2 | 1 | 1 |

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Country Where Event Occurred

LUXEMBOURG

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal distension | 1 | 1 | | | 1 | 1 |
| Acute kidney injury | 1 | 1 | | | 1 | 1 |
| Altered state of consciousness | 1 | 1 | | | 1 | 1 |
| Chills | 1 | 1 | | | 1 | 1 |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dry skin | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 1 | 1 | | | 1 | 1 |
| Fatigue | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | | | 1 | 1 |
| Herpes zoster | | 1 | | 1 | | |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 1 | 1 | | | 1 | 1 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 1 | 1 | | | 1 | 1 |
| Oral herpes | | 1 | | 1 | | |
| Paraesthesia | 1 | 1 | | | 1 | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pulmonary pain | 1 | 1 | | | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Skin haemorrhage | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 1 | 1 | | | 1 | 1 |
| | 24 | 26 | | 2 | 24 | 24 |

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Country Where Event Occurred

MALTA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 3 | 4 | | | 3 | 4 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Asthma | 1 | 2 | | | 1 | 2 |
| Bronchospasm | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 2 | | | 1 | 2 |
| Erythema | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 2 | 2 | | | 2 | 2 |
| Fatigue | 2 | 2 | 2 | 2 | | |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | 1 | 1 | | |
| Limb discomfort | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 2 | 2 | | |
| Musculoskeletal stiffness | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nausea | 1 | 2 | | 1 | 1 | 1 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Off label use | | 1 | | 1 | | |
| Overdose | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Paraesthesia | 3 | 3 | 3 | 3 | | |
| Product use issue | | 1 | | 1 | | |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Rash | 1 | 1 | | | 1 | 1 |
| Rash pruritic | | 1 | | | | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Tachycardia | 1 | 1 | | | 1 | 1 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat tightness | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 2 | | | 1 | 2 |
| | 47 | 55 | 22 | 25 | 25 | 30 |

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Country Where Event Occurred
MEXICO

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 3 | 1 | 2 | 1 | 1 |
| Anaphylactic shock | 1 | 2 | | | 1 | 2 |
| Angioedema | | 1 | | | | 1 |
| Anxiety | 2 | 2 | 1 | 1 | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 3 | 3 | 3 | 3 | | |
| Asthma | | 1 | | 1 | | |
| Bronchospasm | 3 | 3 | 1 | 1 | 2 | 2 |
| Cellulitis | 1 | 1 | | | 1 | 1 |
| Chest pain | 1 | 1 | 1 | 1 | | |
| Chills | 4 | 4 | 3 | 3 | 1 | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| COVID-19 pneumonia | | 1 | | | | 1 |
| Cyanosis | | 1 | | 1 | | |
| Decreased appetite | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Dizziness | 5 | 6 | 4 | 5 | 1 | 1 |
| Drug ineffective | | 1 | | | | 1 |
| Dysphagia | 1 | 1 | 1 | 1 | | |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 5 | 6 | 3 | 4 | 2 | 2 |
| Encephalitis post immunisation | | 1 | | | | 1 |
| Eye injury | 1 | 1 | 1 | 1 | | |
| Eye irritation | 1 | 1 | 1 | 1 | | |
| Eye swelling | | 1 | | 1 | | |
| Fatigue | 4 | 4 | 3 | 3 | 1 | 1 |
| Headache | 6 | 6 | 6 | 6 | | |
| Hypersensitivity | 1 | 2 | | 1 | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hyperthermia | 1 | 1 | 1 | 1 | | |
| Induration | 1 | 1 | 1 | 1 | | |
| Laryngeal oedema | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | | 1 | | | | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Masticatory pain | | 1 | | 1 | | |
| Maternal exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Muscle spasms | | 1 | | | | 1 |
| Myalgia | 3 | 3 | 3 | 3 | | |
| Myelitis transverse | | 1 | | | | 1 |
| Nasal congestion | | 1 | | 1 | | |
| Nausea | 3 | 3 | 2 | 2 | 1 | 1 |
| Nervousness | 1 | 1 | 1 | 1 | | |
| Neuropathy peripheral | 1 | 1 | | | 1 | 1 |
| Nodule | 1 | 1 | 1 | 1 | | |
| Occupational exposure to SARS-CoV-2 | 1 | 1 | 1 | 1 | | |
| Odynophagia | 1 | 1 | 1 | 1 | | |
| Oedema | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oropharyngeal discomfort | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 2 | 2 | 2 | 2 | | |
| Pain | 2 | 2 | 2 | 2 | | |
| Paraesthesia | | 1 | | | | 1 |
| Paraesthesia oral | 1 | 1 | 1 | 1 | | |
| Paralysis | | 1 | | | | 1 |
| Parotid gland enlargement | | 1 | | 1 | | |
| Parotitis | | 1 | | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pruritus | 2 | 3 | 2 | 3 | | |
| Pyrexia | 1 | 1 | 1 | 1 | | |
| Rash | | 1 | | | | 1 |
| Respiratory distress | 4 | 5 | | | 4 | 5 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Seizure | | 1 | | | | 1 |
| Sensitive skin | 1 | 1 | 1 | 1 | | |
| Sneezing | | 1 | | 1 | | |
| Speech disorder | 1 | 1 | 1 | 1 | | |
| Tachycardia | 3 | 3 | 2 | 2 | 1 | 1 |
| Tachypnoea | 1 | 1 | | | 1 | 1 |
| Throat irritation | | 1 | | 1 | | |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Transaminases increased | 1 | 1 | | | 1 | 1 |
| Vaccination site cellulitis | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 1 | 1 | 1 | | |
| Vaccination site hypersensitivity | 1 | 1 | 1 | 1 | | |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site inflammation | 1 | 1 | 1 | 1 | | |
| Vaccination site nodule | 1 | 1 | 1 | 1 | | |
| Vaccination site oedema | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 103 | 131 | 74 | 89 | 29 | 42 |

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Country Where Event Occurred

NETHERLANDS

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute respiratory failure | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 3 | 4 | | | 3 | 4 |
| Apallic syndrome | 1 | 1 | | | 1 | 1 |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Atrial f brillation | 1 | 1 | | | 1 | 1 |
| Balance disorder | 1 | 1 | 1 | 1 | | |
| Bedridden | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 4 | 4 | | | 4 | 4 |
| Cardiac failure acute | 2 | 2 | | | 2 | 2 |
| Cerebral haemorrhage | 1 | 1 | | | 1 | 1 |
| Cerebral infarction | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 3 | 3 | | | 3 | 3 |
| Chills | 6 | 6 | 3 | 3 | 3 | 3 |
| Choking | 1 | 1 | | | 1 | 1 |
| Choking sensation | | 1 | | | | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | 6 | 6 | | | 6 | 6 |
| Decreased appetite | 1 | 1 | 1 | 1 | | |
| Dehydration | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 1 | 1 | | | 1 | 1 |
| Diplopia | 1 | 1 | 1 | 1 | | |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dizziness | 1 | 1 | 1 | 1 | | |
| Dysarthria | 1 | 1 | 1 | 1 | | |
| Dysphagia | 2 | 2 | | | 2 | 2 |
| Dyspnoea | 8 | 8 | 3 | 3 | 5 | 5 |
| Epilepsy | 4 | 4 | | | 4 | 4 |
| Erythema | | 1 | | 1 | | |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Fall | 1 | 1 | | | 1 | 1 |
| Fatigue | 8 | 9 | 3 | 4 | 5 | 5 |
| Feeding disorder | 1 | 1 | 1 | 1 | | |
| Fluid retention | 1 | 1 | 1 | 1 | | |
| Flushing | 1 | 1 | 1 | 1 | | |
| Gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Gaze palsy | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 1 | 1 | | | 1 | 1 |
| Headache | 5 | 5 | 4 | 4 | 1 | 1 |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Hemianaesthesia | 1 | 1 | 1 | 1 | | |
| Hemiparesis | 2 | 2 | | | 2 | 2 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hyperpyrexia | 1 | 1 | | | 1 | 1 |
| Hypertension | 2 | 2 | | | 2 | 2 |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Lymph node pain | 1 | 1 | 1 | 1 | | |
| Malaise | 14 | 15 | 5 | 6 | 9 | 9 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Muscle twitching | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Myalgia | 8 | 9 | 6 | 7 | 2 | 2 |
| Nasopharyngitis | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Nausea | 11 | 11 | 6 | 6 | 5 | 5 |
| Nystagmus | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 4 | 4 | | | 4 | 4 |
| Paraesthesia oral | | 1 | | 1 | | |
| Peripheral coldness | 1 | 1 | 1 | 1 | | |
| Pharyngeal oedema | | 1 | | | | 1 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Polyuria | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pupillary disorder | 1 | 1 | 1 | 1 | | |
| Pyrexia | 9 | 9 | 1 | 1 | 8 | 8 |
| Rash erythematous | 1 | 1 | 1 | 1 | | |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Rhinitis | 1 | 1 | | | 1 | 1 |
| Seizure | 1 | 1 | | | 1 | 1 |
| Somnolence | 1 | 1 | 1 | 1 | | |
| Status epilepticus | 1 | 1 | | | 1 | 1 |
| Sudden death | 4 | 4 | | | 4 | 4 |
| Swelling face | | 1 | | 1 | | |
| Syncope | 1 | 1 | 1 | 1 | | |
| Tachypnoea | 1 | 1 | 1 | 1 | | |
| Tongue oedema | | 1 | | | | 1 |
| Torticollis | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 2 | 1 | 2 | | |
| Vaccination site bruising | 1 | 1 | 1 | 1 | | |
| Vaccination site erythema | 1 | 2 | 1 | 2 | | |
| Vaccination site haematoma | 2 | 2 | 2 | 2 | | |
| Vaccination site inflammation | 3 | 4 | 3 | 4 | | |
| Vaccination site pain | 6 | 7 | 4 | 5 | 2 | 2 |
| Vaccination site pruritus | | 1 | | 1 | | |
| Vaccination site swelling | 2 | 3 | 2 | 3 | | |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-------------------------|--|--|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site warmth | 3 | 4 | 3 | 4 | | |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vomiting | 1 | 1 | | | 1 | 1 |
| Weight decreased | 1 | 1 | | | 1 | 1 |
| | 191 | 209 | 79 | 92 | 112 | 117 |

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Country Where Event Occurred

NORWAY

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Abdominal pain upper | 2 | 2 | | | 2 | 2 |
| Acute kidney injury | | 1 | | | | 1 |
| Acute myocardial infarction | | 1 | | | | 1 |
| Altered state of consciousness | 5 | 5 | | | 5 | 5 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 2 | | 1 | 1 | 1 |
| Apathy | | 1 | | | | 1 |
| Apnoea | 2 | 2 | | | 2 | 2 |
| Arthralgia | 1 | 1 | 1 | 1 | | |
| Arthritis | 1 | 1 | 1 | 1 | | |
| Asthenia | 3 | 3 | 2 | 2 | 1 | 1 |
| Atrial flutter | 1 | 1 | | | 1 | 1 |
| Atrioventricular block first degree | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Bedridden | 4 | 4 | | | 4 | 4 |
| Blood pressure decreased | | 2 | | | | 2 |
| Blood pressure diastolic decreased | | 1 | | 1 | | |
| Body temperature decreased | | 1 | | 1 | | |
| Bradycardia | 3 | 3 | | | 3 | 3 |
| Breast enlargement | 1 | 1 | 1 | 1 | | |
| Breast pain | 1 | 1 | 1 | 1 | | |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 2 | 3 | | | 2 | 3 |
| Cardiovascular disorder | | 1 | | | | 1 |
| Cerebral haemorrhage | 1 | 2 | | | 1 | 2 |
| Cerebral infarction | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 3 | 5 | | | 3 | 5 |
| Cerebrovascular disorder | 1 | 1 | | | 1 | 1 |
| Chest pain | 2 | 2 | | | 2 | 2 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chills | 4 | 4 | 3 | 3 | 1 | 1 |
| Chronic kidney disease | 1 | 1 | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | 1 | 1 |
| Circulatory collapse | 1 | 1 | | | 1 | 1 |
| Cognitive disorder | 1 | 1 | | | 1 | 1 |
| Cold sweat | 1 | 3 | | | 1 | 3 |
| Communication disorder | 1 | 1 | 1 | 1 | | |
| Concomitant disease aggravated | | 1 | | | | 1 |
| Condition aggravated | 1 | 2 | 1 | 1 | | 1 |
| Confusional state | 7 | 10 | 2 | 2 | 5 | 8 |
| Conjunctivitis | 1 | 1 | 1 | 1 | | |
| Constipation | 1 | 1 | 1 | 1 | | |
| Coordination abnormal | | 1 | | | | 1 |
| Cough | 4 | 5 | 2 | 2 | 2 | 3 |
| C-reactive protein increased | 6 | 6 | 1 | 1 | 5 | 5 |
| Death | 11 | 18 | | | 11 | 18 |
| Decreased appetite | 4 | 6 | 1 | 1 | 3 | 5 |
| Delirium | 1 | 2 | | | 1 | 2 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 2 | 4 | | | 2 | 4 |
| Diarrhoea | 3 | 5 | 1 | 1 | 2 | 4 |
| Disease recurrence | | 1 | | | | 1 |
| Diverticulitis | 1 | 1 | | | 1 | 1 |
| Dizziness | 3 | 3 | 2 | 2 | 1 | 1 |
| Drooling | 1 | 1 | 1 | 1 | | |
| Dry skin | 1 | 1 | 1 | 1 | | |
| Dysarthria | 2 | 2 | | | 2 | 2 |
| Dysgeusia | 1 | 1 | 1 | 1 | | |
| Dysphagia | 3 | 4 | | | 3 | 4 |
| Dysphonia | 1 | 1 | 1 | 1 | | |
| Dyspnoea | 13 | 16 | 2 | 2 | 11 | 14 |
| Ear pain | 1 | 1 | 1 | 1 | | |
| Ear swelling | 1 | 1 | 1 | 1 | | |

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|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Facial paresis | 1 | 1 | | | 1 | 1 |
| Faeces discoloured | 1 | 1 | | | 1 | 1 |
| Fall | 4 | 4 | 1 | 1 | 3 | 3 |
| Fatigue | 13 | 17 | 8 | 9 | 5 | 8 |
| Feeling abnormal | 2 | 2 | 1 | 1 | 1 | 1 |
| Feeling cold | 1 | 1 | 1 | 1 | | |
| Feeling hot | | 1 | | | | 1 |
| Food refusal | 1 | 1 | | | 1 | 1 |
| Fracture | 1 | 1 | | | 1 | 1 |
| Gastrointestinal haemorrhage | | 1 | | | | 1 |
| General physical health deterioration | 18 | 25 | 1 | 1 | 17 | 24 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Hallucination | 1 | 2 | | | 1 | 2 |
| Headache | 4 | 4 | 3 | 3 | 1 | 1 |
| Heart rate increased | 4 | 5 | 2 | 2 | 2 | 3 |
| Heart rate irregular | 1 | 1 | | | 1 | 1 |
| Hemiplegia | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hyperkalaemia | 1 | 1 | | | 1 | 1 |
| Hypertension | 2 | 2 | 2 | 2 | | |
| Hyperventilation | 2 | 3 | 2 | 3 | | |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Hypotension | 3 | 4 | | | 3 | 4 |
| Hypoxia | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 1 | 1 | 1 | 1 | | |
| Increased bronchial secretion | 1 | 1 | | | 1 | 1 |
| Infection | 5 | 6 | 1 | 1 | 4 | 5 |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Infective exacerbation of chronic obstructive airways disease | 1 | 1 | | | 1 | 1 |
| Influenza like illness | | 1 | | | | 1 |
| Ischaemic stroke | 1 | 1 | | | 1 | 1 |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Leukocytosis | 1 | 1 | 1 | 1 | | |
| Local reaction | | 1 | | | | 1 |
| Loss of consciousness | 2 | 3 | | | 2 | 3 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 3 | 5 | 2 | 2 | 1 | 3 |
| Malignant hypertension | | 1 | | | | 1 |
| Malnutrition | 1 | 1 | | | 1 | 1 |
| Melaena | 1 | 1 | | | 1 | 1 |
| Metastases to peritoneum | 1 | 1 | | | 1 | 1 |
| Middle insomnia | 1 | 1 | 1 | 1 | | |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Motor dysfunction | 1 | 1 | 1 | 1 | | |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 3 | 3 | 1 | 1 | 2 | 2 |
| Muscular weakness | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal stiffness | 3 | 3 | 3 | 3 | | |
| Myalgia | 3 | 3 | 2 | 2 | 1 | 1 |
| Nausea | 10 | 11 | 6 | 6 | 4 | 5 |
| Oedema peripheral | 2 | 2 | 2 | 2 | | |
| Ophthalmic herpes zoster | 1 | 1 | | | 1 | 1 |
| Oropharyngeal pain | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 3 | 4 | | | 3 | 4 |
| Pain | 3 | 3 | 2 | 2 | 1 | 1 |
| Pain in extremity | 2 | 2 | 2 | 2 | | |
| Pallor | | 2 | | | | 2 |
| Paralysis | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Pneumonia | 9 | 10 | | | 9 | 10 |

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|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Presyncope | 2 | 2 | | | 2 | 2 |
| Productive cough | 3 | 3 | | | 3 | 3 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pupil fixed | | 2 | | | | 2 |
| Pyelonephritis | 1 | 1 | | | 1 | 1 |
| Pyrexia | 16 | 20 | 4 | 4 | 12 | 16 |
| Rales | 1 | 2 | 1 | 1 | | 1 |
| Rash | 3 | 3 | 3 | 3 | | |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Respiratory arrest | 1 | 2 | | | 1 | 2 |
| Respiratory failure | 4 | 4 | | | 4 | 4 |
| Respiratory rate increased | 1 | 3 | 1 | 1 | | 2 |
| Restlessness | 3 | 4 | 1 | 2 | 2 | 2 |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Secretion discharge | 1 | 1 | | | 1 | 1 |
| Sepsis | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 4 | 1 | 1 | 1 | 3 |
| Speech disorder | 2 | 2 | 2 | 2 | | |
| Sputum increased | 1 | 1 | 1 | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Sudden death | 3 | 5 | | | 3 | 5 |
| Syncope | 2 | 4 | | | 2 | 4 |
| Tendon pain | 1 | 1 | 1 | 1 | | |
| Terminal state | 2 | 2 | | | 2 | 2 |
| Thrombotic stroke | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 2 | | | 1 | 2 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 1 | 1 | 1 | | |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 2 | 1 | 1 | | 1 |
| Vaccination site pain | 4 | 5 | 4 | 4 | | 1 |

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|---------------------------|--|--|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site reaction | 1 | 1 | 1 | 1 | | |
| Vaccination site swelling | | 1 | | | | 1 |
| Vomiting | 9 | 13 | 4 | 5 | 5 | 8 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 337 | 432 | 114 | 121 | 223 | 311 |

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Country Where Event Occurred
POLAND

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain upper | 1 | 1 | 1 | 1 | | |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 2 | 2 | 2 | 2 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| Contusion | 1 | 1 | | | 1 | 1 |
| Death | 1 | 1 | | | 1 | 1 |
| Disease recurrence | | 1 | | | | 1 |
| Hyperhidrosis | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | | 1 | | 1 | | |
| Inflammation | | 1 | | 1 | | |
| Iritis | | 1 | | 1 | | |
| Joint effusion | 1 | 1 | 1 | 1 | | |
| Joint swelling | 1 | 1 | 1 | 1 | | |
| Lividity | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Off label use | 1 | 1 | 1 | 1 | | |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 1 | 1 | 1 | 1 | | |
| Paraparesis | | 1 | | | | 1 |
| Parosmia | 1 | 1 | 1 | 1 | | |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 3 | 2 | 3 | | |
| Rash macular | | 1 | | 1 | | |
| Rhinorrhoea | 1 | 1 | 1 | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|---------------------------------|--|--|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Taste disorder | 1 | 1 | 1 | 1 | | |
| Therapeutic response unexpected | 1 | 1 | 1 | 1 | | |
| Tremor | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| | 31 | 39 | 25 | 31 | 6 | 8 |

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Country Where Event Occurred
PORTUGAL

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Anaphylactoid reaction | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Anxiety | | 1 | | 1 | | |
| Arrhythmia | 2 | 2 | | | 2 | 2 |
| Arthralgia | 7 | 7 | | | 7 | 7 |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Axillary pain | 1 | 1 | | | 1 | 1 |
| Balance disorder | | 1 | | | | 1 |
| Blood pressure decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Breast pain | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 3 | 3 | | | 3 | 3 |
| Cardio-respiratory arrest | 1 | 2 | | | 1 | 2 |
| Chest discomfort | 2 | 3 | | | 2 | 3 |
| Chest pain | 1 | 2 | | | 1 | 2 |
| Chills | 7 | 9 | | | 7 | 9 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Circumoral oedema | | 1 | | | | 1 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 2 | | | 1 | 2 |
| COVID-19 | 3 | 3 | 2 | 2 | 1 | 1 |
| Crohn's disease | 1 | 1 | | | 1 | 1 |
| Cutaneous vasculitis | 1 | 1 | | | 1 | 1 |
| Cyanosis | 1 | 1 | | | 1 | 1 |
| Death | | 1 | | | | 1 |
| Diarrhoea | 5 | 5 | | | 5 | 5 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Dizziness | 5 | 6 | 1 | 1 | 4 | 5 |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dysgeusia | | 1 | | | | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 7 | 7 | | | 7 | 7 |
| Erythema | 2 | 3 | | | 2 | 3 |
| Exposure during pregnancy | 1 | 1 | 1 | 1 | | |
| Eye irritation | 1 | 1 | 1 | 1 | | |
| Face oedema | 1 | 1 | | | 1 | 1 |
| Fatigue | 8 | 9 | | | 8 | 9 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | | 1 | | | | 1 |
| Headache | 28 | 28 | | | 28 | 28 |
| Hyperglycaemia | 2 | 2 | | | 2 | 2 |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | | 1 | | | | 1 |
| Hypertension | 3 | 3 | | | 3 | 3 |
| Hypertensive crisis | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 1 | 1 | | | 1 | 1 |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 2 | | | 2 | 2 |
| Hypothyroidism | | 1 | | | | 1 |
| Inappropriate schedule of product administration | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 1 | 2 | 1 | 2 | | |
| Laryngeal oedema | | 1 | | | | 1 |
| Lip oedema | | 2 | | | | 2 |
| Localised oedema | 2 | 2 | | | 2 | 2 |
| Loss of personal independence in daily activities | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 6 | 6 | | | 6 | 6 |
| Malaise | 4 | 5 | | | 4 | 5 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 21 | 23 | | | 21 | 23 |
| Myalgia intercostal | 1 | 1 | | | 1 | 1 |

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|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Nasal discomfort | 1 | 1 | 1 | 1 | | |
| Nasal dryness | 1 | 1 | 1 | 1 | | |
| Nasal obstruction | | 1 | | | | 1 |
| Nausea | 5 | 7 | | | 5 | 7 |
| Night sweats | 1 | 1 | | | 1 | 1 |
| Occupational exposure to SARS-CoV-2 | 1 | 1 | 1 | 1 | | |
| Odynophagia | 2 | 2 | | | 2 | 2 |
| Oedema peripheral | 1 | 1 | | | 1 | 1 |
| Off label use | 3 | 3 | 3 | 3 | | |
| Oropharyngeal discomfort | 1 | 2 | | | 1 | 2 |
| Overdose | 1 | 1 | 1 | 1 | | |
| Pain | 2 | 3 | | 1 | 2 | 2 |
| Pain in extremity | 3 | 4 | 1 | 1 | 2 | 3 |
| Pain in jaw | | 1 | | | | 1 |
| Pallor | 1 | 1 | | | 1 | 1 |
| Palmar-plantar erythrodysesthesia syndrome | | 1 | | | | 1 |
| Palpitations | 1 | 2 | | 1 | 1 | 1 |
| Paraesthesia | 3 | 3 | | | 3 | 3 |
| Paraesthesia oral | 2 | 2 | | | 2 | 2 |
| Perineal pain | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | | 1 | | | | 1 |
| Phlebitis | 1 | 1 | | | 1 | 1 |
| Postural orthostatic tachycardia syndrome | 1 | 1 | | | 1 | 1 |
| Presyncope | 4 | 4 | | | 4 | 4 |
| Product use issue | 3 | 3 | 3 | 3 | | |
| Pruritus | 2 | 5 | | 1 | 2 | 4 |
| Pyrexia | 19 | 20 | | | 19 | 20 |
| Rash | 5 | 7 | | | 5 | 7 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 1 | 1 | | | 1 | 1 |
| Rash papular | 1 | 1 | | | 1 | 1 |

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|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | | 1 | | | | 1 |
| Sensory loss | 1 | 2 | | | 1 | 2 |
| Sinus tachycardia | | 1 | | | | 1 |
| Sleep disorder | 1 | 1 | | | 1 | 1 |
| Somnolence | 3 | 3 | | | 3 | 3 |
| Swelling | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Synovial cyst | 1 | 1 | | | 1 | 1 |
| Tachyarrhythmia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 3 | 3 | | | 3 | 3 |
| Tachypnoea | | 1 | | | | 1 |
| Taste disorder | 1 | 1 | | | 1 | 1 |
| Tenosynovitis | | 1 | | 1 | | |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Thrombophlebitis | 1 | 1 | | | 1 | 1 |
| Thyroid function test abnormal | | 1 | | 1 | | |
| Tongue discomfort | 1 | 1 | | | 1 | 1 |
| Tongue dry | | 1 | | | | 1 |
| Tongue oedema | 1 | 1 | | | 1 | 1 |
| Tremor | 1 | 1 | | | 1 | 1 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Urticaria papular | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | 13 | 14 | 1 | 1 | 12 | 13 |
| Vaccination site paraesthesia | 1 | 1 | | | 1 | 1 |
| Vaccination site pruritus | | 1 | | | | 1 |
| Vaccination site warmth | 2 | 2 | | | 2 | 2 |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vision blurred | 1 | 1 | | | 1 | 1 |
| Vomiting | 2 | 2 | 1 | 1 | 1 | 1 |

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| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|--------------------------------|--|--|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vulvovaginal burning sensation | 1 | 1 | | | 1 | 1 |
| Vulvovaginal swelling | 1 | 1 | | | 1 | 1 |
| Wheezing | 1 | 1 | | | 1 | 1 |
| | 270 | 319 | 20 | 27 | 250 | 292 |

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Country Where Event Occurred
PUERTO RICO

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal discomfort | | 1 | | 1 | | |
| Arthralgia | | 2 | | 2 | | |
| Chills | | 1 | | 1 | | |
| Diarrhoea | | 1 | | 1 | | |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Dyskinesia | | 1 | | | | 1 |
| Facial paralysis | | 1 | | | | 1 |
| Fatigue | | 2 | | 2 | | |
| Gait disturbance | | 1 | | 1 | | |
| Headache | | 3 | | 3 | | |
| Heart rate decreased | | 1 | | | | 1 |
| Hypertension | | 1 | | 1 | | |
| Hypoaesthesia | | 1 | | 1 | | |
| Joint range of motion decreased | | 1 | | 1 | | |
| Limb discomfort | | 1 | | 1 | | |
| Lymphadenopathy | | 1 | | 1 | | |
| Migraine | | 1 | | | | 1 |
| Musculoskeletal stiffness | | 1 | | 1 | | |
| Myalgia | | 1 | | 1 | | |
| Neuralgia | | 1 | | 1 | | |
| Night sweats | | 1 | | | | 1 |
| Pain | | 1 | | 1 | | |
| Pain in extremity | | 2 | | 2 | | |
| Palpitations | | 1 | | 1 | | |
| Photophobia | | 1 | | 1 | | |
| Puncture site swelling | | 1 | | 1 | | |
| Pyrexia | | 1 | | 1 | | |
| Rash | | 1 | | 1 | | |
| Rhinorrhoea | | 1 | | 1 | | |
| Sinus arrhythmia | | 1 | | | | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Tachycardia | | 1 | | 1 | | |
| Vaccination site induration | | 1 | | 1 | | |
| | 1 | 37 | 1 | 31 | | 6 |

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Country Where Event Occurred
QATAR

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenia | 1 | 1 | 1 | 1 | | |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Dizziness | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Feeling hot | 1 | 1 | | | 1 | 1 |
| Heart rate increased | 1 | 1 | 1 | 1 | | |
| Hyperhidrosis | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 3 | 3 | 4 | 4 |

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Country Where Event Occurred
ROMANIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | 1 | 1 | | | 1 | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Anxiety | | 1 | | | | 1 |
| Arthralgia | 1 | 2 | | | 1 | 2 |
| Asphyxia | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 2 | | | 1 | 2 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Blood pressure fluctuation | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 2 | 2 | | | 2 | 2 |
| Chest pain | 1 | 2 | | | 1 | 2 |
| Chills | 2 | 3 | 1 | 1 | 1 | 2 |
| Condition aggravated | 1 | 1 | | | 1 | 1 |
| Cough | 1 | 2 | | | 1 | 2 |
| Dizziness | | 1 | | 1 | | |
| Drug eruption | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Exposure during pregnancy | | 1 | | 1 | | |
| Fatigue | 2 | 3 | 1 | 1 | 1 | 2 |
| Flushing | | 1 | | 1 | | |
| General physical health deterioration | 1 | 1 | 1 | 1 | | |
| Headache | 4 | 5 | 1 | 1 | 3 | 4 |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypokinesia | 1 | 1 | 1 | 1 | | |
| Hypotension | 1 | 1 | | | 1 | 1 |
| Lip oedema | 2 | 2 | | | 2 | 2 |
| Loss of consciousness | 1 | 1 | | | 1 | 1 |
| Lymphadenopathy | 2 | 2 | | | 2 | 2 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Maternal exposure during pregnancy | | 1 | | 1 | | |
| Migraine | | 1 | | | | 1 |
| Myalgia | 4 | 6 | 1 | 2 | 3 | 4 |
| Nausea | 3 | 4 | 1 | 1 | 2 | 3 |
| Off label use | | 1 | | 1 | | |
| Oxygen saturation decreased | 1 | 1 | | | 1 | 1 |
| Palpitations | | 1 | | | | 1 |
| Paraesthesia | | 2 | | 1 | | 1 |
| Product use issue | | 1 | | 1 | | |
| Pyrexia | 3 | 3 | 1 | 1 | 2 | 2 |
| Rash | 1 | 2 | | 1 | 1 | 1 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Raynaud's phenomenon | 1 | 1 | | | 1 | 1 |
| Renal pain | 1 | 1 | | | 1 | 1 |
| Respiration abnormal | 1 | 1 | | | 1 | 1 |
| Rhinalgia | 1 | 1 | | | 1 | 1 |
| Sensory loss | 1 | 1 | 1 | 1 | | |
| Somnolence | | 1 | | 1 | | |
| Syncope | 1 | 1 | | | 1 | 1 |
| Systolic hypertension | | 1 | | | | 1 |
| Tachycardia | 1 | 2 | | | 1 | 2 |
| Urticaria | 1 | 1 | | | 1 | 1 |
| Vaccination site erythema | | 1 | | 1 | | |
| Vaccination site pain | 3 | 5 | | 2 | 3 | 3 |
| Vertigo | 1 | 1 | | | 1 | 1 |
| Vomiting | 2 | 3 | | | 2 | 3 |
| | 62 | 91 | 10 | 23 | 52 | 68 |

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Country Where Event Occurred
SAUDI ARABIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Fatigue | 1 | 2 | 1 | 2 |
| Gait disturbance | 1 | 1 | 1 | 1 |
| Headache | | 1 | | 1 |
| Movement disorder | | 1 | | 1 |
| Musculoskeletal stiffness | | 1 | | 1 |
| Nasopharyngitis | | 1 | | 1 |
| Pain | | 1 | | 1 |
| Rhinorrhoea | | 1 | | 1 |
| Somnolence | 1 | 1 | 1 | 1 |
| Vaccination site pain | | 1 | | 1 |
| | 3 | 11 | 3 | 11 |

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Country Where Event Occurred
SERBIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abscess | | 1 | | | | 1 |
| Axillary pain | | 1 | | | | 1 |
| Body temperature increased | 1 | 1 | 1 | 1 | | |
| Chills | | 1 | | | | 1 |
| Facial paralysis | 1 | 1 | | | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Lymphadenitis | | 1 | | | | 1 |
| Lymphadenopathy | | 1 | | | | 1 |
| Pain | 1 | 2 | 1 | 1 | | 1 |
| Phlebitis | | 1 | | | | 1 |
| Pyrexia | 1 | 3 | 1 | 2 | | 1 |
| Swelling | | 1 | | | | 1 |
| Vaccination site pain | 1 | 2 | 1 | 2 | | |
| | 6 | 17 | 5 | 7 | 1 | 10 |

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Country Where Event Occurred
SINGAPORE

| <i>Preferred Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | | | |
|-----------------------|--|--|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaphylactic reaction | | 1 | | | | 1 |
| Anaphylactic shock | | 1 | | | | 1 |
| Chills | | 1 | | 1 | | |
| Diarrhoea | | 1 | | 1 | | |
| Head discomfort | | 1 | | 1 | | |
| | | 5 | | 3 | | 2 |

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Country Where Event Occurred

SLOVAKIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthralgia | 2 | 2 | 2 | 2 | | |
| Asthenia | 1 | 1 | | | 1 | 1 |
| Axillary pain | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling of body temperature change | 1 | 1 | 1 | 1 | | |
| Hypoaesthesia | | 1 | | 1 | | |
| Incorrect dose administered | 1 | 1 | 1 | 1 | | |
| Insulin resistance | 1 | 1 | | | 1 | 1 |
| Limb discomfort | | 1 | | 1 | | |
| Lymphadenopathy | | 2 | | 2 | | |
| Malaise | 1 | 1 | 1 | 1 | | |
| Medication error | 1 | 1 | 1 | 1 | | |
| Movement disorder | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Myocardial ischaemia | 1 | 1 | | | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 | | |
| No adverse event | 1 | 1 | 1 | 1 | | |
| Pain in extremity | | 2 | | 2 | | |
| Product administered at inappropriate site | | 1 | | 1 | | |
| Pruritus | 1 | 1 | 1 | 1 | | |
| Pyrexia | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash | 1 | 2 | 1 | 2 | | |
| Rash pruritic | | 1 | | 1 | | |
| Vaccination site pain | 2 | 2 | 2 | 2 | | |
| Vaccination site urticaria | | 1 | | 1 | | |
| Vomiting | 1 | 1 | 1 | 1 | | |
| | 24 | 35 | 18 | 29 | 6 | 6 |

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Country Where Event Occurred

SLOVENIA

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 1 | 1 | 1 | 1 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Asthenia | | 1 | | 1 | | |
| Blood pressure increased | 1 | 1 | 1 | 1 | | |
| Body temperature increased | 1 | 1 | | | 1 | 1 |
| Cardiopulmonary failure | | 1 | | | | 1 |
| Chest discomfort | 1 | 1 | 1 | 1 | | |
| Chills | 1 | 1 | 1 | 1 | | |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 1 | 1 | 1 | 1 | | |
| Disease recurrence | | 1 | | | | 1 |
| Drug ineffective | 1 | 1 | | | 1 | 1 |
| Erythema | 1 | 1 | 1 | 1 | | |
| Eyelid oedema | 1 | 1 | 1 | 1 | | |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Feeling hot | 2 | 2 | 1 | 1 | 1 | 1 |
| Headache | 1 | 1 | 1 | 1 | | |
| Malaise | 2 | 2 | 1 | 1 | 1 | 1 |
| Myalgia | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain | 1 | 1 | 1 | 1 | | |
| Pain in extremity | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash pruritic | 1 | 1 | 1 | 1 | | |
| Restlessness | 1 | 1 | 1 | 1 | | |
| Sudden death | | 1 | | | | 1 |
| Tachycardia | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 1 | 1 | 1 | 1 | | |
| | 25 | 30 | 18 | 19 | 7 | 11 |

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Country Where Event Occurred

SPAIN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute kidney injury | 2 | 2 | | | 2 | 2 |
| Acute leukaemia | 1 | 1 | | | 1 | 1 |
| Acute respiratory failure | 2 | 3 | | | 2 | 3 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anal sphincter atony | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 14 | 14 | | | 14 | 14 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angina pectoris | 1 | 1 | | | 1 | 1 |
| Angioedema | 3 | 3 | | | 3 | 3 |
| Angular cheilitis | | 1 | | 1 | | |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety | 1 | 1 | 1 | 1 | | |
| Aphasia | 1 | 1 | | | 1 | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arthralgia | 2 | 4 | | 2 | 2 | 2 |
| Asphyxia | 2 | 2 | | | 2 | 2 |
| Aspiration | | 1 | | | | 1 |
| Asthenia | 9 | 9 | 1 | 1 | 8 | 8 |
| Asthma | 3 | 3 | | | 3 | 3 |
| Asthmatic crisis | 1 | 1 | | | 1 | 1 |
| Asymptomatic COVID-19 | 3 | 3 | | | 3 | 3 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial f brillation | 2 | 2 | | | 2 | 2 |
| Autoantibody negative | 1 | 1 | | | 1 | 1 |
| Autoimmune demyelinating disease | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Blister | 1 | 1 | | | 1 | 1 |
| Blood chloride decreased | 1 | 1 | 1 | 1 | | |
| Blood glucose increased | 1 | 1 | 1 | 1 | | |

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|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure decreased | 1 | 1 | 1 | 1 | | |
| Blood pressure diastolic decreased | 1 | 1 | | | 1 | 1 |
| Blood pressure increased | 2 | 2 | 2 | 2 | | |
| Blood sodium decreased | 1 | 1 | 1 | 1 | | |
| Bradycardia | 1 | 1 | | | 1 | 1 |
| Bradykinesia | 2 | 2 | 1 | 1 | 1 | 1 |
| Bradyphrenia | 1 | 1 | 1 | 1 | | |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 |
| Bronchospasm | 7 | 7 | | | 7 | 7 |
| Cardiac arrest | 1 | 1 | | | 1 | 1 |
| Cardiac failure | 3 | 3 | | | 3 | 3 |
| Cardiac failure acute | 3 | 3 | | | 3 | 3 |
| Cardio-respiratory arrest | 2 | 2 | | | 2 | 2 |
| Cardio-respiratory distress | | 1 | | | | 1 |
| Carotid bruit | 1 | 1 | | | 1 | 1 |
| Cerebrovascular accident | 1 | 1 | | | 1 | 1 |
| Chest discomfort | 1 | 2 | | | 1 | 2 |
| Chest pain | | 1 | | | | 1 |
| Chills | 5 | 7 | 1 | 3 | 4 | 4 |
| Choking sensation | 1 | 1 | | | 1 | 1 |
| Chronic respiratory failure | 1 | 1 | | | 1 | 1 |
| Citrobacter infection | 1 | 1 | | | 1 | 1 |
| Cold sweat | 2 | 2 | 1 | 1 | 1 | 1 |
| Condition aggravated | 2 | 2 | | | 2 | 2 |
| Conjunctival haemorrhage | 1 | 1 | | | 1 | 1 |
| Contusion | 2 | 2 | 2 | 2 | | |
| Cough | 5 | 5 | 1 | 1 | 4 | 4 |
| COVID-19 | 10 | 10 | 1 | 1 | 9 | 9 |
| COVID-19 pneumonia | 4 | 4 | | | 4 | 4 |
| C-reactive protein increased | 2 | 2 | 2 | 2 | | |
| Cyanosis | 2 | 2 | | | 2 | 2 |
| Death | 1 | 1 | | | 1 | 1 |
| Deep vein thrombosis | 1 | 1 | | | 1 | 1 |

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|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dehydration | 1 | 1 | 1 | 1 | | |
| Depressed level of consciousness | 3 | 3 | | | 3 | 3 |
| Depressed mood | | 1 | | 1 | | |
| Diabetes mellitus | 1 | 1 | | | 1 | 1 |
| Diabetic ketoacidosis | 1 | 1 | | | 1 | 1 |
| Diarrhoea | 10 | 12 | 3 | 5 | 7 | 7 |
| Discomfort | 1 | 2 | | 1 | 1 | 1 |
| Disease recurrence | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | 1 | 1 | | |
| Dizziness | 15 | 18 | 2 | 4 | 13 | 14 |
| Drowning | 1 | 1 | | | 1 | 1 |
| Drug ineffective | 9 | 9 | | | 9 | 9 |
| Drug interaction | 1 | 2 | | 1 | 1 | 1 |
| Dysarthria | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysgeusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Dysphagia | 1 | 1 | | | 1 | 1 |
| Dysphonia | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 23 | 28 | 1 | 1 | 22 | 27 |
| Dystonia | 1 | 1 | | | 1 | 1 |
| Ecchymosis | 1 | 1 | | | 1 | 1 |
| Eczema | 1 | 1 | | | 1 | 1 |
| Electrocardiogram QRS complex prolonged | 1 | 1 | | | 1 | 1 |
| Electrocardiogram repolarisation abnormality | 1 | 1 | | | 1 | 1 |
| Electrocardiogram ST-T change | 1 | 1 | | | 1 | 1 |
| Epigastric discomfort | 1 | 1 | | | 1 | 1 |
| Epilepsy | 2 | 2 | | | 2 | 2 |
| Erythema | 4 | 4 | | | 4 | 4 |
| Essential tremor | 1 | 1 | | | 1 | 1 |
| Extensor plantar response | 1 | 1 | 1 | 1 | | |
| Extrapyramidal disorder | 1 | 1 | | | 1 | 1 |
| Eyelid oedema | 1 | 1 | | | 1 | 1 |
| Face oedema | 5 | 5 | | | 5 | 5 |
| Facial paralysis | 4 | 5 | | | 4 | 5 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fall | 2 | 2 | 1 | 1 | 1 | 1 |
| Fatigue | 4 | 4 | 2 | 2 | 2 | 2 |
| Feeling hot | 2 | 2 | 1 | 1 | 1 | 1 |
| Formication | | 1 | | 1 | | |
| Gait disturbance | 2 | 2 | | | 2 | 2 |
| Gamma-glutamyltransferase increased | 1 | 1 | 1 | 1 | | |
| Gastroesophageal reflux disease | 1 | 1 | 1 | 1 | | |
| Generalised oedema | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizure | 2 | 2 | | | 2 | 2 |
| General physical health deterioration | 1 | 1 | | | 1 | 1 |
| Glossodynia | 1 | 1 | | | 1 | 1 |
| Haematocrit decreased | 1 | 1 | 1 | 1 | | |
| Haematoma | 2 | 2 | 1 | 1 | 1 | 1 |
| Haematoma muscle | | 1 | | | | 1 |
| Haematuria | 1 | 1 | 1 | 1 | | |
| Haemoglobin decreased | 1 | 1 | 1 | 1 | | |
| Haemophagocytic lymphohistiocytosis | 1 | 1 | | | 1 | 1 |
| Haemorrhagic diathesis | 1 | 1 | | | 1 | 1 |
| Headache | 13 | 16 | 2 | 4 | 11 | 12 |
| Head injury | 1 | 1 | 1 | 1 | | |
| Hemiparaesthesia | 2 | 2 | | | 2 | 2 |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Hepatic failure | 1 | 1 | | | 1 | 1 |
| Hepatitis acute | 2 | 2 | | | 2 | 2 |
| Herpes zoster | 4 | 4 | | | 4 | 4 |
| Hyperglycaemia | | 1 | | 1 | | |
| Hyperhidrosis | 1 | 2 | | 1 | 1 | 1 |
| Hypernatraemia | 2 | 2 | | | 2 | 2 |
| Hypersensitivity | 2 | 3 | | | 2 | 3 |
| Hypertension | 7 | 7 | 1 | 1 | 6 | 6 |
| Hypertensive crisis | 7 | 7 | | | 7 | 7 |
| Hypoaesthesia | 3 | 3 | | | 3 | 3 |
| Hypoaesthesia oral | 1 | 1 | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypotension | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypoxia | 8 | 9 | | | 8 | 9 |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Inappropriate schedule of product administration | | 1 | | 1 | | |
| Incorrect dose administered | | 1 | | 1 | | |
| Increased bronchial secretion | 1 | 1 | | | 1 | 1 |
| Inflammatory bowel disease | 1 | 1 | | | 1 | 1 |
| Insulin resistance | | 1 | | 1 | | |
| Interstitial lung disease | 1 | 1 | | | 1 | 1 |
| Ischaemic stroke | 4 | 4 | | | 4 | 4 |
| Laryngeal oedema | 1 | 2 | | | 1 | 2 |
| Leukoencephalopathy | 1 | 1 | | | 1 | 1 |
| Lip oedema | 5 | 5 | | | 5 | 5 |
| Localised infection | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 2 | 2 | | | 2 | 2 |
| Lung disorder | 1 | 1 | | | 1 | 1 |
| Lung infiltration | 2 | 2 | 2 | 2 | | |
| Lymphadenopathy | 5 | 6 | | 1 | 5 | 5 |
| Lymphocyte percentage decreased | 1 | 1 | 1 | 1 | | |
| Malaise | 15 | 16 | 2 | 2 | 13 | 14 |
| Migraine with aura | 1 | 1 | | | 1 | 1 |
| Mobility decreased | 1 | 1 | 1 | 1 | | |
| Mouth swelling | 1 | 1 | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 1 | | | 1 | 1 |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscular weakness | 1 | 1 | 1 | 1 | | |
| Musculoskeletal chest pain | 1 | 1 | 1 | 1 | | |
| Musculoskeletal discomfort | 1 | 1 | | | 1 | 1 |
| Musculoskeletal pain | 1 | 1 | 1 | 1 | | |
| Myalgia | 6 | 7 | 1 | 2 | 5 | 5 |
| Myocardial infarction | 1 | 1 | | | 1 | 1 |

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|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Myoclonic dystonia | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | | 1 | | 1 | | |
| Nausea | 9 | 10 | 3 | 4 | 6 | 6 |
| Neck pain | 1 | 1 | | | 1 | 1 |
| Neoplasm | 1 | 1 | 1 | 1 | | |
| Neuralgia | 1 | 1 | | | 1 | 1 |
| Neutrophil count increased | 2 | 2 | 2 | 2 | | |
| Neutrophil percentage increased | 1 | 1 | 1 | 1 | | |
| Odynophagia | 1 | 1 | | | 1 | 1 |
| Oedema peripheral | 2 | 2 | | | 2 | 2 |
| Off label use | 4 | 4 | 4 | 4 | | |
| Oral pruritus | 1 | 1 | | | 1 | 1 |
| Oropharyngeal discomfort | 1 | 1 | | | 1 | 1 |
| Overdose | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 5 | 5 | | | 5 | 5 |
| Pain | 1 | 1 | | | 1 | 1 |
| Pain in extremity | 2 | 3 | | 1 | 2 | 2 |
| Palatal oedema | 3 | 3 | | | 3 | 3 |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Palpitations | 2 | 3 | | | 2 | 3 |
| Pancytopenia | 1 | 1 | | | 1 | 1 |
| Paraesthesia | 3 | 4 | 1 | 2 | 2 | 2 |
| Paraesthesia oral | 2 | 2 | | | 2 | 2 |
| Paraparesis | 2 | 2 | | | 2 | 2 |
| Partial seizures | 1 | 1 | | | 1 | 1 |
| Peripheral ischaemia | | 1 | | | | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Persistent depressive disorder | 1 | 1 | | | 1 | 1 |
| Petechiae | 2 | 2 | 1 | 1 | 1 | 1 |
| Petit mal epilepsy | 1 | 1 | | | 1 | 1 |
| Pharyngotonsillitis | 1 | 1 | | | 1 | 1 |
| Photophobia | 1 | 1 | | | 1 | 1 |

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Platelet count increased | 1 | 1 | 1 | 1 | | |
| Pleural effusion | | 1 | | | | 1 |
| Pneumonia | 4 | 5 | | | 4 | 5 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 1 | 1 | 1 | | |
| Product use issue | 4 | 4 | 4 | 4 | | |
| Prothrombin time prolonged | 1 | 1 | 1 | 1 | | |
| Pruritus | 6 | 6 | | | 6 | 6 |
| Pulmonary embolism | 2 | 2 | | | 2 | 2 |
| Pulmonary thrombosis | 1 | 1 | | | 1 | 1 |
| Purpura | 1 | 1 | | | 1 | 1 |
| Pyrexia | 33 | 40 | 8 | 13 | 25 | 27 |
| Rash | 3 | 5 | | 2 | 3 | 3 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Rash maculo-papular | 2 | 2 | 1 | 1 | 1 | 1 |
| Rash papular | 1 | 1 | | | 1 | 1 |
| Rash pruritic | 2 | 2 | 1 | 1 | 1 | 1 |
| Rectal haemorrhage | 1 | 2 | | | 1 | 2 |
| Renal failure | 1 | 1 | | | 1 | 1 |
| Renal impairment | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 3 | 4 | | | 3 | 4 |
| Respiratory failure | 2 | 3 | | | 2 | 3 |
| Respiratory tract infection | 2 | 2 | | | 2 | 2 |
| Restlessness | 1 | 1 | 1 | 1 | | |
| SARS-CoV-2 ant body test positive | 1 | 1 | 1 | 1 | | |
| Seizure | 2 | 2 | | | 2 | 2 |
| Sensation of foreign body | 2 | 2 | | | 2 | 2 |
| Sense of oppression | 1 | 1 | | | 1 | 1 |
| Sepsis | | 1 | | | | 1 |
| Shock | 1 | 1 | | | 1 | 1 |
| Sinus bradycardia | 1 | 1 | 1 | 1 | | |
| Skin exfoliation | 1 | 1 | | | 1 | 1 |
| Skin lesion | 1 | 1 | | | 1 | 1 |

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|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Skin ulcer | 1 | 1 | | | 1 | 1 |
| Slow speech | 1 | 1 | | | 1 | 1 |
| Somnolence | 2 | 2 | 1 | 1 | 1 | 1 |
| Speech disorder | 2 | 2 | 1 | 1 | 1 | 1 |
| Spinal cord injury | 1 | 1 | | | 1 | 1 |
| Status epilepticus | 1 | 1 | | | 1 | 1 |
| Stomatitis | | 1 | | 1 | | |
| Stridor | 1 | 1 | | | 1 | 1 |
| Sudden death | 2 | 4 | | | 2 | 4 |
| Swelling | 1 | 1 | 1 | 1 | | |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 9 | 9 | | | 9 | 9 |
| Tachyarrhythmia | 1 | 1 | | | 1 | 1 |
| Tachycardia | 8 | 8 | 1 | 1 | 7 | 7 |
| Tachypnoea | 4 | 4 | 1 | 1 | 3 | 3 |
| Temperature regulation disorder | 2 | 2 | 2 | 2 | | |
| Tension headache | 2 | 2 | | | 2 | 2 |
| Throat irritation | 4 | 4 | | | 4 | 4 |
| Thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Tongue oedema | 2 | 2 | | | 2 | 2 |
| Tongue pruritus | 2 | 2 | | | 2 | 2 |
| Tonic clonic movements | 1 | 1 | | | 1 | 1 |
| Transaminases increased | 1 | 1 | | | 1 | 1 |
| Transient global amnesia | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 2 | 1 | 1 | 1 | 1 |
| Troponin T increased | | 1 | | | | 1 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary sediment present | 1 | 1 | 1 | 1 | | |
| Urinary tract infection | 1 | 1 | | | 1 | 1 |
| Urinary tract infection bacterial | 1 | 1 | | | 1 | 1 |
| Urticaria | 5 | 5 | 1 | 1 | 4 | 4 |
| Vaccination complication | 1 | 1 | | | 1 | 1 |

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|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination failure | 3 | 3 | | | 3 | 3 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | 1 | 1 | | | 1 | 1 |
| Vaccination site inflammation | 1 | 1 | | | 1 | 1 |
| Vaccination site joint erythema | | 1 | | 1 | | |
| Vaccination site movement impairment | 1 | 2 | | 1 | 1 | 1 |
| Vaccination site pain | 6 | 9 | 1 | 4 | 5 | 5 |
| Vaccination site pruritus | 2 | 3 | | 1 | 2 | 2 |
| Vaccination site rash | 1 | 1 | | | 1 | 1 |
| Vaccination site warmth | | 1 | | 1 | | |
| Ventricular extrasystoles | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vision blurred | 4 | 4 | 1 | 1 | 3 | 3 |
| Vomiting | 9 | 11 | 3 | 5 | 6 | 6 |
| Wheezing | 3 | 3 | | | 3 | 3 |
| White blood cell count increased | 2 | 2 | 2 | 2 | | |
| | 613 | 688 | 110 | 153 | 503 | 535 |

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Country Where Event Occurred
SWEDEN

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Abnormal behaviour | 1 | 2 | | 1 | 1 | 1 |
| Acute kidney injury | | 1 | | | | 1 |
| Acute left ventricular failure | 1 | 1 | | | 1 | 1 |
| Acute myocardial infarction | 1 | 2 | | | 1 | 2 |
| Ageusia | 1 | 1 | | | 1 | 1 |
| Aggression | 1 | 1 | | | 1 | 1 |
| Agitation | 1 | 1 | | | 1 | 1 |
| Allergy to vaccine | 1 | 1 | | | 1 | 1 |
| Anaphylactic reaction | 4 | 4 | | | 4 | 4 |
| Anaphylactic shock | | 1 | | | | 1 |
| Angioedema | 3 | 3 | | | 3 | 3 |
| Anosmia | 1 | 1 | | | 1 | 1 |
| Anxiety | 4 | 5 | | | 4 | 5 |
| Apnoea | | 1 | | | | 1 |
| Arrhythmia | 1 | 1 | | | 1 | 1 |
| Arteriosclerosis | | 1 | | | | 1 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Arthralgia | 5 | 5 | 4 | 4 | 1 | 1 |
| Arthritis | 1 | 1 | | | 1 | 1 |
| Ascites | | 1 | | | | 1 |
| Asthenia | 4 | 4 | 1 | 1 | 3 | 3 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atelectasis | 1 | 1 | | | 1 | 1 |
| Atrial fibrillation | 2 | 2 | | | 2 | 2 |
| Atrioventricular block complete | 2 | 2 | | | 2 | 2 |
| Autonomic nervous system imbalance | 1 | 1 | | | 1 | 1 |
| Back pain | 2 | 2 | 1 | 1 | 1 | 1 |
| Balance disorder | 1 | 1 | | | 1 | 1 |
| Blood glucose increased | 2 | 2 | | | 2 | 2 |

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| Blood pressure abnormal | | 1 | | | | 1 | |
| Blood pressure decreased | 3 | 4 | 1 | 1 | 2 | 3 | |
| Blood pressure diastolic decreased | | 1 | | 1 | | | |
| Blood pressure systolic increased | 1 | 1 | | | 1 | 1 | |
| Body temperature decreased | 2 | 2 | | | 2 | 2 | |
| Body temperature increased | 2 | 2 | 1 | 1 | 1 | 1 | |
| Bone disorder | 1 | 1 | 1 | 1 | | | |
| Breath sounds abnormal | 1 | 1 | | | 1 | 1 | |
| Bronchitis | 1 | 1 | | | 1 | 1 | |
| Bundle branch block left | 1 | 1 | | | 1 | 1 | |
| Cachexia | 1 | 1 | | | 1 | 1 | |
| Cardiac arrest | 3 | 7 | | | 3 | 7 | |
| Cardiac disorder | | 1 | | | | 1 | |
| Cardiac failure | 6 | 7 | | | 6 | 7 | |
| Cardiac failure acute | 1 | 2 | | | 1 | 2 | |
| Cardiopulmonary failure | 1 | 1 | | | 1 | 1 | |
| Cerebrovascular accident | 3 | 4 | | | 3 | 4 | |
| Chest discomfort | 2 | 2 | | | 2 | 2 | |
| Chest pain | 4 | 4 | 1 | 1 | 3 | 3 | |
| Chills | 9 | 10 | 5 | 6 | 4 | 4 | |
| Chronic obstructive pulmonary disease | 4 | 5 | | | 4 | 5 | |
| Chronic respiratory failure | | 1 | | | | 1 | |
| Circulatory collapse | 2 | 4 | | | 2 | 4 | |
| Cognitive disorder | 1 | 1 | | | 1 | 1 | |
| Cold sweat | 1 | 1 | 1 | 1 | | | |
| Condition aggravated | 3 | 4 | | | 3 | 4 | |
| Confusional state | 6 | 7 | | | 6 | 7 | |
| Cough | 6 | 7 | 4 | 4 | 2 | 3 | |
| COVID-19 | 2 | 3 | | | 2 | 3 | |
| C-reactive protein increased | 2 | 3 | 2 | 2 | | 1 | |
| Crepitations | 1 | 2 | | 1 | 1 | 1 | |
| Cyanosis | 1 | 1 | | | 1 | 1 | |
| Death | 18 | 23 | | | 18 | 23 | |

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|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Decreased appetite | 8 | 8 | 3 | 3 | 5 | 5 |
| Decubitus ulcer | | 1 | | 1 | | |
| Deep vein thrombosis | 2 | 2 | | | 2 | 2 |
| Dehydration | 2 | 3 | | | 2 | 3 |
| Delusional disorder, unspecified type | 1 | 1 | | | 1 | 1 |
| Dementia | 1 | 1 | | | 1 | 1 |
| Depressed level of consciousness | 8 | 9 | | | 8 | 9 |
| Dermatitis | 1 | 2 | | 1 | 1 | 1 |
| Diarrhoea | 11 | 13 | 4 | 5 | 7 | 8 |
| Discomfort | 1 | 1 | 1 | 1 | | |
| Disorganised speech | 1 | 1 | | | 1 | 1 |
| Disorientation | 1 | 1 | | | 1 | 1 |
| Dissociation | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | 1 | 1 | | |
| Diverticulitis | 1 | 1 | | | 1 | 1 |
| Dizziness | 8 | 9 | 4 | 5 | 4 | 4 |
| Drug ineffective | 2 | 3 | | | 2 | 3 |
| Dry mouth | 1 | 1 | | | 1 | 1 |
| Dysgeusia | 2 | 2 | | | 2 | 2 |
| Dysphagia | 5 | 6 | 2 | 3 | 3 | 3 |
| Dyspnoea | 25 | 31 | 2 | 2 | 23 | 29 |
| Dysstasia | 1 | 2 | | | 1 | 2 |
| Epilepsy | 1 | 1 | | | 1 | 1 |
| Epistaxis | | 1 | | 1 | | |
| Erysipelas | 1 | 1 | | | 1 | 1 |
| Erythema | 6 | 7 | 4 | 5 | 2 | 2 |
| Escherichia infection | 1 | 1 | | | 1 | 1 |
| Escherichia sepsis | | 1 | | | | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 |
| Eye disorder | 1 | 1 | | | 1 | 1 |
| Eye pain | 1 | 1 | | | 1 | 1 |
| Face injury | 1 | 1 | | | 1 | 1 |
| Facial neuralgia | 1 | 1 | | | 1 | 1 |

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| | | | I | C | I | C |
| Facial paralysis | 3 | 4 | | | 3 | 4 |
| Facial paresis | 2 | 3 | | | 2 | 3 |
| Fall | 2 | 2 | | | 2 | 2 |
| Fatigue | 30 | 34 | 11 | 13 | 19 | 21 |
| Feeling abnormal | 1 | 1 | | | 1 | 1 |
| Feeling hot | 4 | 4 | 1 | 1 | 3 | 3 |
| Feeling of body temperature change | 1 | 1 | | | 1 | 1 |
| Fluid intake reduced | 1 | 1 | | | 1 | 1 |
| Food refusal | 1 | 1 | | | 1 | 1 |
| Generalised oedema | 1 | 1 | | | 1 | 1 |
| General physical health deterioration | 17 | 21 | 4 | 5 | 13 | 16 |
| Glossodynia | 1 | 1 | 1 | 1 | | |
| Goitre | | 1 | | | | 1 |
| Haematemesis | 1 | 1 | | | 1 | 1 |
| Haematoma | 2 | 2 | | | 2 | 2 |
| Haemoglobin decreased | 1 | 1 | | | 1 | 1 |
| Haemoptysis | 1 | 1 | | | 1 | 1 |
| Hallucination | 2 | 2 | | | 2 | 2 |
| Headache | 18 | 19 | 14 | 15 | 4 | 4 |
| Head injury | 2 | 2 | 1 | 1 | 1 | 1 |
| Heart rate decreased | 1 | 1 | 1 | 1 | | |
| Heart rate increased | 1 | 1 | | | 1 | 1 |
| Heart rate irregular | 1 | 1 | 1 | 1 | | |
| Hemiparesis | 1 | 1 | | | 1 | 1 |
| Herpes zoster | 2 | 2 | 1 | 1 | 1 | 1 |
| Hiccups | 1 | 1 | | | 1 | 1 |
| Hyperglycaemia | 1 | 1 | | | 1 | 1 |
| Hyperhidrosis | 2 | 2 | 2 | 2 | | |
| Hypernatraemia | 1 | 1 | | | 1 | 1 |
| Hypersensitivity | 8 | 9 | 1 | 1 | 7 | 8 |
| Hypertension | 1 | 1 | | | 1 | 1 |
| Hypoaesthesia | 4 | 4 | 3 | 3 | 1 | 1 |
| Hypoaesthesia oral | 2 | 2 | | | 2 | 2 |

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|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Hypoglycaemia | 1 | 1 | | | 1 | 1 |
| Hypokalaemia | 1 | 1 | | | 1 | 1 |
| Hypokinesia | 1 | 1 | | | 1 | 1 |
| Hypophagia | 1 | 1 | | | 1 | 1 |
| Hypotension | 7 | 9 | 1 | 1 | 6 | 8 |
| Hypothermia | 1 | 1 | | | 1 | 1 |
| Illness | 1 | 1 | | | 1 | 1 |
| Immunisation reaction | 1 | 1 | | | 1 | 1 |
| Incontinence | 1 | 1 | 1 | 1 | | |
| Incorrect route of product administration | 2 | 2 | 2 | 2 | | |
| Increased upper airway secretion | 1 | 1 | 1 | 1 | | |
| Infection | 4 | 7 | | | 4 | 7 |
| Infrequent bowel movements | 1 | 1 | 1 | 1 | | |
| Insomnia | | 1 | | 1 | | |
| Intestinal haemorrhage | | 1 | | | | 1 |
| Intestinal ischaemia | | 1 | | | | 1 |
| Ischaemic stroke | | 2 | | | | 2 |
| Jaw disorder | 1 | 1 | | | 1 | 1 |
| Lacrimation increased | 1 | 1 | | | 1 | 1 |
| Lactic acidosis | 1 | 1 | | | 1 | 1 |
| Lethargy | 1 | 1 | | | 1 | 1 |
| Leukocytosis | 1 | 1 | | | 1 | 1 |
| Lip swelling | 1 | 1 | | | 1 | 1 |
| Loss of consciousness | 5 | 6 | | | 5 | 6 |
| Lymphadenopathy | 1 | 1 | 1 | 1 | | |
| Malaise | 8 | 8 | 2 | 2 | 6 | 6 |
| Memory impairment | 1 | 1 | 1 | 1 | | |
| Migraine | 1 | 1 | 1 | 1 | | |
| Muscle spasms | 1 | 1 | | | 1 | 1 |
| Muscle tone disorder | 1 | 1 | | | 1 | 1 |
| Musculoskeletal stiffness | 1 | 1 | | | 1 | 1 |
| Myalgia | 8 | 9 | 5 | 5 | 3 | 4 |
| Myelosuppression | 1 | 1 | | | 1 | 1 |

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| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Myocardial infarction | 4 | 5 | | | 4 | 5 |
| Myocardial ischaemia | | 1 | | | | 1 |
| Myocardial rupture | | 1 | | | | 1 |
| Myocarditis | 1 | 1 | | | 1 | 1 |
| Nail discolouration | 1 | 1 | | | 1 | 1 |
| Nasal congestion | 1 | 1 | | | 1 | 1 |
| Nasopharyngitis | 2 | 2 | | | 2 | 2 |
| Nausea | 16 | 17 | 6 | 7 | 10 | 10 |
| Neck pain | 1 | 1 | 1 | 1 | | |
| Neoplasm progression | | 1 | | | | 1 |
| Obstructive airways disorder | 1 | 1 | | | 1 | 1 |
| Off label use | 1 | 1 | 1 | 1 | | |
| Oral herpes | 2 | 2 | 2 | 2 | | |
| Oral pain | 1 | 1 | 1 | 1 | | |
| Oral pruritus | 1 | 1 | 1 | 1 | | |
| Oropharyngeal pain | 7 | 8 | 5 | 5 | 2 | 3 |
| Oropharyngeal spasm | | 1 | | | | 1 |
| Oxygen saturation abnormal | 1 | 1 | 1 | 1 | | |
| Oxygen saturation decreased | 8 | 12 | | 2 | 8 | 10 |
| Pain | 8 | 9 | 4 | 4 | 4 | 5 |
| Pain in extremity | 6 | 6 | 3 | 3 | 3 | 3 |
| Pain in jaw | 1 | 1 | | | 1 | 1 |
| Pain of skin | 1 | 1 | 1 | 1 | | |
| Pallor | 2 | 2 | 1 | 1 | 1 | 1 |
| Palpitations | 2 | 4 | | 2 | 2 | 2 |
| Paraesthesia | 4 | 5 | 1 | 1 | 3 | 4 |
| Parosmia | 1 | 1 | | | 1 | 1 |
| Pericardial haemorrhage | | 1 | | | | 1 |
| Periorbital oedema | 1 | 1 | | | 1 | 1 |
| Peripheral coldness | 1 | 1 | | | 1 | 1 |
| Peripheral swelling | 1 | 1 | 1 | 1 | | |
| Petechiae | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorder | 1 | 1 | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pharyngeal swelling | 3 | 3 | | | 3 | 3 |
| Pharyngitis | | 1 | | 1 | | |
| Pleural effusion | 1 | 1 | | | 1 | 1 |
| Pneumonia | 3 | 5 | | | 3 | 5 |
| Pneumonia aspiration | 1 | 1 | | | 1 | 1 |
| Pneumonia bacterial | | 1 | | | | 1 |
| Pneumonia pneumococcal | 1 | 1 | | | 1 | 1 |
| Pneumonia streptococcal | 1 | 1 | | | 1 | 1 |
| Postoperative wound complication | 1 | 1 | | | 1 | 1 |
| Presyncope | 1 | 1 | | | 1 | 1 |
| Productive cough | 1 | 3 | | | 1 | 3 |
| Product use issue | 1 | 1 | 1 | 1 | | |
| Pruritus | 4 | 4 | 1 | 1 | 3 | 3 |
| Psoriasis | 1 | 1 | 1 | 1 | | |
| Pulmonary artery thrombosis | 1 | 1 | | | 1 | 1 |
| Pulmonary embolism | 3 | 3 | | | 3 | 3 |
| Pulmonary oedema | 3 | 6 | | | 3 | 6 |
| Pulse abnormal | 2 | 2 | 2 | 2 | | |
| Pulse pressure decreased | 1 | 1 | 1 | 1 | | |
| Pyrexia | 37 | 41 | 16 | 17 | 21 | 24 |
| Rash | 4 | 4 | 3 | 3 | 1 | 1 |
| Rash erythematous | 1 | 1 | | | 1 | 1 |
| Renal failure | | 1 | | | | 1 |
| Respiratory arrest | 2 | 2 | | | 2 | 2 |
| Respiratory distress | 3 | 5 | | | 3 | 5 |
| Respiratory failure | 1 | 1 | | | 1 | 1 |
| Respiratory rate increased | 3 | 4 | | | 3 | 4 |
| Restless legs syndrome | 1 | 1 | | | 1 | 1 |
| Rhinorrhoea | 2 | 2 | 2 | 2 | | |
| Seizure | 3 | 3 | | | 3 | 3 |
| Seizure like phenomena | 1 | 1 | | | 1 | 1 |
| Sensation of foreign body | | 1 | | | | 1 |
| Sepsis | 5 | 6 | | | 5 | 6 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Skin discolouration | 1 | 1 | | | 1 | 1 |
| Slow speech | 1 | 1 | | | 1 | 1 |
| Somnolence | 3 | 3 | | | 3 | 3 |
| Speech disorder | 1 | 1 | | | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 1 | | | 1 | 1 |
| Streptococcal bacteraemia | 1 | 1 | | | 1 | 1 |
| Stress | 1 | 1 | 1 | 1 | | |
| Sudden death | | 1 | | | | 1 |
| Swelling | 1 | 2 | | 1 | 1 | 1 |
| Swelling face | 1 | 2 | | 1 | 1 | 1 |
| Swollen tongue | 1 | 1 | | | 1 | 1 |
| Syncope | 1 | 1 | | | 1 | 1 |
| Systemic inflammatory response syndrome | | 1 | | | | 1 |
| Tachycardia | | 1 | | | | 1 |
| Tachypnoea | 1 | 2 | | 1 | 1 | 1 |
| Throat irritation | 1 | 1 | 1 | 1 | | |
| Throat tightness | | 1 | | | | 1 |
| Thrombosis | 1 | 1 | | | 1 | 1 |
| Toxic epidermal necrolysis | 1 | 1 | | | 1 | 1 |
| Transient ischaemic attack | 1 | 1 | | | 1 | 1 |
| Tremor | 2 | 2 | | | 2 | 2 |
| Upper gastrointestinal haemorrhage | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infection | | 1 | | | | 1 |
| Urinary incontinence | 1 | 1 | | | 1 | 1 |
| Urinary retention | 1 | 1 | | | 1 | 1 |
| Urinary tract infection | 1 | 2 | | | 1 | 2 |
| Urine output decreased | 1 | 1 | | | 1 | 1 |
| Urosepsis | 1 | 3 | | | 1 | 3 |
| Urticaria | 6 | 7 | 1 | 2 | 5 | 5 |
| Vaccination site erythema | 8 | 8 | 7 | 7 | 1 | 1 |
| Vaccination site haematoma | 1 | 1 | | | 1 | 1 |
| Vaccination site induration | 1 | 1 | 1 | 1 | | |
| Vaccination site pain | 13 | 13 | 11 | 11 | 2 | 2 |

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|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vaccination site pruritus | 1 | 1 | 1 | 1 | | |
| Vaccination site reaction | 2 | 2 | 1 | 1 | 1 | 1 |
| Vaccination site swelling | 7 | 7 | 6 | 6 | 1 | 1 |
| Vaccination site warmth | 3 | 3 | 3 | 3 | | |
| Vascular dementia | 1 | 1 | | | 1 | 1 |
| Ventricular tachycardia | 1 | 1 | | | 1 | 1 |
| Vertigo | 1 | 1 | 1 | 1 | | |
| Vomiting | 17 | 18 | 2 | 3 | 15 | 15 |
| Wheezing | 4 | 5 | | 1 | 4 | 4 |
| White blood cell count increased | 1 | 1 | 1 | 1 | | |
| White blood cells urine positive | 1 | 1 | 1 | 1 | | |
| | 669 | 798 | 195 | 224 | 474 | 574 |

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Country Where Event Occurred
SWITZERLAND

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal pain | | 1 | | 1 | | |
| Acute myocardial infarction | | 1 | | | | 1 |
| Acute pulmonary oedema | 1 | 1 | | | 1 | 1 |
| Anal haemorrhage | | 1 | | 1 | | |
| Anaphylactic reaction | 2 | 2 | | | 2 | 2 |
| Anaphylactic shock | 1 | 1 | | | 1 | 1 |
| Angioedema | 1 | 1 | | | 1 | 1 |
| Aphasia | | 1 | | | | 1 |
| Arteriosclerosis | | 1 | | | | 1 |
| Arteriosclerosis coronary artery | | 1 | | | | 1 |
| Arthralgia | 1 | 1 | | | 1 | 1 |
| Asthenia | 1 | 2 | | 1 | 1 | 1 |
| Asthma | 1 | 1 | | | 1 | 1 |
| Atrophy | | 1 | | | | 1 |
| Back pain | | 1 | | 1 | | |
| Blood pressure decreased | | 1 | | | | 1 |
| Cerebrovascular accident | | 1 | | | | 1 |
| Chills | 1 | 1 | 1 | 1 | | |
| Chronic obstructive pulmonary disease | | 1 | | | | 1 |
| Coma | 1 | 2 | | | 1 | 2 |
| COVID-19 | 1 | 1 | | | 1 | 1 |
| C-reactive protein increased | | 1 | | | | 1 |
| Death | 1 | 3 | | | 1 | 3 |
| Diarrhoea | 1 | 1 | | | 1 | 1 |
| Disturbance in attention | 1 | 1 | | | 1 | 1 |
| Dyspnoea | 1 | 1 | | | 1 | 1 |
| Embolism | | 1 | | | | 1 |
| Epistaxis | 1 | 1 | 1 | 1 | | |
| Erythema | 1 | 1 | | | 1 | 1 |
| Fall | | 1 | | | | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fatigue | 1 | 2 | | 1 | 1 | 1 |
| Feeling cold | | 1 | | 1 | | |
| Gastric disorder | | 1 | | | | 1 |
| General physical health deterioration | | 1 | | | | 1 |
| Headache | 1 | 1 | | | 1 | 1 |
| Heart rate decreased | | 1 | | | | 1 |
| Hemiplegia | | 1 | | | | 1 |
| Hepatic cirrhosis | | 1 | | | | 1 |
| Hypertension | 1 | 1 | 1 | 1 | | |
| Hypertensive emergency | 1 | 1 | | | 1 | 1 |
| Hyperthermia | 1 | 1 | 1 | 1 | | |
| Immune thrombocytopenia | 1 | 1 | | | 1 | 1 |
| Influenza like illness | 1 | 1 | | | 1 | 1 |
| Malaise | 2 | 3 | 1 | 2 | 1 | 1 |
| Myalgia | | 1 | | | | 1 |
| Oxygen saturation decreased | 1 | 2 | | | 1 | 2 |
| Peripheral vascular disorder | 1 | 1 | | | 1 | 1 |
| Pneumonia | | 1 | | | | 1 |
| Pruritus | 1 | 1 | | | 1 | 1 |
| Pyrexia | 1 | 2 | | | 1 | 2 |
| Respiratory depression | 1 | 1 | | | 1 | 1 |
| Respiratory distress | 1 | 1 | | | 1 | 1 |
| Respiratory failure | | 1 | | | | 1 |
| Somnolence | | 2 | | | | 2 |
| Tachypnoea | | 1 | | | | 1 |
| Urticaria | 1 | 2 | | | 1 | 2 |
| Vaccination site erythema | 1 | 1 | | | 1 | 1 |
| Vaccination site pain | | 3 | | 3 | | |
| Vaccination site swelling | 1 | 1 | | | 1 | 1 |
| Vaccination site urticaria | 1 | 1 | | | 1 | 1 |
| Vomiting | 1 | 1 | | | 1 | 1 |
| | 37 | 75 | 5 | 15 | 32 | 60 |

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Country Where Event Occurred
TURKS AND CAICOS ISLANDS

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Fatigue | 1 | 1 | 1 | 1 | | |
| Myalgia | 1 | 1 | 1 | 1 | | |
| Nodule | 1 | 1 | 1 | 1 | | |
| Seizure | 1 | 1 | | | 1 | 1 |
| Tonic convulsion | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 3 | 3 | 2 | 2 |

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Country Where Event Occurred

UNITED ARAB EMIRATES

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Arthralgia | 1 | 1 | 1 | 1 |
| Back pain | 1 | 1 | 1 | 1 |
| Chills | 1 | 1 | 1 | 1 |
| Diarrhoea | | 1 | | 1 |
| Fatigue | 1 | 1 | 1 | 1 |
| Feeling abnormal | 1 | 1 | 1 | 1 |
| Nausea | 1 | 1 | 1 | 1 |
| Off label use | | 1 | | 1 |
| Product use issue | | 1 | | 1 |
| Pyrexia | 2 | 2 | 2 | 2 |
| Somnolence | 1 | 1 | 1 | 1 |
| | 9 | 12 | 9 | 12 |

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Country Where Event Occurred

UNITED KINGDOM

| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 18 | 23 | 1 | 1 | 2 | 4 | 16 | 19 |
| Abdominal distension | 6 | 9 | | | | 2 | 6 | 7 |
| Abdominal pain | 32 | 47 | | | 1 | 10 | 31 | 37 |
| Abdominal pain lower | 4 | 5 | | | | | 4 | 5 |
| Abdominal pain upper | 51 | 76 | | | 8 | 19 | 43 | 57 |
| Abdominal tenderness | 1 | 1 | | | | | 1 | 1 |
| Abnormal dreams | 2 | 4 | | | | 2 | 2 | 2 |
| Abnormal sensation in eye | 2 | 2 | | | | | 2 | 2 |
| Abnormal weight gain | 1 | 1 | | | | | 1 | 1 |
| Abortion spontaneous | 1 | 1 | | | | | 1 | 1 |
| Abscess oral | 2 | 2 | | | | | 2 | 2 |
| Acidosis | | 2 | | | | 1 | | 1 |
| Acne | 1 | 1 | | | | | 1 | 1 |
| Acute febrile neutrophilic dermatosis | 1 | 1 | | | | | 1 | 1 |
| Acute kidney injury | 4 | 8 | | | | | 4 | 8 |
| Acute myocardial infarction | 2 | 5 | | | | | 2 | 5 |
| Acute respiratory failure | | 1 | | | | | | 1 |
| Adrenocortical insufficiency acute | 1 | 1 | | | | | 1 | 1 |
| Adverse drug reaction | 1 | 1 | | | | | 1 | 1 |
| Adverse reaction | | | 1 | 1 | | | | |
| Ageusia | 10 | 15 | | | 1 | 3 | 9 | 12 |
| Aggression | 2 | 2 | | | | | 2 | 2 |
| Agitation | 3 | 6 | | | 1 | 2 | 2 | 4 |
| Airway burns | 1 | 1 | | | | | 1 | 1 |
| Alcohol interaction | 1 | 1 | | | | | 1 | 1 |
| Alexia | 1 | 1 | | | 1 | 1 | | |
| Allergic oedema | | 1 | | | | | | 1 |
| Allergic reaction to excipient | 1 | 1 | | | | | 1 | 1 |
| Allergic sinusitis | 1 | 1 | | | | | 1 | 1 |
| Allergy to vaccine | 4 | 4 | | | | | 4 | 4 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|--------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|-----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Allodynia | | 1 | | | | | | 1 | |
| Alopecia | 1 | 1 | | | | | 1 | | 1 |
| Altered state of consciousness | | 1 | | | | | | | 1 |
| Amnesia | 2 | 2 | | | | | 2 | | 2 |
| Anaemia | 2 | 2 | | | 2 | 2 | | | |
| Anal haemorrhage | | 1 | | | | | | | 1 |
| Anal incontinence | 3 | 4 | 1 | 1 | 1 | 1 | 2 | | 3 |
| Anaphylactic reaction | 35 | 50 | | | | | 35 | | 50 |
| Anaphylactic shock | 2 | 2 | | | | | 2 | | 2 |
| Anaphylactoid reaction | 1 | 1 | | | | | 1 | | 1 |
| Anger | | 1 | | | | | | | 1 |
| Angina pectoris | 3 | 3 | | | | | 3 | | 3 |
| Angioedema | 9 | 16 | | | | | 9 | | 16 |
| Ankylosing spondylitis | 2 | 3 | | | | | 2 | | 3 |
| Anosmia | 5 | 7 | | | | 1 | 5 | | 6 |
| Anuria | | 1 | | | | | | | 1 |
| Anxiety | 15 | 25 | | | 3 | 7 | 12 | | 18 |
| Aortic stenosis | 1 | 1 | | | | | 1 | | 1 |
| Aphasia | 1 | 3 | | | 1 | 1 | | | 2 |
| Aphonia | 3 | 5 | | | | | 3 | | 5 |
| Aphthous ulcer | 1 | 1 | | | | | 1 | | 1 |
| Apparent death | 1 | 1 | | | | | 1 | | 1 |
| Arrhythmia | 3 | 5 | | | | | 3 | | 5 |
| Arthralgia | 218 | 349 | 3 | 4 | 28 | 72 | 190 | | 277 |
| Arthritis | 14 | 19 | | | | 3 | 14 | | 16 |
| Arthritis reactive | | 1 | | | | | | | 1 |
| Arthropathy | 2 | 2 | | | 2 | 2 | | | |
| Ascites | 2 | 2 | | | | | 2 | | 2 |
| Aspiration | 2 | 2 | | | | | 2 | | 2 |
| Asthenia | 70 | 110 | | | 18 | 30 | 52 | | 80 |
| Asthenopia | 2 | 3 | | | | 1 | 2 | | 2 |
| Asthma | 35 | 50 | | | 4 | 8 | 31 | | 42 |
| Asthma prophylaxis | | 1 | | | | | | | 1 |

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|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Atrial fibrillation | 7 | 15 | | | | | 7 | 15 |
| Aura | | 1 | | | | | | 1 |
| Auricular swelling | 1 | 1 | | | | | 1 | 1 |
| Autoimmune disorder | 3 | 3 | | | | | 3 | 3 |
| Autoscopy | 1 | 1 | | | | | 1 | 1 |
| Axillary mass | | 4 | | | | 3 | | 1 |
| Axillary pain | 18 | 30 | | | 4 | 6 | 14 | 24 |
| Axonal neuropathy | 1 | 1 | | | | | 1 | 1 |
| Back pain | 42 | 69 | 1 | 1 | 4 | 18 | 38 | 51 |
| Bacterial infection | 1 | 1 | | | | | 1 | 1 |
| Balance disorder | 13 | 24 | | 1 | 2 | 4 | 11 | 20 |
| Bedridden | 2 | 2 | | | | | 2 | 2 |
| Behaviour disorder | 1 | 1 | | | | | 1 | 1 |
| Behcet's syndrome | 2 | 2 | | | | | 2 | 2 |
| Blindness | 6 | 6 | | | | | 6 | 6 |
| Blindness transient | 1 | 1 | | | | | 1 | 1 |
| Blister | 8 | 9 | | | | 1 | 8 | 8 |
| Blood blister | 1 | 1 | | | | | 1 | 1 |
| Blood creatine phosphokinase increased | | 1 | | | | | | 1 |
| Blood creatinine increased | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Blood glucose | 1 | 1 | | | | | 1 | 1 |
| Blood glucose decreased | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Blood glucose fluctuation | 2 | 2 | | | | | 2 | 2 |
| Blood glucose increased | 8 | 13 | | | | 1 | 8 | 12 |
| Blood ketone body increased | 1 | 1 | | | | | 1 | 1 |
| Blood ketone body present | | 1 | | | | | | 1 |
| Blood lactic acid increased | 1 | 3 | | | | 1 | 1 | 2 |
| Blood magnesium decreased | 1 | 1 | | | 1 | 1 | | |
| Blood potassium abnormal | | 1 | | | | | | 1 |
| Blood potassium decreased | 1 | 1 | | | 1 | 1 | | |
| Blood pressure abnormal | 1 | 1 | | | | | 1 | 1 |
| Blood pressure decreased | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Blood pressure increased | 16 | 24 | | | 2 | 4 | 14 | 20 |

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|-----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|---|----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Blood pressure systolic decreased | | 1 | | | | | | | 1 |
| Blood pressure systolic increased | 3 | 4 | | | 1 | 2 | 2 | | 2 |
| Blood sodium decreased | 1 | 1 | | | | | 1 | | 1 |
| Blood urea increased | 1 | 1 | | | | | 1 | | 1 |
| Body temperature abnormal | 2 | 5 | | | | 1 | 2 | | 4 |
| Body temperature decreased | 6 | 7 | | | | 1 | 6 | | 6 |
| Body temperature fluctuation | 1 | 1 | | | 1 | 1 | | | |
| Body temperature increased | 15 | 28 | | 1 | 5 | 9 | 10 | | 19 |
| Bone pain | 13 | 17 | | | 4 | 6 | 9 | | 11 |
| Bone swelling | 1 | 2 | | | 1 | 1 | | | 1 |
| Bradycardia | 3 | 6 | | | | | 3 | | 6 |
| Bradyphrenia | 1 | 1 | | | | | 1 | | 1 |
| Brain oedema | 1 | 1 | | | | | 1 | | 1 |
| Brain stem stroke | 1 | 1 | | | | | 1 | | 1 |
| Breast cancer | 1 | 1 | | | | | 1 | | 1 |
| Breast enlargement | 1 | 1 | | | | | 1 | | 1 |
| Breast mass | 2 | 2 | | | | | 2 | | 2 |
| Breast pain | 3 | 6 | | | 1 | 1 | 2 | | 5 |
| Breast swelling | 1 | 3 | | | 1 | 3 | | | |
| Breast tenderness | 4 | 4 | | | 1 | 1 | 3 | | 3 |
| Breath sounds abnormal | 1 | 1 | | | | | 1 | | 1 |
| Bronchiectasis | 2 | 2 | | | | | 2 | | 2 |
| Bronchitis | 1 | 1 | | | | | 1 | | 1 |
| Bronchopulmonary aspergillosis | 1 | 1 | | | | | 1 | | 1 |
| Bronchospasm | 1 | 4 | | | | | 1 | | 4 |
| Bundle branch block right | | 1 | | | | 1 | | | |
| Burning sensation | 5 | 12 | | | 2 | 2 | 3 | | 10 |
| Burn oesophageal | 1 | 1 | | | | | 1 | | 1 |
| Cardiac arrest | 6 | 15 | | | | | 6 | | 15 |
| Cardiac disorder | 1 | 2 | | | | | 1 | | 2 |
| Cardiac failure | 3 | 3 | | | | | 3 | | 3 |
| Cardiac failure congestive | 1 | 2 | | | | | 1 | | 2 |
| Cardiac flutter | 4 | 4 | | | | | 4 | | 4 |

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|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Cardiopulmonary failure | | 1 | | | | | | 1 |
| Cardio-respiratory arrest | | 1 | | | | | | 1 |
| Cardiovascular disorder | 1 | 1 | | | | | 1 | 1 |
| Carpal tunnel syndrome | 1 | 1 | | | | | 1 | 1 |
| Cataplexy | | 1 | | | | | | 1 |
| Catatonia | 1 | 1 | | | | | 1 | 1 |
| Cellulitis | 7 | 11 | | | | | 7 | 11 |
| Cerebral disorder | 1 | 1 | | | | | 1 | 1 |
| Cerebral haemorrhage | 3 | 5 | | | | | 3 | 5 |
| Cerebral infarction | 3 | 4 | | | | | 3 | 4 |
| Cerebral venous sinus thrombosis | | 1 | | | | | | 1 |
| Cerebrovascular accident | 14 | 22 | | | | | 14 | 22 |
| Chapped lips | 2 | 2 | | | | | 2 | 2 |
| Cheilitis | 2 | 3 | | | | | 2 | 3 |
| Chest discomfort | 42 | 64 | | | 3 | 9 | 39 | 55 |
| Chest pain | 73 | 105 | 1 | 1 | 5 | 11 | 68 | 94 |
| Chest X-ray abnormal | 1 | 1 | | | 1 | 1 | | |
| Chillblains | | 1 | | | | | | 1 |
| Chills | 219 | 393 | 2 | 2 | 28 | 88 | 191 | 305 |
| Choking | 1 | 1 | | | | | 1 | 1 |
| Choking sensation | 1 | 1 | | | | | 1 | 1 |
| Cholecystitis infective | | 1 | | | | | | 1 |
| Chorea | 1 | 1 | | | | | 1 | 1 |
| Choroidal neovascularisation | 1 | 1 | | | | | 1 | 1 |
| Chromaturia | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Chronic fatigue syndrome | 2 | 3 | | | | 1 | 2 | 2 |
| Chronic obstructive pulmonary disease | 2 | 2 | | | | | 2 | 2 |
| Chronic spontaneous urticaria | 1 | 1 | | | | | 1 | 1 |
| Circulatory collapse | 3 | 15 | | | | | 3 | 15 |
| Circumstance or information capable of leading to medication error | | 1 | | | | 1 | | |
| Cluster headache | 1 | 1 | | | | | 1 | 1 |
| Cognitive disorder | 4 | 5 | | | 1 | 1 | 3 | 4 |

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|---------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Cold sweat | 20 | 33 | | | 3 | 6 | 17 | 27 |
| Colitis | 2 | 2 | | | | | 2 | 2 |
| Colitis microscopic | 1 | 1 | | | | | 1 | 1 |
| Colitis ulcerative | 3 | 4 | | | | | 3 | 4 |
| Coma | 1 | 1 | | | | | 1 | 1 |
| Coma scale abnormal | | 2 | | | | | | 2 |
| Communication disorder | | 1 | | | | | | 1 |
| Condition aggravated | 27 | 43 | | | 2 | 7 | 25 | 36 |
| Confusional state | 44 | 58 | | | 7 | 11 | 37 | 47 |
| Conjunctival haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Conjunctivitis | 2 | 3 | | | | | 2 | 3 |
| Constipation | 4 | 5 | | | | 1 | 4 | 4 |
| Contrast media reaction | 1 | 1 | | | | | 1 | 1 |
| Contusion | 7 | 11 | | | 1 | 1 | 6 | 10 |
| Coordination abnormal | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Corneal reflex decreased | 1 | 1 | | | 1 | 1 | | |
| Coronary artery disease | | 2 | | | | | | 2 |
| Cortisol decreased | | 1 | | | | | | 1 |
| Costochondritis | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Cough | 68 | 108 | 1 | 1 | 11 | 22 | 57 | 86 |
| COVID-19 | 37 | 62 | | | | | 37 | 62 |
| COVID-19 pneumonia | 4 | 5 | | | | | 4 | 5 |
| C-reactive protein increased | 1 | 2 | | | | 1 | 1 | 1 |
| Crohn's disease | 5 | 5 | | | | | 5 | 5 |
| Crying | 4 | 6 | | | | 1 | 4 | 5 |
| Cyanosis | 1 | 5 | | | | 2 | 1 | 3 |
| Cystitis | 2 | 2 | | | | | 2 | 2 |
| Deafness | 3 | 4 | | | | | 3 | 4 |
| Deafness neurosensory | 2 | 2 | | | | | 2 | 2 |
| Deafness unilateral | 1 | 1 | | | | | 1 | 1 |
| Death | 7 | 31 | | | | | 7 | 31 |
| Decreased appetite | 61 | 90 | 1 | 1 | 14 | 19 | 47 | 71 |
| Decreased immune responsiveness | 1 | 1 | | | | | 1 | 1 |

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|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Decreased interest | | 1 | | | | | | 1 |
| Deep vein thrombosis | | 2 | | | | | | 2 |
| Defaecation urgency | 1 | 2 | | | | | 1 | 2 |
| Dehydration | 3 | 8 | | | | 4 | 3 | 4 |
| Delirium | 10 | 16 | | | | | 10 | 16 |
| Delusion | 1 | 1 | | | 1 | 1 | | |
| Dementia | 2 | 3 | | | | | 2 | 3 |
| Dementia with Lewy bodies | 1 | 1 | | | | | 1 | 1 |
| Depressed level of consciousness | 1 | 3 | | | | | 1 | 3 |
| Depressed mood | 5 | 6 | | | | 1 | 5 | 5 |
| Depression | 4 | 6 | | | | | 4 | 6 |
| Dermatitis | | 2 | | | | 2 | | |
| Dermatitis allergic | 2 | 4 | | | | 2 | 2 | 2 |
| Dermatitis bullous | 1 | 1 | | | | | 1 | 1 |
| Dermatitis exfoliative | 1 | 1 | | | | | 1 | 1 |
| Diabetes mellitus | 2 | 2 | | | | | 2 | 2 |
| Diabetes mellitus inadequate control | | 2 | | | | | | 2 |
| Diabetic complication | | 1 | | | | | | 1 |
| Diabetic ketoacidosis | 1 | 4 | | | | | 1 | 4 |
| Diarrhoea | 147 | 209 | | | 16 | 34 | 131 | 175 |
| Diarrhoea haemorrhagic | 1 | 1 | | | | | 1 | 1 |
| Diplopia | 3 | 4 | | | | | 3 | 4 |
| Discomfort | 8 | 13 | | | 2 | 4 | 6 | 9 |
| Disease recurrence | 23 | 27 | | | | | 23 | 27 |
| Disorientation | 5 | 8 | | | 1 | 2 | 4 | 6 |
| Disseminated varicella zoster virus infection | 1 | 1 | | | | | 1 | 1 |
| Dissociation | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Disturbance in attention | 14 | 17 | | | 3 | 3 | 11 | 14 |
| Diverticulitis | 1 | 1 | | | | | 1 | 1 |
| Dizziness | 193 | 288 | 1 | 2 | 17 | 49 | 176 | 239 |
| Dizziness exertional | 1 | 1 | | | | | 1 | 1 |
| Dizziness postural | 12 | 23 | | | 2 | 5 | 10 | 18 |
| Drooling | 2 | 2 | | | 1 | 1 | 1 | 1 |

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| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Drug eruption | | 2 | | | | | | 2 | |
| Drug hypersensitivity | 2 | 3 | | | | | 2 | | 3 |
| Drug ineffective | 42 | 93 | | | | | 42 | | 93 |
| Drug withdrawal syndrome | 1 | 1 | | | | | 1 | | 1 |
| Dry eye | 2 | 4 | | | | 2 | 2 | | 2 |
| Dry mouth | 13 | 24 | | | 1 | 4 | 12 | | 20 |
| Dry skin | 2 | 5 | | | | 3 | 2 | | 2 |
| Dry throat | 4 | 7 | | | 1 | 2 | 3 | | 5 |
| Duodenogastric reflux | 1 | 1 | | | | | 1 | | 1 |
| Dysarthria | 4 | 10 | | | | | 4 | | 10 |
| Dysgeusia | 20 | 33 | | | 7 | 15 | 13 | | 18 |
| Dyskinesia | 3 | 5 | | | | 1 | 3 | | 4 |
| Dysmenorrhoea | 1 | 2 | | | | 1 | 1 | | 1 |
| Dysmorphism | 1 | 1 | | | | | 1 | | 1 |
| Dyspepsia | 4 | 5 | | | | 1 | 4 | | 4 |
| Dysphagia | 10 | 17 | | | 1 | 2 | 9 | | 15 |
| Dysphonia | 5 | 6 | | | | | 5 | | 6 |
| Dyspnoea | 130 | 196 | | | 11 | 30 | 119 | | 166 |
| Dyspnoea at rest | 3 | 3 | | | | | 3 | | 3 |
| Dyspnoea exertional | 6 | 10 | | | 2 | 3 | 4 | | 7 |
| Dysstasia | 4 | 7 | | | 2 | 4 | 2 | | 3 |
| Dystonia | 1 | 1 | | | | | 1 | | 1 |
| Dysuria | 1 | 2 | | | | | 1 | | 2 |
| Ear discomfort | 1 | 1 | | | | | 1 | | 1 |
| Ear disorder | 1 | 1 | | | | | 1 | | 1 |
| Ear infection | | 1 | | | | | | | 1 |
| Ear infection bacterial | 1 | 1 | | | | | 1 | | 1 |
| Ear pain | 14 | 24 | | | 1 | 5 | 13 | | 19 |
| Ear pruritus | 1 | 1 | | | | | 1 | | 1 |
| Eating disorder | 2 | 3 | | | 1 | 1 | 1 | | 2 |
| Eczema | 3 | 6 | | | | 1 | 3 | | 5 |
| Eczema weeping | 1 | 1 | | | 1 | 1 | | | |
| Electric shock | 1 | 1 | | | | | 1 | | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Electrocardiogram abnormal | 1 | 1 | | | | | 1 | 1 |
| Electrocardiogram ST segment elevation | | 1 | | | | | | 1 |
| Emotional disorder | 1 | 1 | | | | | 1 | 1 |
| Emotional distress | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Encephalitis | 3 | 3 | | | | | 3 | 3 |
| Encephalopathy | 1 | 1 | | | | | 1 | 1 |
| Epicondylitis | 2 | 2 | | | | | 2 | 2 |
| Epigastric discomfort | 1 | 1 | | | | | 1 | 1 |
| Epiglottic oedema | 1 | 1 | | | | | 1 | 1 |
| Epilepsy | 3 | 7 | | | | | 3 | 7 |
| Epiphyses premature fusion | 1 | 1 | | | | | 1 | 1 |
| Episcleritis | 1 | 1 | | | | | 1 | 1 |
| Epistaxis | 6 | 12 | | | 1 | 3 | 5 | 9 |
| Epstein-Barr virus infection | 1 | 1 | | | | | 1 | 1 |
| Erectile dysfunction | | 1 | | | | | | 1 |
| Eructation | | 3 | | | | | | 3 |
| Erythema | 27 | 55 | | | 6 | 20 | 21 | 35 |
| Erythema multiforme | 3 | 3 | | | | | 3 | 3 |
| Erythema nodosum | 1 | 1 | | | | | 1 | 1 |
| Euphoric mood | 1 | 1 | | | 1 | 1 | | |
| Exposure during pregnancy | 1 | 2 | | | 1 | 2 | | |
| Exposure to SARS-CoV-2 | | 1 | | | | | | 1 |
| External ear cellulitis | 1 | 1 | | | | | 1 | 1 |
| External ear pain | 1 | 1 | | | 1 | 1 | | |
| Extraocular muscle paresis | 1 | 1 | | | | | 1 | 1 |
| Extrasystoles | 1 | 3 | | | | 2 | 1 | 1 |
| Eye allergy | | 1 | | | | | | 1 |
| Eye contusion | 1 | 1 | | | | | 1 | 1 |
| Eye disorder | 2 | 5 | | | | 1 | 2 | 4 |
| Eye haemorrhage | 2 | 2 | | | | | 2 | 2 |
| Eye irritation | 1 | 2 | | | | | 1 | 2 |
| Eyelid pain | 1 | 1 | | | | | 1 | 1 |
| Eyelid ptosis | 2 | 3 | | | 1 | 2 | 1 | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Eye movement disorder | 1 | 2 | | | | | 1 | 2 |
| Eye pain | 23 | 35 | 1 | 1 | 1 | 4 | 22 | 31 |
| Eye pruritus | 4 | 7 | 1 | 1 | 1 | 1 | 3 | 6 |
| Eye swelling | 20 | 29 | | | 3 | 5 | 17 | 24 |
| Facial asymmetry | 1 | 1 | | | 1 | 1 | | |
| Facial discomfort | | 1 | | | | | | 1 |
| Facial neuralgia | 1 | 1 | | | | | 1 | 1 |
| Facial pain | 4 | 10 | | | | 2 | 4 | 8 |
| Facial paralysis | 27 | 37 | | | | 1 | 27 | 36 |
| Facial paresis | 5 | 7 | | | 2 | 2 | 3 | 5 |
| Faeces discoloured | 3 | 5 | | | 3 | 4 | | 1 |
| Fall | 15 | 23 | | | 2 | 4 | 13 | 19 |
| Fatigue | 529 | 794 | 11 | 14 | 62 | 157 | 467 | 637 |
| Feeding disorder | 5 | 5 | | | | | 5 | 5 |
| Feeling abnormal | 42 | 62 | | 1 | 9 | 14 | 33 | 48 |
| Feeling cold | 37 | 70 | | | 7 | 20 | 30 | 50 |
| Feeling drunk | 1 | 2 | | | 1 | 1 | | 1 |
| Feeling hot | 37 | 62 | | | 6 | 17 | 31 | 45 |
| Feeling jittery | 1 | 1 | | | | | 1 | 1 |
| Feeling of body temperature change | 7 | 18 | | | 3 | 6 | 4 | 12 |
| Feeling of despair | 1 | 1 | | | | | 1 | 1 |
| Fibrin D dimer increased | 1 | 1 | | | | | 1 | 1 |
| Fibromyalgia | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Flatulence | 1 | 1 | | | | | 1 | 1 |
| Fluid intake reduced | | 1 | | | | | | 1 |
| Fluid retention | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Flushing | 8 | 22 | | | | 7 | 8 | 15 |
| Food aversion | 2 | 2 | | | | | 2 | 2 |
| Food craving | 1 | 1 | | | | | 1 | 1 |
| Food refusal | 2 | 2 | | | | | 2 | 2 |
| Formication | 3 | 3 | | | | | 3 | 3 |
| Frequent bowel movements | 3 | 6 | | | | 2 | 3 | 4 |
| Gait disturbance | 14 | 25 | | | 4 | 7 | 10 | 18 |

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|---------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Gait inability | 11 | 13 | | | 1 | 1 | 10 | 12 |
| Gastric antral vascular ectasia | 1 | 1 | | | | | 1 | 1 |
| Gastric disorder | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Gastric haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Gastric varices haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Gastritis | 1 | 3 | | | | 1 | 1 | 2 |
| Gastroenteritis | 3 | 4 | | | | | 3 | 4 |
| Gastroenteritis viral | | 1 | | | | | | 1 |
| Gastrointestinal disorder | | 1 | | | | 1 | | |
| Gastrointestinal pain | 4 | 5 | | | | | 4 | 5 |
| Gastrointestinal sounds abnormal | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal stoma complication | | 1 | | | | | | 1 |
| Gastrooesophageal reflux disease | 6 | 8 | | | | | 6 | 8 |
| Generalised tonic-clonic seizure | 1 | 2 | | | | | 1 | 2 |
| General physical health deterioration | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Genital pain | 1 | 1 | | | | | 1 | 1 |
| Giant cell arteritis | 2 | 2 | | | | | 2 | 2 |
| Gingival blister | | 1 | | | | 1 | | |
| Gingival discomfort | 1 | 1 | | | | | 1 | 1 |
| Gingival pain | 3 | 4 | | | 2 | 2 | 1 | 2 |
| Gingival swelling | 1 | 1 | | | | | 1 | 1 |
| Gingivitis | 1 | 1 | | | 1 | 1 | | |
| Gliososis | 1 | 1 | | | | | 1 | 1 |
| Glossodynia | 6 | 8 | | | 3 | 4 | 3 | 4 |
| Goitre | 1 | 1 | | | | | 1 | 1 |
| Gout | 3 | 3 | | | | | 3 | 3 |
| Grip strength decreased | 1 | 3 | | | | | 1 | 3 |
| Groin pain | 5 | 5 | | | | | 5 | 5 |
| Guillain-Barre syndrome | 1 | 1 | | | | | 1 | 1 |
| Haematemesis | 3 | 8 | | | | | 3 | 8 |
| Haematochezia | 2 | 3 | | | | | 2 | 3 |
| Haematocrit increased | 1 | 1 | | | | | 1 | 1 |
| Haematoma | | 1 | | | | 1 | | |

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|---------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Haemoglobin decreased | 2 | 4 | | | | 1 | 2 | 3 |
| Haemoglobin increased | 1 | 1 | | | | | 1 | 1 |
| Haemoptysis | 3 | 4 | | | | | 3 | 4 |
| Haemorrhage | 4 | 4 | | | | | 4 | 4 |
| Haemorrhage intracranial | | 1 | | | | | | 1 |
| Haemorrhage urinary tract | 1 | 1 | | | | | 1 | 1 |
| Haemorrhagic stroke | | 1 | | | | | | 1 |
| Hallucination | 6 | 10 | | | | | 6 | 10 |
| Hallucination, auditory | 1 | 1 | | | | | 1 | 1 |
| Hallucination, visual | | 2 | | | | | | 2 |
| Hangover | | 2 | | | | 1 | | 1 |
| Headache | 544 | 873 | 7 | 10 | 61 | 178 | 483 | 695 |
| Head discomfort | 5 | 8 | | | 2 | 4 | 3 | 4 |
| Head injury | 1 | 3 | | | | 1 | 1 | 2 |
| Heart rate abnormal | 2 | 2 | | | | | 2 | 2 |
| Heart rate decreased | 1 | 3 | | | | | 1 | 3 |
| Heart rate increased | 24 | 41 | | | 3 | 7 | 21 | 34 |
| Heart rate irregular | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Heat illness | | 1 | | | | | | 1 |
| Heat stroke | | 1 | | | | 1 | | |
| Hemiparesis | 1 | 6 | | | | | 1 | 6 |
| Hepatic artery embolism | | 1 | | | | | | 1 |
| Hepatic enzyme increased | | 1 | | | | 1 | | |
| Hepatic pain | 1 | 2 | | | | | 1 | 2 |
| Herpes simplex | 2 | 2 | | | | | 2 | 2 |
| Herpes virus infection | | 1 | | | | | | 1 |
| Herpes zoster | 20 | 27 | | | 2 | 7 | 18 | 20 |
| Hot flush | 20 | 32 | | | 3 | 5 | 17 | 27 |
| Hyperacusis | 2 | 3 | | | | | 2 | 3 |
| Hyperaesthesia | 4 | 7 | | | 2 | 3 | 2 | 4 |
| Hypercapnia | 1 | 1 | | | | | 1 | 1 |
| Hyperchlorhydria | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Hypergeusia | 1 | 1 | | | | | 1 | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Hyperglycaemia | 3 | 9 | | | 1 | 2 | 2 | 7 |
| Hyperhidrosis | 52 | 73 | 1 | 1 | 3 | 6 | 49 | 67 |
| Hyperkalaemia | 1 | 1 | | | | | 1 | 1 |
| Hypersensitivity | 10 | 23 | | | 1 | 5 | 9 | 18 |
| Hypersensitivity pneumonitis | | 1 | | | | | | 1 |
| Hypersomnia | 13 | 18 | | | 4 | 4 | 9 | 14 |
| Hypertension | 15 | 27 | 1 | 1 | 3 | 5 | 12 | 22 |
| Hypertonia | 1 | 2 | | | | | 1 | 2 |
| Hyperventilation | | 1 | | | | | | 1 |
| Hypoacusis | 1 | 1 | | | | | 1 | 1 |
| Hypoaesthesia | 36 | 55 | | | 10 | 17 | 26 | 38 |
| Hypoaesthesia oral | 12 | 20 | | | 3 | 9 | 9 | 11 |
| Hypoglycaemia | 9 | 17 | | | | 2 | 9 | 15 |
| Hypokalaemic syndrome | 1 | 1 | | | | | 1 | 1 |
| Hypokinesia | 2 | 2 | | | | | 2 | 2 |
| Hyponatraemia | 1 | 2 | | | | | 1 | 2 |
| Hypophagia | 1 | 2 | | | | | 1 | 2 |
| Hypopnoea | 5 | 6 | | | | | 5 | 6 |
| Hyporeflexia | 1 | 2 | | | | | 1 | 2 |
| Hyporesponsive to stimuli | | 1 | | | | | | 1 |
| Hyposmia | 1 | 2 | | | | | 1 | 2 |
| Hyposomnia | 1 | 1 | | | | | 1 | 1 |
| Hypotension | 11 | 24 | | | 3 | 6 | 8 | 18 |
| Hypothermia | 1 | 5 | | | | | 1 | 5 |
| Hypothyroidism | 1 | 1 | | | | | 1 | 1 |
| Hypotonia | 1 | 2 | | | | | 1 | 2 |
| Hypoxia | 4 | 7 | | | | | 4 | 7 |
| Idiopathic intracranial hypertension | | 1 | | | | | | 1 |
| Illness | 52 | 60 | | | 4 | 7 | 48 | 53 |
| Immobile | 2 | 2 | | | | | 2 | 2 |
| Immune system disorder | 1 | 2 | | | | | 1 | 2 |
| Immune thrombocytopenia | 2 | 3 | | | | | 2 | 3 |
| Impaired driving ability | 1 | 1 | | | 1 | 1 | | |

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| | | | I | C | I | C | I | C |
| Impaired gastric emptying | 1 | 1 | | | | | 1 | 1 |
| Impaired work ability | 1 | 1 | | | | | 1 | 1 |
| Inappropriate schedule of product administration | 3 | 6 | | | 3 | 6 | | |
| Incoherent | | 2 | | | | | | 2 |
| Incontinence | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Incorrect route of product administration | 3 | 6 | | | 3 | 6 | | |
| Increased insulin requirement | 1 | 1 | | | | | 1 | 1 |
| Increased upper airway secretion | | 1 | | | | | | 1 |
| Increased viscosity of upper respiratory secretion | 1 | 2 | | | | | 1 | 2 |
| Infarction | | 1 | | | | | | 1 |
| Infection | 1 | 3 | | | | | 1 | 3 |
| Inflammation | 4 | 7 | | | | 2 | 4 | 5 |
| Inflammatory marker increased | 1 | 1 | | | 1 | 1 | | |
| Influenza | 39 | 46 | | | 6 | 8 | 33 | 38 |
| Influenza like illness | 62 | 119 | | | 13 | 41 | 49 | 78 |
| Injected limb mobility decreased | 1 | 1 | | | | | 1 | 1 |
| Injection related reaction | 3 | 3 | | | | | 3 | 3 |
| Injection site mass | | 1 | | | | 1 | | |
| Injection site pain | 1 | 8 | | | | 7 | 1 | 1 |
| Injection site rash | | 1 | | | | 1 | | |
| Injection site swelling | | 2 | | | | 2 | | |
| Injury corneal | | 1 | | | | | | 1 |
| Insomnia | 48 | 70 | | | 13 | 21 | 35 | 49 |
| International normalised ratio decreased | 2 | 2 | | | | | 2 | 2 |
| International normalised ratio increased | 2 | 2 | | | | | 2 | 2 |
| Intestinal ischaemia | 1 | 1 | | | | | 1 | 1 |
| Intestinal perforation | 1 | 1 | | | | | 1 | 1 |
| Iridocyclitis | 2 | 4 | | | | | 2 | 4 |
| Iritis | 1 | 1 | | | 1 | 1 | | |
| Irritability | 1 | 2 | | | | 1 | 1 | 1 |
| Irritable bowel syndrome | 1 | 4 | | | | 2 | 1 | 2 |
| Ischaemic stroke | 1 | 4 | | | | | 1 | 4 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Jaundice | 1 | 1 | | | | | 1 | 1 |
| Joint effusion | 2 | 3 | | | | | 2 | 3 |
| Joint range of motion decreased | 9 | 11 | | | 3 | 4 | 6 | 7 |
| Joint stiffness | 6 | 11 | | | | 2 | 6 | 9 |
| Joint swelling | 12 | 21 | | | 1 | 3 | 11 | 18 |
| Kidney infection | 1 | 1 | | | | | 1 | 1 |
| Labile blood pressure | 2 | 2 | | | | | 2 | 2 |
| Labyrinthitis | 2 | 3 | | | | | 2 | 3 |
| Lacrimation increased | 5 | 11 | | | | 2 | 5 | 9 |
| Left ventricular dysfunction | 1 | 1 | | | | | 1 | 1 |
| Left ventricular failure | 1 | 1 | | | | | 1 | 1 |
| Lethargy | 49 | 89 | | | 12 | 24 | 37 | 65 |
| Leukaemia | | 1 | | | | | | 1 |
| Limb discomfort | 29 | 51 | | | 7 | 14 | 22 | 37 |
| Limb immobilisation | 1 | 2 | | | 1 | 2 | | |
| Limb injury | 1 | 1 | | | | | 1 | 1 |
| Limb mass | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Lip blister | | 1 | | | | | | 1 |
| Lip disorder | 1 | 2 | | | 1 | 2 | | |
| Lip dry | 1 | 2 | | | | | 1 | 2 |
| Lip oedema | 2 | 2 | | | | | 2 | 2 |
| Lip swelling | 24 | 37 | | | 4 | 9 | 20 | 28 |
| Listless | 1 | 1 | | | | | 1 | 1 |
| Livedo reticularis | 1 | 2 | | | | | 1 | 2 |
| Liver function test increased | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Localised oedema | 1 | 1 | | | | | 1 | 1 |
| Local reaction | 1 | 4 | | | | 1 | 1 | 3 |
| Long thoracic nerve palsy | 1 | 1 | | | 1 | 1 | | |
| Loss of consciousness | 19 | 26 | | | | | 19 | 26 |
| Loss of personal independence in daily activities | 6 | 9 | | | 2 | 3 | 4 | 6 |
| Lower respiratory tract infection | 11 | 22 | | | | | 11 | 22 |
| Lung consolidation | | 1 | | | | | | 1 |
| Lung disorder | 1 | 1 | | | | | 1 | 1 |

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|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Lymphadenitis | 2 | 3 | | | | | 2 | 3 |
| Lymphadenopathy | 87 | 148 | | | 12 | 41 | 75 | 107 |
| Lymph node pain | 24 | 39 | | | 4 | 9 | 20 | 30 |
| Lymphoedema | 3 | 4 | | | | | 3 | 4 |
| Lymphopenia | 1 | 1 | | | 1 | 1 | | |
| Malaise | 179 | 318 | 2 | 2 | 29 | 77 | 150 | 241 |
| Mastication disorder | | 2 | | | | | | 2 |
| Mastitis | 1 | 2 | | | | | 1 | 2 |
| Maternal exposure during pregnancy | 5 | 5 | | | 3 | 3 | 2 | 2 |
| Medial tibial stress syndrome | 1 | 1 | | | | | 1 | 1 |
| Melaena | 1 | 1 | | | | | 1 | 1 |
| Memory impairment | 7 | 8 | | | 1 | 1 | 6 | 7 |
| Meniere's disease | 2 | 2 | | | | | 2 | 2 |
| Meningitis | 1 | 1 | | | | | 1 | 1 |
| Menopausal symptoms | | 1 | | | | 1 | | |
| Menorrhagia | 2 | 3 | | | | | 2 | 3 |
| Menstruation delayed | 1 | 1 | | | | | 1 | 1 |
| Mental disorder | 1 | 1 | | | 1 | 1 | | |
| Mental fatigue | 8 | 10 | | | 1 | 2 | 7 | 8 |
| Mental impairment | | 2 | | | | | | 2 |
| Micturition disorder | 1 | 2 | | | | | 1 | 2 |
| Micturition urgency | 1 | 2 | | | | 1 | 1 | 1 |
| Middle ear inflammation | | 1 | | | | | | 1 |
| Migraine | 52 | 79 | | | 5 | 13 | 47 | 66 |
| Migraine with aura | 4 | 7 | | | 1 | 1 | 3 | 6 |
| Miosis | 1 | 1 | | | | | 1 | 1 |
| Mobility decreased | 19 | 29 | | | 7 | 11 | 12 | 18 |
| Monoparesis | 3 | 3 | | | | | 3 | 3 |
| Monoplegia | 2 | 4 | | | | | 2 | 4 |
| Mood altered | | 1 | | | | 1 | | |
| Mouth breathing | 2 | 2 | | | | | 2 | 2 |
| Mouth swelling | 4 | 6 | | | | | 4 | 6 |
| Mouth ulceration | 9 | 17 | | | 3 | 8 | 6 | 9 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Movement disorder | 8 | 9 | | | 1 | 2 | 7 | 7 |
| Multiple injuries | 1 | 1 | | | | | 1 | 1 |
| Multiple organ dysfunction syndrome | 1 | 2 | | | | | 1 | 2 |
| Multiple sclerosis | | 1 | | | | | | 1 |
| Multiple sclerosis relapse | 5 | 7 | | | | | 5 | 7 |
| Muscle contractions involuntary | 1 | 2 | | | | 1 | 1 | 1 |
| Muscle disorder | 1 | 1 | | | | | 1 | 1 |
| Muscle fatigue | 17 | 19 | | | 3 | 3 | 14 | 16 |
| Muscle rigidity | 1 | 3 | | | | | 1 | 3 |
| Muscle rupture | 1 | 1 | | | | | 1 | 1 |
| Muscle spasms | 16 | 26 | | | 3 | 4 | 13 | 22 |
| Muscle strain | 1 | 2 | | | | | 1 | 2 |
| Muscle swelling | | 1 | | | | | | 1 |
| Muscle tightness | 5 | 5 | | | 1 | 1 | 4 | 4 |
| Muscle tone disorder | | 1 | | | | | | 1 |
| Muscle twitching | 5 | 8 | | | 1 | 2 | 4 | 6 |
| Muscular weakness | 32 | 48 | | | 4 | 7 | 28 | 41 |
| Musculoskeletal chest pain | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Musculoskeletal discomfort | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Musculoskeletal disorder | 2 | 3 | | | | | 2 | 3 |
| Musculoskeletal pain | 2 | 3 | | | | | 2 | 3 |
| Musculoskeletal stiffness | 23 | 41 | 1 | 1 | 2 | 7 | 21 | 34 |
| Myalgia | 218 | 403 | 2 | 4 | 20 | 81 | 198 | 322 |
| Myasthenia gravis | 2 | 2 | | | | | 2 | 2 |
| Mydriasis | 1 | 2 | | | | | 1 | 2 |
| Myocardial infarction | 3 | 12 | | | | | 3 | 12 |
| Myocardial ischaemia | 1 | 2 | | | | | 1 | 2 |
| Myocarditis | 1 | 1 | | | | | 1 | 1 |
| Myoclonus | 1 | 1 | | | | | 1 | 1 |
| Nail discolouration | 1 | 2 | | | | | 1 | 2 |
| Nasal congestion | 9 | 12 | | | 2 | 3 | 7 | 9 |
| Nasal discharge discolouration | | 1 | | | | 1 | | |
| Nasal discomfort | 1 | 1 | | | | | 1 | 1 |

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| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Nasal obstruction | | 1 | | | | | | 1 | |
| Nasal odour | 1 | 1 | | | | | 1 | 1 | |
| Nasopharyngitis | 22 | 35 | | | 3 | 10 | 19 | 25 | |
| Nausea | 314 | 504 | 3 | 5 | 33 | 99 | 281 | 405 | |
| Neck pain | 52 | 82 | | | 5 | 16 | 47 | 66 | |
| Necrotising fasciitis | 1 | 1 | | | | | 1 | 1 | |
| Negative thoughts | | 1 | | | | | | 1 | |
| Nephrotic syndrome | | 1 | | | | | | 1 | |
| Nerve compression | 1 | 1 | | | | | 1 | 1 | |
| Nerve injury | 1 | 1 | | | | | 1 | 1 | |
| Nervousness | 7 | 12 | | | 1 | 2 | 6 | 10 | |
| Nervous system disorder | 1 | 1 | | | | | 1 | 1 | |
| Neuralgia | 5 | 6 | | | 1 | 1 | 4 | 5 | |
| Neurogenic shock | | 1 | | | | | | 1 | |
| Neurological symptom | 1 | 1 | | | | | 1 | 1 | |
| Neurologic neglect syndrome | 1 | 1 | | | | | 1 | 1 | |
| Neuropathy peripheral | 5 | 6 | | | | | 5 | 6 | |
| Neuropsychiatric symptoms | 1 | 1 | | | 1 | 1 | | | |
| Neutropenia | 3 | 3 | | | | | 3 | 3 | |
| Nightmare | | 2 | | | | | 1 | 1 | |
| Night sweats | 15 | 19 | 2 | 2 | | 2 | 15 | 17 | |
| Nipple pain | 2 | 3 | | | | | 1 | 2 | 2 |
| Nipple swelling | | 1 | | | | | 1 | | |
| Nodule | 1 | 1 | | | | | 1 | 1 | |
| Non-cardiac chest pain | 2 | 2 | | | 1 | 1 | 1 | 1 | |
| Noninfective gingivitis | 1 | 1 | | | | | 1 | 1 | |
| Numb chin syndrome | 1 | 1 | | | | | 1 | 1 | |
| Obsessive-compulsive symptom | | 1 | | | | | | 1 | |
| Occipital neuralgia | 1 | 1 | | | | | 1 | 1 | |
| Occupational exposure to SARS-CoV-2 | | 2 | | | | 2 | | | |
| Ocular discomfort | 1 | 1 | | | | | 1 | 1 | |
| Ocular hyperaemia | 5 | 9 | | | | 1 | 5 | 8 | |
| Odynophagia | 2 | 3 | | | 1 | 1 | 1 | 2 | |

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| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Oedema | | 3 | | | | 1 | | | 2 |
| Oedema mouth | 1 | 1 | | | | | 1 | | 1 |
| Oedema peripheral | 1 | 2 | | | 1 | 1 | | | 1 |
| Off label use | 230 | 243 | | | 226 | 239 | 4 | | 4 |
| Oliguria | 1 | 1 | | | | | 1 | | 1 |
| Optic neuritis | | 1 | | | | | | | 1 |
| Oral blood blister | | 1 | | | | | | | 1 |
| Oral discomfort | 3 | 5 | | | | 1 | 3 | | 4 |
| Oral disorder | 2 | 2 | | | 2 | 2 | | | |
| Oral herpes | 6 | 9 | | | 1 | 3 | 5 | | 6 |
| Oral mucosal blistering | 1 | 4 | | | 1 | 3 | | | 1 |
| Oral mucosal erythema | | 1 | | | | | | | 1 |
| Oral mucosal exfoliation | 1 | 1 | | | 1 | 1 | | | |
| Oral pain | 7 | 8 | | | | | 7 | | 8 |
| Oral pruritus | 1 | 1 | | | | | 1 | | 1 |
| Orchitis | 1 | 1 | | | | | 1 | | 1 |
| Oropharyngeal blistering | 2 | 3 | | | | | 2 | | 3 |
| Oropharyngeal discomfort | 2 | 2 | | | | | 2 | | 2 |
| Oropharyngeal oedema | 1 | 1 | | | | | 1 | | 1 |
| Oropharyngeal pain | 66 | 99 | | | 9 | 29 | 57 | | 70 |
| Oropharyngeal spasm | 1 | 1 | | | | | 1 | | 1 |
| Orthopnoea | | 1 | | | | 1 | | | |
| Orthostatic hypotension | 1 | 1 | | | | | 1 | | 1 |
| Osteoarthritis | 1 | 1 | | | | | 1 | | 1 |
| Otitis externa | 1 | 1 | | | | | 1 | | 1 |
| Overdose | | 1 | | | | 1 | | | |
| Oxygen saturation decreased | 11 | 17 | | | 3 | 3 | 8 | | 14 |
| Pain | 158 | 275 | 5 | 5 | 27 | 74 | 131 | | 201 |
| Painful respiration | 1 | 1 | | | | | 1 | | 1 |
| Pain in extremity | 233 | 365 | 5 | 6 | 41 | 101 | 192 | | 264 |
| Pain in jaw | 5 | 7 | | | | 1 | 5 | | 6 |
| Pain of skin | 8 | 11 | | | | | 8 | | 11 |
| Palatal swelling | 1 | 1 | | | | | 1 | | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Pallor | 5 | 13 | | | | 1 | 5 | 12 |
| Palpitations | 42 | 61 | | | 3 | 8 | 39 | 53 |
| Panic attack | 2 | 2 | | | | | 2 | 2 |
| Panic reaction | 1 | 1 | | | | | 1 | 1 |
| Papule | | 1 | | | | | | 1 |
| Paraesthesia | 58 | 101 | | | 7 | 23 | 51 | 78 |
| Paraesthesia oral | 30 | 51 | 1 | 1 | 6 | 12 | 24 | 39 |
| Paralysis | 2 | 5 | | | | | 2 | 5 |
| Paranoia | 1 | 1 | | | | | 1 | 1 |
| Paresis | 1 | 1 | | | | | 1 | 1 |
| Parkinsonism | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Parkinson's disease | 1 | 2 | | | | | 1 | 2 |
| Parosmia | 6 | 9 | | | | 1 | 6 | 8 |
| Peak expiratory flow rate decreased | 1 | 1 | | | | | 1 | 1 |
| Pelvic discomfort | 1 | 1 | | | | | 1 | 1 |
| Pelvic pain | 1 | 1 | | | 1 | 1 | | |
| Pemphigoid | 2 | 2 | | | | | 2 | 2 |
| Pemphigus | 1 | 1 | | | | | 1 | 1 |
| Periarthritis | | 1 | | | | | | 1 |
| Pericarditis | 3 | 4 | | | | | 3 | 4 |
| Periorbital cellulitis | 1 | 1 | | | | | 1 | 1 |
| Periorbital haematoma | 1 | 1 | | | | | 1 | 1 |
| Periorbital oedema | 3 | 3 | | | | | 3 | 3 |
| Periorbital swelling | 4 | 7 | | | | 3 | 4 | 4 |
| Peripheral circulatory failure | | 1 | | | | | | 1 |
| Peripheral coldness | 13 | 22 | | | 2 | 4 | 11 | 18 |
| Peripheral sensory neuropathy | 1 | 1 | | | | | 1 | 1 |
| Peripheral swelling | 59 | 83 | | | 9 | 18 | 50 | 65 |
| Peroneal nerve palsy | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Persistent postural-perceptual dizziness | 1 | 1 | | | | | 1 | 1 |
| Petechiae | 1 | 4 | | | | | 1 | 4 |
| Petit mal epilepsy | 1 | 1 | | | | | 1 | 1 |
| Pharyngeal erythema | | 1 | | | | | | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Pharyngeal hypoaesthesia | 1 | 2 | | | | | 1 | 2 |
| Pharyngeal inflammation | | 2 | | | | | | 2 |
| Pharyngeal paraesthesia | 2 | 3 | | | | | 2 | 3 |
| Pharyngeal swelling | 9 | 18 | | | | 2 | 9 | 16 |
| Pharyngeal ulceration | 1 | 1 | | | | | 1 | 1 |
| Pharyngitis | | 1 | | | | | | 1 |
| Pharyngitis streptococcal | | 1 | | | | | | 1 |
| Phlebitis | 1 | 1 | | | | | 1 | 1 |
| Photophobia | 9 | 17 | | | | 1 | 9 | 16 |
| Photopsia | 1 | 1 | | | 1 | 1 | | |
| Photosensitivity reaction | 4 | 4 | | | 3 | 3 | 1 | 1 |
| pH urine increased | 1 | 1 | | | | | 1 | 1 |
| Piloerection | | 2 | | | | | | 2 |
| Plantar fasciitis | 1 | 1 | | | | | 1 | 1 |
| Platelet count decreased | 1 | 1 | | | | | 1 | 1 |
| Pleural effusion | | 1 | | | | | | 1 |
| Pleurisy | 2 | 3 | | | | | 2 | 3 |
| Pleuritic pain | 2 | 2 | | | | | 2 | 2 |
| Plicated tongue | | 1 | | | | | | 1 |
| Pneumonia | 4 | 7 | | | | | 4 | 7 |
| Pneumonitis | 2 | 3 | | | | | 2 | 3 |
| Pollakiuria | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Polymenorrhoea | | 1 | | | | 1 | | |
| Polymyalgia rheumatica | 4 | 5 | | | | | 4 | 5 |
| Polymyositis | 1 | 1 | | | | | 1 | 1 |
| Polyuria | | 1 | | | | 1 | | |
| Poor quality sleep | 7 | 10 | | | 1 | 2 | 6 | 8 |
| Postprandial hypoglycaemia | 1 | 1 | | | | | 1 | 1 |
| Post procedural complication | 1 | 1 | | | | | 1 | 1 |
| Post viral fatigue syndrome | 1 | 2 | | | | | 1 | 2 |
| Pre-existing condition improved | | 1 | | | | 1 | | |
| Presyncope | 7 | 15 | | | 1 | 1 | 6 | 14 |
| Procedural nausea | 1 | 1 | | | | | 1 | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Proctalgia | 1 | 1 | | | 1 | 1 | | |
| Proctitis ulcerative | | 1 | | | | | | 1 |
| Product administered at inappropriate site | 1 | 1 | | | 1 | 1 | | |
| Product administered to patient of inappropriate age | 8 | 12 | | | 7 | 11 | 1 | 1 |
| Productive cough | 11 | 15 | | | 2 | 2 | 9 | 13 |
| Product use issue | 231 | 245 | | | 227 | 241 | 4 | 4 |
| Prostatomegaly | | 1 | | | | 1 | | |
| Pruritus | 60 | 106 | 1 | 1 | 11 | 34 | 49 | 72 |
| Psoriasis | 3 | 4 | 1 | 1 | 2 | 2 | 1 | 2 |
| Psoriatic arthropathy | 1 | 2 | | | | | 1 | 2 |
| Psychiatric symptom | 1 | 1 | | | | | 1 | 1 |
| Psychomotor hyperactivity | 2 | 2 | | | | | 2 | 2 |
| Psychotic behaviour | | 1 | | | | | | 1 |
| Psychotic disorder | 2 | 2 | | | | | 2 | 2 |
| Pulmonary artery thrombosis | 1 | 1 | | | | | 1 | 1 |
| Pulmonary congestion | 1 | 1 | | | | | 1 | 1 |
| Pulmonary embolism | 5 | 6 | | | | | 5 | 6 |
| Pulmonary oedema | | 1 | | | | | | 1 |
| Pulmonary pain | 6 | 7 | | | 1 | 2 | 5 | 5 |
| Pulmonary thrombosis | 1 | 2 | | | | | 1 | 2 |
| Pulseless electrical activity | | 1 | | | | | | 1 |
| Pupillary disorder | 1 | 1 | | | | | 1 | 1 |
| Purpura | 1 | 1 | | | | | 1 | 1 |
| Pustular psoriasis | 1 | 1 | | | | | 1 | 1 |
| Pustule | 1 | 1 | | | | | 1 | 1 |
| Pyelonephritis | | 1 | | | | | | 1 |
| Pyrexia | 292 | 557 | 2 | 3 | 28 | 117 | 264 | 440 |
| Q fever | 2 | 3 | | | | | 2 | 3 |
| Rales | | 1 | | | | | | 1 |
| Rash | 63 | 90 | | | 3 | 14 | 60 | 76 |
| Rash erythematous | 19 | 24 | | | 3 | 6 | 16 | 18 |
| Rash macular | 3 | 13 | | | 1 | 8 | 2 | 5 |

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| | | | I | C | I | C | I | C |
| Rash maculo-papular | 1 | 2 | | | | | 1 | 2 |
| Rash papular | 1 | 3 | | | | 1 | 1 | 2 |
| Rash pruritic | 15 | 26 | | | 1 | 4 | 14 | 22 |
| Rash vesicular | 1 | 2 | | | | 1 | 1 | 1 |
| Raynaud's phenomenon | | 1 | | | | | | 1 |
| Reaction to preservatives | 1 | 1 | | | | | 1 | 1 |
| Rectal haemorrhage | 5 | 5 | | | | | 5 | 5 |
| Renal failure | 1 | 2 | | | | | 1 | 2 |
| Renal pain | 6 | 8 | | | | 1 | 6 | 7 |
| Respiration abnormal | 4 | 5 | | | | | 4 | 5 |
| Respiratory arrest | | 4 | | | | | | 4 |
| Respiratory disorder | 2 | 2 | | | | | 2 | 2 |
| Respiratory distress | | 1 | | | | | | 1 |
| Respiratory failure | 1 | 1 | | | | | 1 | 1 |
| Respiratory rate increased | 6 | 11 | | | | | 6 | 11 |
| Respiratory symptom | | | 1 | 1 | | | | |
| Respiratory tract oedema | 1 | 2 | | | | | 1 | 2 |
| Restless legs syndrome | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Restlessness | 5 | 9 | | | | 2 | 5 | 7 |
| Retching | 3 | 8 | | | 1 | 4 | 2 | 4 |
| Retinal haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Retinal migraine | 2 | 2 | | | | | 2 | 2 |
| Retinal toxicity | 1 | 1 | | | | | 1 | 1 |
| Rhabdomyolysis | | 1 | | | | | | 1 |
| Rheumatoid arthritis | 9 | 11 | | | | | 9 | 11 |
| Rhinalgia | 1 | 1 | | | | | 1 | 1 |
| Rhinitis | 4 | 5 | | | | 1 | 4 | 4 |
| Rhinitis allergic | 1 | 1 | | | | | 1 | 1 |
| Rhinorrhoea | 21 | 28 | 1 | 1 | 1 | 4 | 20 | 24 |
| Right ventricular enlargement | | 1 | | | | 1 | | |
| Road traffic accident | 1 | 1 | | | | | 1 | 1 |
| Rotator cuff syndrome | 1 | 1 | | | | | 1 | 1 |
| Sacroiliitis | 1 | 2 | | | 1 | 1 | | 1 |

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| | | | I | C | I | C | I | C |
| Salivary hypersecretion | 1 | 4 | | | | 2 | 1 | 2 |
| Salt craving | 1 | 1 | | | | | 1 | 1 |
| Sarcoidosis | 2 | 2 | | | | | 2 | 2 |
| Sarcoma | 1 | 1 | | | | | 1 | 1 |
| SARS-CoV-2 ant body test negative | 1 | 2 | | | | 1 | 1 | 1 |
| SARS-CoV-2 test | 1 | 1 | | | | | 1 | 1 |
| SARS-CoV-2 test positive | 2 | 6 | | | 1 | 1 | 1 | 5 |
| Sciatica | 1 | 1 | | | | | 1 | 1 |
| Scleral discolouration | 1 | 1 | | | 1 | 1 | | |
| Scleroderma associated digital ulcer | 1 | 1 | | | | | 1 | 1 |
| Scratch | 2 | 2 | | | | | 2 | 2 |
| Seasonal allergy | | 1 | | | | 1 | | |
| Secretion discharge | | 1 | | | | | | 1 |
| Seizure | 10 | 18 | | | | | 10 | 18 |
| Sensation of blood flow | 1 | 1 | | | | | 1 | 1 |
| Sensation of foreign body | 2 | 4 | | | | | 2 | 4 |
| Sensitive skin | 4 | 5 | | | | | 4 | 5 |
| Sensory disturbance | 3 | 7 | | | 2 | 4 | 1 | 3 |
| Sensory loss | 1 | 1 | | | | | 1 | 1 |
| Sepsis | 2 | 3 | | | | | 2 | 3 |
| Serotonin syndrome | | 1 | | | | | | 1 |
| Serum sickness | 1 | 1 | | | | | 1 | 1 |
| Shock | 1 | 1 | | | | | 1 | 1 |
| Sinus congestion | 1 | 1 | | | | | 1 | 1 |
| Sinus headache | 7 | 10 | | | 1 | 2 | 6 | 8 |
| Sinusitis | 2 | 2 | | | | | 2 | 2 |
| Sinus pain | 5 | 8 | | | 1 | 2 | 4 | 6 |
| Sinus tachycardia | 1 | 1 | | | | | 1 | 1 |
| Sjogren's syndrome | 1 | 2 | | | | | 1 | 2 |
| Skin abrasion | 1 | 1 | | | | | 1 | 1 |
| Skin burning sensation | 3 | 7 | | | | 1 | 3 | 6 |
| Skin cancer | | 1 | | | | | | 1 |
| Skin discolouration | 2 | 5 | | | 1 | 3 | 1 | 2 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Skin disorder | 1 | 2 | | | | 1 | 1 | 1 |
| Skin erosion | 1 | 3 | | | | 1 | 1 | 2 |
| Skin exfoliation | | 3 | | | | | | 3 |
| Skin induration | | 1 | | | | 1 | | |
| Skin irritation | 4 | 6 | | | 1 | 2 | 3 | 4 |
| Skin laceration | 1 | 1 | | | | | 1 | 1 |
| Skin mass | 1 | 1 | | | | | 1 | 1 |
| Skin sensitisation | | 1 | | | | | | 1 |
| Skin swelling | 2 | 2 | | | | | 2 | 2 |
| Skin tightness | 1 | 4 | | | | 1 | 1 | 3 |
| Skin ulcer | | 1 | | | | | | 1 |
| Skin warm | 5 | 12 | | | 1 | 4 | 4 | 8 |
| Skin weeping | | 1 | | | | | | 1 |
| Skull fracture | 1 | 1 | | | | | 1 | 1 |
| Sleep attacks | | 1 | | | | | | 1 |
| Sleep disorder | 10 | 17 | | | 2 | 7 | 8 | 10 |
| Sleep disorder due to a general medical condition | | 3 | | | | 1 | | 2 |
| Sleep disorder due to general medical condition, insomnia type | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Slow speech | 1 | 1 | | | | | 1 | 1 |
| Sneezing | 9 | 15 | | | 1 | 7 | 8 | 8 |
| Social avoidant behaviour | 1 | 1 | | | | | 1 | 1 |
| Somnolence | 33 | 59 | | | 8 | 14 | 25 | 45 |
| Speech disorder | 3 | 4 | | | 3 | 3 | | 1 |
| Spinal disorder | | 1 | | | | 1 | | |
| Spinal pain | 4 | 5 | | | 1 | 1 | 3 | 4 |
| Splenomegaly | 1 | 1 | | | | | 1 | 1 |
| Sputum abnormal | 1 | 1 | | | | | 1 | 1 |
| Stevens-Johnson syndrome | 1 | 2 | | | | | 1 | 2 |
| Stoma site discharge | | 1 | | | | | | 1 |
| Stridor | 1 | 1 | | | | | 1 | 1 |
| Subarachnoid haemorrhage | 1 | 2 | | | | | 1 | 2 |

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|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Sudden death | 6 | 10 | | | | | 6 | 10 |
| Suffocation feeling | 1 | 1 | | | 1 | 1 | | |
| Suicidal ideation | 1 | 1 | | | | | 1 | 1 |
| Sunburn | 1 | 1 | | | | | 1 | 1 |
| Suprapubic pain | 1 | 1 | | | 1 | 1 | | |
| Suspected COVID-19 | 23 | 47 | | | 4 | 7 | 19 | 40 |
| Sweating fever | 3 | 4 | | | | | 3 | 4 |
| Swelling | 28 | 41 | | | 3 | 8 | 25 | 33 |
| Swelling face | 29 | 43 | | | 5 | 8 | 24 | 35 |
| Swelling of eyelid | 1 | 3 | | | | | 1 | 3 |
| Swollen tongue | 12 | 25 | | | 2 | 6 | 10 | 19 |
| Syncope | 24 | 40 | | | | | 24 | 40 |
| Synovial cyst | | 1 | | | | 1 | | |
| Synovitis | 2 | 3 | | | | | 2 | 3 |
| Systemic inflammatory response syndrome | | 1 | | | | | | 1 |
| Systemic lupus erythematosus | 1 | 2 | | | | | 1 | 2 |
| Systolic hypertension | 2 | 2 | | | | | 2 | 2 |
| Tachycardia | 27 | 55 | | | 2 | 11 | 25 | 44 |
| Tachypnoea | 1 | 3 | | | 1 | 1 | | 2 |
| Taste disorder | 10 | 13 | | | 2 | 4 | 8 | 9 |
| Temperature regulation disorder | | 1 | | | | | | 1 |
| Temporomandibular joint syndrome | | 1 | | | | 1 | | |
| Tenderness | 2 | 4 | 2 | 2 | | 2 | 2 | 2 |
| Tension headache | 5 | 9 | | | | 1 | 5 | 8 |
| Therapeutic response unexpected | 4 | 6 | | | 2 | 3 | 2 | 3 |
| Thermal burn | 2 | 2 | | | | | 2 | 2 |
| Thinking abnormal | 1 | 1 | | | | | 1 | 1 |
| Thirst | 10 | 13 | | | 2 | 3 | 8 | 10 |
| Throat clearing | | 1 | | | | | | 1 |
| Throat irritation | 11 | 20 | | | | 2 | 11 | 18 |
| Throat tightness | 13 | 27 | | | 1 | 2 | 12 | 25 |
| Thrombocytopenia | 2 | 4 | | | | | 2 | 4 |
| Thrombosis | 1 | 3 | | | | | 1 | 3 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Tinnitus | 20 | 26 | | | 1 | 3 | 19 | 23 |
| Tongue blistering | 1 | 1 | | | 1 | 1 | | |
| Tongue discomfort | 1 | 2 | | | | 1 | 1 | 1 |
| Tongue disorder | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Tongue movement disturbance | 1 | 1 | | | 1 | 1 | | |
| Tongue oedema | 3 | 3 | | | | | 3 | 3 |
| Tongue pruritus | | 1 | | | | | | 1 |
| Tongue ulceration | | 1 | | | | | | 1 |
| Tonic convulsion | 1 | 1 | | | | | 1 | 1 |
| Tonsillar hypertrophy | 2 | 3 | | | | | 2 | 3 |
| Tonsillar inflammation | | 1 | | | | | | 1 |
| Toothache | 1 | 2 | | | | 1 | 1 | 1 |
| Toxic epidermal necrolysis | | 1 | 1 | 1 | | | | 1 |
| Transient ischaemic attack | 2 | 3 | | | | | 2 | 3 |
| Traumatic haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Tremor | 49 | 75 | | | 7 | 12 | 42 | 63 |
| Trigeminal neuralgia | 1 | 1 | | | | | 1 | 1 |
| Tri-iodothyronine decreased | | 1 | | | | | | 1 |
| Troponin increased | 1 | 1 | | | | | 1 | 1 |
| Tunnel vision | 2 | 2 | | | | | 2 | 2 |
| Type IV hypersensitivity reaction | | 2 | | | | | | 2 |
| Ulcer | 1 | 1 | | | | | 1 | 1 |
| Ulcerative keratitis | 1 | 1 | | | | | 1 | 1 |
| Unresponsive to stimuli | 2 | 9 | | | | | 2 | 9 |
| Upper-airway cough syndrome | | 1 | | | | 1 | | |
| Urinary incontinence | 4 | 4 | | | | | 4 | 4 |
| Urinary retention | 3 | 5 | | | | | 3 | 5 |
| Urinary tract disorder | | 1 | | | | | | 1 |
| Urinary tract infection | 7 | 9 | | | 2 | 2 | 5 | 7 |
| Urinary tract infection bacterial | | 1 | | | | | | 1 |
| Urine abnormality | 1 | 1 | | | 1 | 1 | | |
| Urine flow decreased | 1 | 1 | | | | | 1 | 1 |
| Urosepsis | 1 | 2 | | | | | 1 | 2 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Urticaria | 27 | 49 | | | 2 | 8 | 25 | 41 |
| Uveitis | 5 | 5 | | | | | 5 | 5 |
| Vaccination complication | | 1 | | | | 1 | | |
| Vaccination failure | 1 | 1 | | | | | 1 | 1 |
| Vaccination site bruising | 6 | 11 | | | 1 | 2 | 5 | 9 |
| Vaccination site cellulitis | 1 | 1 | | | 1 | 1 | | |
| Vaccination site discolouration | | 2 | | | | | | 2 |
| Vaccination site discomfort | 3 | 9 | | | 1 | 6 | 2 | 3 |
| Vaccination site dryness | 1 | 1 | | | | | 1 | 1 |
| Vaccination site erythema | 18 | 46 | | | 3 | 18 | 15 | 28 |
| Vaccination site haemorrhage | 2 | 4 | | | | 1 | 2 | 3 |
| Vaccination site hyperaesthesia | 1 | 1 | | | | | 1 | 1 |
| Vaccination site hypoaesthesia | 1 | 2 | | | | | 1 | 2 |
| Vaccination site induration | 3 | 6 | | | 2 | 3 | 1 | 3 |
| Vaccination site infection | 1 | 3 | | | | | 1 | 3 |
| Vaccination site inflammation | | 3 | | | | 2 | | 1 |
| Vaccination site irritation | 2 | 2 | | | | | 2 | 2 |
| Vaccination site joint movement impairment | 1 | 3 | | | 1 | 2 | | 1 |
| Vaccination site joint pain | 1 | 2 | | | | | 1 | 2 |
| Vaccination site lymphadenopathy | 2 | 3 | | | | | 2 | 3 |
| Vaccination site mass | 9 | 15 | | | | 3 | 9 | 12 |
| Vaccination site movement impairment | 2 | 7 | 1 | 1 | 1 | 3 | 1 | 4 |
| Vaccination site pain | 142 | 276 | | 3 | 25 | 87 | 117 | 189 |
| Vaccination site paraesthesia | 2 | 4 | | | 1 | 1 | 1 | 3 |
| Vaccination site pruritus | 9 | 16 | | | | 3 | 9 | 13 |
| Vaccination site rash | 1 | 7 | | | | 2 | 1 | 5 |
| Vaccination site reaction | 1 | 4 | | | 1 | 2 | | 2 |
| Vaccination site swelling | 30 | 60 | | | 5 | 14 | 25 | 46 |
| Vaccination site ulcer | | 1 | | | | | | 1 |
| Vaccination site urticaria | | 1 | | | | | | 1 |
| Vaccination site warmth | 16 | 31 | | | 2 | 6 | 14 | 25 |
| Vaginal haemorrhage | 1 | 2 | | | | | 1 | 2 |
| Vascular dementia | | 1 | | | | | | 1 |

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|----------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vascular headache | 1 | 1 | | | | | 1 | 1 |
| Vascular pain | 1 | 1 | | | 1 | 1 | | |
| Vasculitic rash | 1 | 1 | | | | | 1 | 1 |
| Vasculitis | 2 | 3 | | | | | 2 | 3 |
| Vasodilatation | 1 | 1 | | | | | 1 | 1 |
| Vein rupture | | 1 | | | | | | 1 |
| Ventricular extrasystoles | 1 | 4 | | | | 1 | 1 | 3 |
| Ventricular fibrillation | | 2 | | | | | | 2 |
| Vertigo | 22 | 28 | | | 2 | 3 | 20 | 25 |
| Vertigo positional | 2 | 3 | | | | | 2 | 3 |
| Viral infection | 2 | 2 | | | | | 2 | 2 |
| Viral labyrinthitis | 1 | 2 | | | 1 | 2 | | |
| Viral rash | 1 | 1 | | | | | 1 | 1 |
| Virologic failure | 1 | 1 | | | | | 1 | 1 |
| Vision blurred | 22 | 33 | | | 2 | 5 | 20 | 28 |
| Visual field defect | 1 | 1 | | | | | 1 | 1 |
| Visual impairment | 7 | 11 | | | 1 | 2 | 6 | 9 |
| Vital capacity | 1 | 1 | | | | | 1 | 1 |
| Vlth nerve paralysis | 1 | 1 | | | | | 1 | 1 |
| Vitreous floaters | 1 | 2 | | | | 1 | 1 | 1 |
| Vocal cord disorder | | 1 | | | | | | 1 |
| Vomiting | 91 | 161 | | | 13 | 36 | 78 | 125 |
| Vomiting projectile | 1 | 2 | | | | 1 | 1 | 1 |
| Vomiting psychogenic | | 1 | | | | | | 1 |
| Vulvovaginal candidiasis | 2 | 3 | | | | 1 | 2 | 2 |
| Weight bearing difficulty | 1 | 1 | | | | | 1 | 1 |
| Weight decreased | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Weight loss diet | | 1 | | | | | | 1 |
| Wheezing | 24 | 36 | | | 3 | 6 | 21 | 30 |
| White blood cell count decreased | 1 | 2 | | | | | 1 | 2 |
| White blood cell count increased | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Wound | 2 | 2 | | | | | 2 | 2 |
| Wound complication | 1 | 1 | | | | | 1 | 1 |

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|----------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|-------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| | 3 | 4 | | | 3 | 4 | | |
| | 8,567 | 13,693 | 66 | 86 | 1505 | 3182 | 7062 | 10511 |

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Country Where Event Occurred

UNITED STATES

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|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal discomfort | 13 | 28 | | | 13 | 27 | | 1 |
| Abdominal distension | | 2 | | | | 2 | | |
| Abdominal pain | 8 | 32 | | | 7 | 27 | 1 | 5 |
| Abdominal pain lower | 1 | 4 | | | 1 | 3 | | 1 |
| Abdominal pain upper | 18 | 31 | | | 16 | 27 | 2 | 4 |
| Abdominal rigidity | | 1 | | | | | | 1 |
| Abnormal behaviour | 2 | 3 | | | 2 | 2 | | 1 |
| Abnormal dreams | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Abnormal faeces | 1 | 1 | | | 1 | 1 | | |
| Abnormal sensation in eye | | 1 | | | | 1 | | |
| Abortion spontaneous | 2 | 2 | | | | | 2 | 2 |
| Accidental exposure to product | 1 | 4 | | | 1 | 3 | | 1 |
| Accidental overdose | | 2 | | | | 2 | | |
| Acetonaemia | | 1 | | | | 1 | | |
| Acne | | 2 | | | | 2 | | |
| Acute disseminated encephalomyelitis | | 1 | | | | | | 1 |
| Acute hepatic failure | | 1 | | | | | | 1 |
| Acute kidney injury | | 3 | | | | | | 3 |
| Acute myeloid leukaemia | 1 | 1 | | | | | 1 | 1 |
| Acute myocardial infarction | | 1 | | | | | | 1 |
| Acute pulmonary oedema | 1 | 1 | | | | | 1 | 1 |
| Adrenocortical insufficiency acute | 2 | 2 | | | | | 2 | 2 |
| Ageusia | 9 | 23 | | | 8 | 21 | 1 | 2 |
| Aggression | | 1 | | | | 1 | | |
| Agitation | 1 | 4 | | | 1 | 4 | | |
| Alanine aminotransferase increased | 1 | 1 | | | 1 | 1 | | |
| Allergy to vaccine | 3 | 12 | | | 2 | 6 | 1 | 6 |
| Alopecia | | 1 | | | | 1 | | |
| Altered state of consciousness | 2 | 2 | | | | | 2 | 2 |
| Amnesia | 4 | 5 | | | 3 | 4 | 1 | 1 |

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|------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Amyloidosis | 1 | 1 | | | | | 1 | 1 |
| Anaemia | 2 | 2 | | | | | 2 | 2 |
| Anal haemorrhage | 1 | 1 | | | 1 | 1 | | |
| Anal incontinence | 1 | 1 | | | 1 | 1 | | |
| Anaphylactic reaction | 16 | 47 | | | 1 | 2 | 15 | 45 |
| Anaphylactic shock | 1 | 1 | | | | | 1 | 1 |
| Anaphylactoid reaction | | 1 | | | | | | 1 |
| Anger | 1 | 4 | | | | 3 | 1 | 1 |
| Angina pectoris | 2 | 2 | | | | | 2 | 2 |
| Angioedema | 3 | 6 | | | | | 3 | 6 |
| Angiopathy | 1 | 1 | | | 1 | 1 | | |
| Anorectal discomfort | 1 | 1 | | | 1 | 1 | | |
| Anosmia | 6 | 17 | | | 5 | 14 | 1 | 3 |
| Anterior chamber cell | 1 | 1 | | | | | 1 | 1 |
| Anxiety | 20 | 40 | | | 16 | 34 | 4 | 6 |
| Aphasia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Aphonia | 1 | 3 | | | 1 | 2 | | 1 |
| Appendicitis | | 3 | | | | | | 3 |
| Appetite disorder | 1 | 2 | | | 1 | 2 | | |
| Aptyalism | 1 | 1 | | | 1 | 1 | | |
| Areflexia | 1 | 1 | | | | | 1 | 1 |
| Arrhythmia | 2 | 5 | | | | | 2 | 5 |
| Arthralgia | 98 | 272 | | | 96 | 258 | 2 | 14 |
| Arthritis | 3 | 14 | | | 3 | 13 | | 1 |
| Arthropathy | 2 | 4 | | | 2 | 4 | | |
| Arthropod bite | | 1 | | | | 1 | | |
| Asthenia | 67 | 151 | | | 57 | 132 | 10 | 19 |
| Asthenopia | | 3 | | | | 2 | | 1 |
| Asthma | 8 | 17 | | | 6 | 13 | 2 | 4 |
| Ataxia | | 1 | | | | | | 1 |
| Atelectasis | 1 | 1 | | | | | 1 | 1 |
| Atrial fibrillation | 6 | 6 | | | | | 6 | 6 |
| Autoimmune disorder | 1 | 2 | | | | | 1 | 2 |

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|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|---|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Autoimmune haemolytic anaemia | 1 | 1 | | | | | 1 | 1 |
| Autoimmune thyroiditis | 1 | 1 | | | | | 1 | 1 |
| Autonomic nervous system imbalance | 1 | 2 | | | 1 | 1 | | 1 |
| Axillary mass | | 3 | | | | 3 | | |
| Axillary pain | 14 | 21 | | | 14 | 21 | | |
| Back disorder | 2 | 2 | | | 2 | 2 | | |
| Back injury | 1 | 1 | | | 1 | 1 | | |
| Back pain | 35 | 76 | | | 34 | 72 | 1 | 4 |
| Balance disorder | 10 | 17 | | | 9 | 14 | 1 | 3 |
| Bedridden | | 2 | | | | 1 | | 1 |
| Belligerence | 1 | 1 | | | | | 1 | 1 |
| Blepharitis | 1 | 1 | | | 1 | 1 | | |
| Blindness | 5 | 7 | | | | | 5 | 7 |
| Blindness transient | | 1 | | | | | | 1 |
| Blister | 2 | 4 | | | 1 | 3 | 1 | 1 |
| Blood albumin decreased | | 1 | | | | 1 | | |
| Blood bilirubin increased | 1 | 1 | | | | | 1 | 1 |
| Blood calcium decreased | | 1 | | | | 1 | | |
| Blood chloride decreased | | 1 | | | | 1 | | |
| Blood chloride increased | | 1 | | | | 1 | | |
| Blood cholesterol increased | 1 | 1 | | | 1 | 1 | | |
| Blood creatinine increased | 1 | 1 | | | 1 | 1 | | |
| Blood glucose abnormal | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Blood glucose decreased | 3 | 4 | | | 2 | 3 | 1 | 1 |
| Blood glucose fluctuation | | 1 | | | | 1 | | |
| Blood glucose increased | 7 | 15 | | | 4 | 10 | 3 | 5 |
| Blood iron decreased | 1 | 1 | | | | | 1 | 1 |
| Blood ketone body increased | 1 | 1 | | | | | 1 | 1 |
| Blood potassium decreased | | 3 | | | | 3 | | |
| Blood pressure abnormal | 1 | 2 | | | | 1 | 1 | 1 |
| Blood pressure decreased | 5 | 8 | | | 3 | 4 | 2 | 4 |
| Blood pressure diastolic increased | | 2 | | | | 1 | | 1 |
| Blood pressure fluctuation | | 1 | | | | 1 | | |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Blood pressure increased | 20 | 63 | | | 14 | 42 | 6 | 21 |
| Blood pressure systolic increased | 1 | 3 | | | | | 1 | 3 |
| Blood sodium decreased | | 1 | | | | 1 | | |
| Blood thyroid stimulating hormone increased | | 1 | | | | | | 1 |
| Blood triglycerides increased | | 1 | | | | | | 1 |
| Blood urine present | 1 | 2 | | | | 1 | 1 | 1 |
| Body height decreased | 2 | 4 | | | 2 | 4 | | |
| Body temperature abnormal | 2 | 3 | | | 2 | 3 | | |
| Body temperature increased | 8 | 19 | | | 8 | 19 | | |
| Bone pain | 5 | 13 | | | 4 | 9 | 1 | 4 |
| Bradyphrenia | | 1 | | | | | | 1 |
| Brain oedema | | 1 | | | | | | 1 |
| Brain stem haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Brain stem syndrome | 1 | 1 | | | | | 1 | 1 |
| Breast discharge | 1 | 1 | | | 1 | 1 | | |
| Breast discomfort | 1 | 1 | | | 1 | 1 | | |
| Breast pain | 4 | 8 | | | 4 | 8 | | |
| Breast swelling | | 1 | | | | 1 | | |
| Breast tenderness | | 1 | | | | 1 | | |
| Bronchitis | 1 | 2 | | | 1 | 2 | | |
| Bronchospasm | | 1 | | | | 1 | | |
| Burning sensation | 17 | 30 | | | 15 | 25 | 2 | 5 |
| Burn oral cavity | | 1 | | | | | | 1 |
| Butterfly rash | 1 | 1 | | | | | 1 | 1 |
| Candida infection | 1 | 1 | | | 1 | 1 | | |
| Cardiac arrest | 1 | 5 | | | | | 1 | 5 |
| Cardiac disorder | 2 | 4 | | | | 2 | 2 | 2 |
| Cardiac failure | 1 | 1 | | | | | 1 | 1 |
| Cardiac failure congestive | | 2 | | | | | | 2 |
| Cardiac flutter | 3 | 3 | | | | | 3 | 3 |
| Cardiac neoplasm unspecified | | 1 | | | | | | 1 |
| Cardiomyopathy | 1 | 1 | | | | | 1 | 1 |
| Cardio-respiratory arrest | | 1 | | | | | | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Cellulitis | 2 | 5 | | | | | 2 | 5 |
| Central nervous system lesion | 1 | 1 | | | | | 1 | 1 |
| Cerebral disorder | | 1 | | | | 1 | | |
| Cerebral haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Cerebral thrombosis | 1 | 1 | | | | | 1 | 1 |
| Cerebrovascular accident | 9 | 11 | | | | | 9 | 11 |
| Cheilitis | 1 | 1 | | | 1 | 1 | | |
| Chest discomfort | 27 | 80 | | | 19 | 53 | 8 | 27 |
| Chest injury | 1 | 1 | | | | | 1 | 1 |
| Chest pain | 23 | 51 | | | 18 | 35 | 5 | 16 |
| Chest X-ray abnormal | 1 | 1 | | | | | 1 | 1 |
| Chills | 156 | 460 | | | 146 | 432 | 10 | 28 |
| Choking | 1 | 3 | | | | | 1 | 3 |
| Choking sensation | | 1 | | | | | | 1 |
| Chondritis | 1 | 1 | | | 1 | 1 | | |
| Chromaturia | 1 | 1 | | | 1 | 1 | | |
| Chronic myeloid leukaemia recurrent | 1 | 1 | | | | | 1 | 1 |
| Chronic obstructive pulmonary disease | 1 | 1 | | | | | 1 | 1 |
| Circumstance or information capable of leading to medication error | 3 | 10 | | | 3 | 10 | | |
| Claustrophobia | | 1 | | | | 1 | | |
| Clumsiness | | 1 | | | | 1 | | |
| Cognitive disorder | 1 | 3 | | | | 1 | 1 | 2 |
| Cold sweat | 5 | 15 | | | 4 | 12 | 1 | 3 |
| Colitis | 1 | 1 | | | | | 1 | 1 |
| Colon cancer | 1 | 1 | | | | | 1 | 1 |
| Coma | 1 | 2 | | | | | 1 | 2 |
| Computerised tomogram normal | 1 | 1 | | | 1 | 1 | | |
| Condition aggravated | 22 | 28 | | | 13 | 16 | 9 | 12 |
| Confusional state | 12 | 19 | | | 7 | 13 | 5 | 6 |
| Conjunctival haemorrhage | 1 | 2 | | | | | 1 | 2 |
| Conjunctivitis | 2 | 2 | | | 2 | 2 | | |
| Constipation | 3 | 3 | | | 3 | 3 | | |

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| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Contraindicated product administered | | 1 | | | | 1 | | | |
| Contraindication to vaccination | | 1 | | | | 1 | | | |
| Contusion | 3 | 7 | | | 3 | 7 | | | |
| Coordination abnormal | | 1 | | | | 1 | | | |
| Corneal disorder | 1 | 1 | | | | | 1 | 1 | |
| Corneal graft rejection | 1 | 1 | | | | | 1 | 1 | |
| Corneal infiltrates | 1 | 1 | | | | | 1 | 1 | |
| Costochondritis | 1 | 1 | | | 1 | 1 | | | |
| Cough | 31 | 105 | | | 28 | 86 | 3 | 19 | |
| COVID-19 | 31 | 90 | 1 | 1 | 6 | 13 | 25 | 77 | |
| COVID-19 pneumonia | 2 | 3 | | | | | 2 | 3 | |
| C-reactive protein increased | 1 | 4 | | | | 2 | 1 | 2 | |
| Crohn's disease | 2 | 2 | | | | | 2 | 2 | |
| Crying | 4 | 8 | | | 3 | 7 | 1 | 1 | |
| Crystal urine | | 1 | | | | 1 | | | |
| CSF protein increased | 1 | 1 | | | | | 1 | 1 | |
| Culture urine positive | | 1 | | | | 1 | | | |
| Cyanosis | 1 | 4 | | | | 2 | 1 | 2 | |
| Cystitis | 1 | 1 | | | | | 1 | 1 | |
| Daydreaming | 1 | 1 | | | 1 | 1 | | | |
| Deafness | 7 | 9 | | | 1 | 1 | 6 | 8 | |
| Deafness neurosensory | 2 | 3 | | | | | 2 | 3 | |
| Deafness unilateral | 2 | 4 | | | | | 2 | 4 | |
| Death | 10 | 25 | | | | | 10 | 25 | |
| Decreased appetite | 21 | 44 | | | 19 | 38 | 2 | 6 | |
| Decreased interest | 1 | 1 | | | 1 | 1 | | | |
| Deep vein thrombosis | 2 | 3 | | | | | 2 | 3 | |
| Defaecation urgency | 1 | 1 | | | 1 | 1 | | | |
| Dehydration | 5 | 10 | | | 2 | 6 | 3 | 4 | |
| Delirium | 6 | 10 | | | | | 6 | 10 | |
| Delusional perception | | 2 | | | | 1 | | 1 | |
| Dementia | 2 | 2 | | | | | 2 | 2 | |
| Depressed level of consciousness | 1 | 1 | | | | | 1 | 1 | |

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|--------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Depressed mood | | 1 | | | | 1 | | | |
| Depression | 1 | 1 | | | 1 | 1 | | | |
| Dermatitis acneiform | 1 | 1 | | | 1 | 1 | | | |
| Dermatitis allergic | | 1 | | | | 1 | | | |
| Dermatitis diaper | 1 | 1 | | | | | 1 | 1 | |
| Diabetes mellitus | 2 | 5 | | | | | 2 | 5 | |
| Diabetes mellitus inadequate control | 3 | 3 | | | | | 3 | 3 | |
| Diabetic foot infection | 1 | 1 | | | 1 | 1 | | | |
| Diarrhoea | 63 | 148 | | | 58 | 139 | 5 | 9 | |
| Diarrhoea haemorrhagic | 2 | 3 | | | | | 2 | 3 | |
| Diet refusal | | 1 | | | | | | | 1 |
| Diplopia | 2 | 3 | | | 1 | 1 | 1 | 2 | |
| Discomfort | 8 | 16 | | | 8 | 15 | | | 1 |
| Disease recurrence | 13 | 22 | | | 9 | 17 | 4 | 5 | |
| Disorientation | 5 | 6 | | | 4 | 5 | 1 | 1 | |
| Dissociation | 1 | 1 | | | 1 | 1 | | | |
| Disturbance in attention | 3 | 12 | | | 2 | 10 | 1 | 2 | |
| Diverticulitis | 1 | 1 | | | | | 1 | 1 | |
| Diverticulum intestinal | 1 | 1 | | | | | 1 | 1 | |
| Dizziness | 122 | 320 | | | 110 | 272 | 12 | 48 | |
| Dizziness postural | 5 | 8 | | | 4 | 6 | 1 | 2 | |
| Drug eruption | | 1 | | | | 1 | | | |
| Drug hypersensitivity | 3 | 3 | | | 1 | 1 | 2 | 2 | |
| Drug ineffective | 22 | 93 | 1 | 1 | | | 22 | 93 | |
| Drug interaction | 2 | 6 | | | 1 | 5 | 1 | 1 | |
| Drug intolerance | 1 | 1 | | | 1 | 1 | | | |
| Dry eye | 3 | 4 | | | 3 | 4 | | | |
| Dry mouth | 6 | 15 | | | 6 | 13 | | 2 | |
| Dry skin | 2 | 3 | | | 2 | 3 | | | |
| Dry throat | 1 | 2 | | | 1 | 2 | | | |
| Dysaesthesia | 2 | 3 | | | 1 | 2 | 1 | 1 | |
| Dysarthria | 3 | 4 | | | 2 | 3 | 1 | 1 | |
| Dysentery | 1 | 1 | | | | | 1 | 1 | |

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| | | | I | C | I | C | I | C |
| Dysgeusia | 12 | 33 | | | 12 | 32 | | 1 |
| Dyskinesia | 1 | 3 | | | 1 | 1 | | 2 |
| Dyslexia | | 1 | | | | 1 | | |
| Dysmenorrhoea | 1 | 2 | | | 1 | 2 | | |
| Dyspepsia | | 5 | | | | 5 | | |
| Dysphagia | 13 | 24 | | | 10 | 15 | 3 | 9 |
| Dysphonia | 6 | 16 | | | 3 | 10 | 3 | 6 |
| Dyspnoea | 72 | 162 | | | 51 | 105 | 21 | 57 |
| Dyspnoea exertional | 2 | 6 | | | 2 | 5 | | 1 |
| Dysstasia | 5 | 9 | | | 3 | 6 | 2 | 3 |
| Dysuria | 4 | 4 | | | 3 | 3 | 1 | 1 |
| Ear discomfort | 6 | 9 | | | 6 | 9 | | |
| Ear disorder | 5 | 6 | | | 1 | 2 | 4 | 4 |
| Ear haemorrhage | 1 | 1 | | | 1 | 1 | | |
| Ear infection | 1 | 1 | | | 1 | 1 | | |
| Ear pain | 5 | 17 | | | 4 | 15 | 1 | 2 |
| Ear pruritus | 1 | 2 | | | 1 | 2 | | |
| Ear swelling | 2 | 4 | | | 2 | 4 | | |
| Eating disorder | 1 | 5 | | | 1 | 3 | | 2 |
| Eczema | | 1 | | | | 1 | | |
| Ejection fraction decreased | 1 | 1 | | | | | 1 | 1 |
| Electrocardiogram abnormal | 1 | 2 | | | 1 | 2 | | |
| Electrocardiogram QT prolonged | 1 | 1 | | | | | 1 | 1 |
| Emotional disorder | | 2 | | | | 2 | | |
| Encephalitis | 2 | 2 | | | | | 2 | 2 |
| Encephalopathy | | 1 | | | | | | 1 |
| Energy increased | 1 | 3 | | | 1 | 3 | | |
| Enlarged uvula | | 1 | | | | | | 1 |
| Eosinophil count increased | | 1 | | | | | | 1 |
| Eosinophilia | | 1 | | | | 1 | | |
| Epicondylitis | | 1 | | | | 1 | | |
| Epistaxis | 4 | 7 | | | 2 | 5 | 2 | 2 |
| Erectile dysfunction | 2 | 2 | | | | | 2 | 2 |

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| | | | I | C | I | C | I | C |
| Erythema | 32 | 84 | | | 28 | 68 | 4 | 16 |
| Erythema of eyelid | | 3 | | | | 3 | | |
| Euphoric mood | 1 | 1 | | | 1 | 1 | | |
| Exposure during pregnancy | | 2 | | | | 2 | | |
| Exposure to SARS-CoV-2 | 1 | 5 | | | 1 | 5 | | |
| Exposure via skin contact | 1 | 3 | | | 1 | 2 | | 1 |
| Extensive swelling of vaccinated limb | | 1 | | | | 1 | | |
| Extraocular muscle paresis | 1 | 1 | | | | | 1 | 1 |
| Extrasystoles | 1 | 1 | | | 1 | 1 | | |
| Eye contusion | | 2 | | | | 2 | | |
| Eye discharge | 2 | 2 | | | 2 | 2 | | |
| Eye disorder | 2 | 6 | | | 2 | 6 | | |
| Eye haemorrhage | 2 | 5 | | | | | 2 | 5 |
| Eye infection | 1 | 2 | | | 1 | 2 | | |
| Eye inflammation | | 2 | | | | 1 | | 1 |
| Eye irritation | 4 | 6 | | | 4 | 6 | | |
| Eyelid disorder | 1 | 2 | | | 1 | 2 | | |
| Eyelid function disorder | | 1 | | | | 1 | | |
| Eyelid irritation | 1 | 2 | | | 1 | 2 | | |
| Eyelid oedema | | 2 | | | | 2 | | |
| Eyelid pain | | 1 | | | | 1 | | |
| Eyelid ptosis | 1 | 1 | | | | | 1 | 1 |
| Eyelids pruritus | | 3 | | | | 2 | | 1 |
| Eye movement disorder | 1 | 1 | | | 1 | 1 | | |
| Eye oedema | 1 | 2 | | | 1 | 2 | | |
| Eye pain | 9 | 21 | | | 6 | 16 | 3 | 5 |
| Eye paraesthesia | | 1 | | | | | | 1 |
| Eye pruritus | 4 | 10 | | | 4 | 8 | | 2 |
| Eye swelling | 12 | 24 | | | 9 | 20 | 3 | 4 |
| Face oedema | | 1 | | | | | | 1 |
| Facial discomfort | | 1 | | | | 1 | | |
| Facial nerve disorder | | 1 | | | | 1 | | |
| Facial pain | 3 | 12 | | | 2 | 9 | 1 | 3 |

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| | | | I | C | I | C | I | C |
| Facial paralysis | 30 | 46 | | | 1 | 1 | 29 | 45 |
| Facial paresis | 1 | 3 | | | | 1 | 1 | 2 |
| Faeces discoloured | 1 | 1 | | | 1 | 1 | | |
| Faeces soft | 1 | 1 | | | 1 | 1 | | |
| Fall | 18 | 20 | | | 9 | 10 | 9 | 10 |
| Fatigue | 202 | 560 | | | 185 | 524 | 17 | 36 |
| Fear | 4 | 9 | | | 4 | 8 | | 1 |
| Febrile convulsion | | 1 | | | | | | 1 |
| Feeding disorder | 1 | 7 | | | 1 | 6 | | 1 |
| Feeling abnormal | 61 | 130 | | | 57 | 120 | 4 | 10 |
| Feeling cold | 13 | 37 | | | 13 | 34 | | 3 |
| Feeling drunk | 2 | 6 | | | 2 | 6 | | |
| Feeling hot | 35 | 86 | | | 31 | 76 | 4 | 10 |
| Feeling jittery | 3 | 5 | | | 2 | 3 | 1 | 2 |
| Feeling of body temperature change | 3 | 8 | | | 3 | 7 | | 1 |
| Fibrin D dimer increased | 1 | 2 | | | 1 | 2 | | |
| Fibromyalgia | 1 | 2 | | | 1 | 1 | | 1 |
| Flank pain | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Flatulence | 1 | 2 | | | | 1 | 1 | 1 |
| Fluid retention | 1 | 1 | | | 1 | 1 | | |
| Flushing | 18 | 63 | | | 14 | 45 | 4 | 18 |
| Foreign body aspiration | | 1 | | | | | | 1 |
| Formication | 1 | 1 | | | 1 | 1 | | |
| Frequent bowel movements | 1 | 3 | | | 1 | 3 | | |
| Frustration tolerance decreased | | 1 | | | | 1 | | |
| Gait disturbance | 21 | 38 | | | 13 | 25 | 8 | 13 |
| Gait inability | 4 | 8 | | | 1 | 3 | 3 | 5 |
| Gal bladder disorder | | 1 | | | | | | 1 |
| Gal bladder polyp | | 1 | | | | 1 | | |
| Gastric disorder | 1 | 1 | | | 1 | 1 | | |
| Gastroenteritis viral | | 1 | | | | | | 1 |
| Gastrointestinal disorder | 1 | 6 | | | 1 | 5 | | 1 |
| Gastrointestinal haemorrhage | 1 | 1 | | | | | 1 | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Gastrointestinal hypomotility | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal inflammation | 1 | 1 | | | 1 | 1 | | |
| Gastrointestinal motility disorder | 1 | 1 | | | 1 | 1 | | |
| Gastrointestinal pain | | 2 | | | | 2 | | |
| Gastrointestinal stoma complication | 1 | 1 | | | 1 | 1 | | |
| Gastrointestinal viral infection | | 1 | | | | 1 | | |
| Gastroesophageal reflux disease | 1 | 1 | | | 1 | 1 | | |
| Gastroesophageal sphincter insufficiency | | 1 | | | | | | 1 |
| General physical health deterioration | | 2 | | | | | | 2 |
| Gingival bleeding | 1 | 2 | | | 1 | 2 | | |
| Gingival discomfort | | 1 | | | | | | 1 |
| Gingival disorder | | 1 | | | | 1 | | |
| Gingival erythema | | 2 | | | | 2 | | |
| Gingival pain | | 2 | | | | 1 | | 1 |
| Gingival recession | | 1 | | | | 1 | | |
| Gingival swelling | | 2 | | | | 2 | | |
| Glassy eyes | 1 | 1 | | | | | 1 | 1 |
| Glomerular filtration rate decreased | | 1 | | | | 1 | | |
| Glossitis | | 2 | | | | 2 | | |
| Glossodynia | 3 | 4 | | | 2 | 3 | 1 | 1 |
| Glycosylated haemoglobin increased | 1 | 1 | | | | | 1 | 1 |
| Gout | 1 | 1 | | | | | 1 | 1 |
| Grip strength decreased | | 1 | | | | 1 | | |
| Groin pain | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Grunting | | 2 | | | | 1 | | 1 |
| Guillain-Barre syndrome | 2 | 2 | | | | | 2 | 2 |
| Haematochezia | 2 | 3 | | | | | 2 | 3 |
| Haematocrit decreased | 1 | 2 | | | | 1 | 1 | 1 |
| Haematuria | 1 | 1 | | | 1 | 1 | | |
| Haemoglobin decreased | 2 | 4 | | | | 1 | 2 | 3 |
| Haemolytic anaemia | 1 | 1 | | | | | 1 | 1 |
| Haemoptysis | 1 | 2 | | | | | 1 | 2 |
| Haemorrhage | 2 | 3 | | | | | 2 | 3 |

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| | | | I | C | I | C | I | C |
| Haemorrhagic varicella syndrome | 1 | 1 | | | | | 1 | 1 |
| Haemorrhoids | 1 | 1 | | | 1 | 1 | | |
| Hallucination | 4 | 5 | | | | | 4 | 5 |
| Hallucination, visual | 1 | 2 | | | | | 1 | 2 |
| Hangover | | 1 | | | | 1 | | |
| Headache | 245 | 728 | | | 227 | 670 | 18 | 58 |
| Head discomfort | 10 | 22 | | | 8 | 18 | 2 | 4 |
| Head injury | | 1 | | | | 1 | | |
| Heart rate abnormal | 2 | 3 | | | 2 | 3 | | |
| Heart rate decreased | 4 | 6 | | | 2 | 4 | 2 | 2 |
| Heart rate increased | 31 | 96 | | | 25 | 80 | 6 | 16 |
| Heart rate irregular | 3 | 4 | | | 3 | 4 | | |
| Hemiplegia | 1 | 2 | | | | | 1 | 2 |
| Hepatic enzyme increased | 1 | 1 | | | | | 1 | 1 |
| Hepatic pain | | 1 | | | | 1 | | |
| Herpes simplex | | 1 | | | | 1 | | |
| Herpes virus infection | 1 | 1 | | | 1 | 1 | | |
| Herpes zoster | 6 | 13 | | | 5 | 12 | 1 | 1 |
| Hip fracture | 2 | 2 | | | | | 2 | 2 |
| Hordeolum | 1 | 2 | | | | 1 | 1 | 1 |
| Hot flush | 8 | 29 | | | 6 | 24 | 2 | 5 |
| Hunger | | 1 | | | | 1 | | |
| Hyperacusis | | 1 | | | | 1 | | |
| Hyperaesthesia | 1 | 9 | | | 1 | 8 | | 1 |
| Hyperaesthesia teeth | | 1 | | | | 1 | | |
| Hyperglycaemia | 1 | 4 | | | 1 | 2 | | 2 |
| Hyperhidrosis | 31 | 78 | | | 30 | 71 | 1 | 7 |
| Hyperpyrexia | 1 | 1 | | | | | 1 | 1 |
| Hypersensitivity | 13 | 40 | | | 7 | 22 | 6 | 18 |
| Hypersomnia | 3 | 12 | | | 2 | 11 | 1 | 1 |
| Hypertension | 20 | 42 | | | 14 | 25 | 6 | 17 |
| Hypertensive emergency | | 3 | | | | | | 3 |
| Hyperventilation | 2 | 3 | | | 1 | 1 | 1 | 2 |

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| | | | I | C | I | C | I | C | |
| Hypervigilance | | 1 | | | | 1 | | | |
| Hypoacusis | 2 | 3 | | | 1 | 2 | 1 | 1 | |
| Hypoaesthesia | 43 | 122 | | | 34 | 96 | 9 | 26 | |
| Hypoaesthesia eye | 1 | 1 | | | 1 | 1 | | | |
| Hypoaesthesia oral | 17 | 41 | | | 11 | 30 | 6 | 11 | |
| Hypoaesthesia teeth | 1 | 1 | | | 1 | 1 | | | |
| Hypocalcaemia | | 1 | | | | | | | 1 |
| Hypogeusia | | 1 | | | | 1 | | | |
| Hypoglycaemia | 1 | 3 | | | 1 | 3 | | | |
| Hypokalaemia | | 1 | | | | | | | 1 |
| Hypokinesia | | 2 | | | | 2 | | | |
| Hypomagnesaemia | | 1 | | | | | | | 1 |
| Hypophagia | | 2 | | | | 1 | | | 1 |
| Hypopnoea | 2 | 3 | | | 2 | 2 | | | 1 |
| Hyporeflexia | 1 | 1 | | | | | 1 | 1 | |
| Hyposmia | | 1 | | | | 1 | | | |
| Hypotension | 6 | 13 | | | 3 | 7 | 3 | 6 | |
| Hypothermia | 1 | 1 | | | | | 1 | 1 | |
| Hypothyroidism | | 1 | | | | | | | 1 |
| Hypotonia | 1 | 1 | | | | | 1 | 1 | |
| Hypoxia | | 1 | | | | | | | 1 |
| Idiosyncratic drug reaction | | 1 | | | | 1 | | | |
| Illrd nerve paralysis | 1 | 1 | | | | | 1 | 1 | |
| Ill-defined disorder | | 1 | | | | | 1 | | |
| Illness | 13 | 36 | | | 13 | 36 | | | |
| Immune system disorder | 1 | 3 | | | 1 | 3 | | | |
| Immune thrombocytopenia | 5 | 5 | | | | | 5 | 5 | |
| Immunodeficiency | | 1 | | | | | | | 1 |
| Impaired work ability | | 3 | | | | 3 | | | |
| Inappropriate schedule of product administration | 21 | 57 | | | 21 | 57 | | | |
| Incision site haemorrhage | | 1 | | | | | | | 1 |
| Incoherent | 2 | 2 | | | 1 | 1 | 1 | 1 | |
| Incomplete course of vaccination | | 2 | | | | 2 | | | |

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| | | | I | C | I | C | I | C |
| Incontinence | | 1 | | | | | | 1 |
| Incorrect dose administered | | 1 | | | | 1 | | |
| Incorrect route of product administration | 3 | 9 | | | 3 | 8 | | 1 |
| Increased upper airway secretion | 1 | 2 | | | | | 1 | 2 |
| Increased viscosity of bronchial secretion | 1 | 1 | | | | | 1 | 1 |
| Increased viscosity of upper respiratory secretion | 1 | 1 | | | | | 1 | 1 |
| Inflammation | 4 | 7 | | | 4 | 6 | | 1 |
| Inflammatory pain | | 1 | | | | 1 | | |
| Influenza | 9 | 21 | | | 9 | 20 | | 1 |
| Influenza B virus test positive | | 1 | | | | 1 | | |
| Influenza like illness | 10 | 49 | | | 9 | 45 | 1 | 4 |
| Initial insomnia | | 1 | | | | 1 | | |
| Injected limb mobility decreased | 1 | 1 | | | 1 | 1 | | |
| Injection site erythema | | 2 | | | | 2 | | |
| Injection site extravasation | | 1 | | | | 1 | | |
| Injection site hypoaesthesia | | 1 | | | | 1 | | |
| Injection site joint pain | | 1 | | | | 1 | | |
| Injection site mass | | 1 | | | | 1 | | |
| Injection site pain | 1 | 7 | | | | 6 | 1 | 1 |
| Injection site pruritus | | 1 | | | | 1 | | |
| Injection site rash | | 1 | | | | 1 | | |
| Injection site swelling | | 1 | | | | 1 | | |
| Injection site urticaria | | 1 | | | | 1 | | |
| Insomnia | 16 | 41 | | | 16 | 39 | | 2 |
| International normalised ratio decreased | 1 | 1 | | | | | 1 | 1 |
| International normalised ratio increased | | 1 | | | | 1 | | |
| Intervertebral disc protrusion | 1 | 1 | | | | | 1 | 1 |
| Intestinal perforation | 1 | 1 | | | | | 1 | 1 |
| Intracranial pressure increased | | 1 | | | | | | 1 |
| Intranasal paraesthesia | 1 | 2 | | | 1 | 2 | | |
| Intraocular pressure increased | 1 | 1 | | | | | 1 | 1 |
| Intrusive thoughts | | 1 | | | | 1 | | |

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| | | | I | C | I | C | I | C |
| Irregular breathing | 1 | 1 | | | 1 | 1 | | |
| Irritability | | 2 | | | | 2 | | |
| Irritable bowel syndrome | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Ischaemic stroke | 1 | 1 | | | | | 1 | 1 |
| Jaw disorder | 1 | 1 | | | 1 | 1 | | |
| Joint dislocation | | 1 | | | | | | 1 |
| Joint effusion | 1 | 2 | | | 1 | 2 | | |
| Joint instability | | 2 | | | | | | 2 |
| Joint range of motion decreased | 4 | 12 | | | 4 | 11 | | 1 |
| Joint stiffness | 4 | 9 | | | 3 | 7 | 1 | 2 |
| Joint swelling | 10 | 20 | | | 10 | 19 | | 1 |
| Joint warmth | 1 | 1 | | | 1 | 1 | | |
| Keratic precipitates | 1 | 1 | | | | | 1 | 1 |
| Kidney infection | 1 | 1 | | | | | 1 | 1 |
| Labile hypertension | | 1 | | | | 1 | | |
| Laboratory test abnormal | | 1 | | | | | | 1 |
| Laboratory test normal | 1 | 1 | | | 1 | 1 | | |
| Lacrimation increased | 3 | 7 | | | 3 | 6 | | 1 |
| Lacunar infarction | 1 | 1 | | | | | 1 | 1 |
| Laryngeal oedema | 1 | 1 | | | | | 1 | 1 |
| Laryngitis | | 2 | | | | 2 | | |
| Laryngospasm | | 3 | | | | | | 3 |
| Laziness | | 1 | | | | 1 | | |
| Lethargy | 8 | 21 | | | 7 | 18 | 1 | 3 |
| Leukocytosis | | 2 | | | | 2 | | |
| Limb discomfort | 8 | 25 | | | 7 | 21 | 1 | 4 |
| Limb injury | 3 | 6 | | | 3 | 6 | | |
| Lip disorder | 1 | 1 | | | 1 | 1 | | |
| Lip dry | | 1 | | | | 1 | | |
| Lip erythema | | 2 | | | | 2 | | |
| Lipids increased | | 1 | | | | 1 | | |
| Lip injury | | 1 | | | | 1 | | |
| Lip oedema | | 2 | | | | 1 | | 1 |

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|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Lip pain | 1 | 1 | | | 1 | 1 | | |
| Lip pruritus | 2 | 4 | | | | 2 | 2 | 2 |
| Lip swelling | 10 | 31 | | | 6 | 16 | 4 | 15 |
| Livedo reticularis | 1 | 3 | | | | 1 | 1 | 2 |
| Liver function test abnormal | | 1 | | | | | | 1 |
| Liver injury | | 1 | | | | | | 1 |
| Localised oedema | | 1 | | | | 1 | | |
| Loss of consciousness | 18 | 26 | | | 1 | 1 | 17 | 25 |
| Loss of personal independence in daily activities | 3 | 9 | | | 3 | 8 | | 1 |
| Loss of proprioception | | 1 | | | | | | 1 |
| Lower respiratory tract congestion | | 1 | | | | 1 | | |
| Lumbar puncture abnormal | 1 | 1 | | | | | 1 | 1 |
| Lung disorder | 1 | 2 | | | | 1 | 1 | 1 |
| Lung infiltration | | 1 | | | | 1 | | |
| Lymphadenitis | | 1 | | | | 1 | | |
| Lymphadenopathy | 53 | 134 | | | 51 | 122 | 2 | 12 |
| Lymph gland infection | 1 | 1 | | | 1 | 1 | | |
| Lymph node pain | 13 | 34 | | | 13 | 32 | | 2 |
| Lymphocyte count abnormal | 1 | 1 | | | 1 | 1 | | |
| Lymphocyte count decreased | | 1 | | | | 1 | | |
| Lymphocytosis | 1 | 1 | | | 1 | 1 | | |
| Lymphoedema | 2 | 3 | | | 2 | 3 | | |
| Lymphoma | 1 | 1 | | | | | 1 | 1 |
| Malaise | 70 | 183 | | | 65 | 173 | 5 | 10 |
| Mania | 1 | 1 | | | 1 | 1 | | |
| Mass | 3 | 3 | | | 3 | 3 | | |
| Maternal exposure during pregnancy | | 5 | | | | 5 | | |
| May-Thurner syndrome | 1 | 1 | | | | | 1 | 1 |
| Mechanical urticaria | | 1 | | | | 1 | | |
| Memory impairment | 4 | 7 | | | 2 | 5 | 2 | 2 |
| Meningitis noninfective | 1 | 1 | | | | | 1 | 1 |
| Menorrhagia | 1 | 2 | | | 1 | 2 | | |
| Menstrual disorder | 2 | 4 | | | 2 | 4 | | |

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| | | | I | C | I | C | I | C |
| Menstruation delayed | 1 | 1 | | | | | 1 | 1 |
| Menstruation irregular | | 1 | | | | 1 | | |
| Mental disorder | 1 | 3 | | | 1 | 2 | | 1 |
| Mental impairment | 6 | 11 | | | | | 6 | 11 |
| Mental status changes | 1 | 2 | | | 1 | 1 | | 1 |
| Metrorrhagia | 1 | 3 | | | 1 | 3 | | |
| Micturition urgency | 1 | 1 | | | 1 | 1 | | |
| Middle insomnia | 1 | 2 | | | | 1 | 1 | 1 |
| Migraine | 15 | 37 | | | 14 | 36 | 1 | 1 |
| Migraine with aura | | 1 | | | | 1 | | |
| Miliaria | 2 | 2 | | | 2 | 2 | | |
| Mobility decreased | 4 | 9 | | | 3 | 7 | 1 | 2 |
| Motor dysfunction | | 2 | | | | 1 | | 1 |
| Mouth haemorrhage | 2 | 2 | | | 2 | 2 | | |
| Mouth swelling | 1 | 3 | | | | 1 | 1 | 2 |
| Mouth ulceration | 1 | 1 | | | 1 | 1 | | |
| Movement disorder | 5 | 8 | | | 3 | 6 | 2 | 2 |
| Mucosal disorder | | 1 | | | | 1 | | |
| Multiple organ dysfunction syndrome | 1 | 2 | | | | | 1 | 2 |
| Muscle discomfort | | 1 | | | | 1 | | |
| Muscle rupture | 1 | 1 | | | | | 1 | 1 |
| Muscle spasms | 13 | 39 | | | 13 | 35 | | 4 |
| Muscle spasticity | 1 | 1 | | | 1 | 1 | | |
| Muscle strain | 1 | 1 | | | 1 | 1 | | |
| Muscle tightness | 6 | 19 | | | 5 | 17 | 1 | 2 |
| Muscle twitching | 4 | 7 | | | 3 | 6 | 1 | 1 |
| Muscular weakness | 21 | 37 | | | 13 | 25 | 8 | 12 |
| Musculoskeletal chest pain | 5 | 10 | | | 4 | 9 | 1 | 1 |
| Musculoskeletal discomfort | 2 | 12 | | | 2 | 11 | | 1 |
| Musculoskeletal disorder | | 1 | | | | 1 | | |
| Musculoskeletal pain | 2 | 4 | | | 2 | 3 | | 1 |
| Musculoskeletal stiffness | 16 | 31 | | | 15 | 30 | 1 | 1 |
| Mutism | | 1 | | | | | | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Myalgia | 91 | 260 | | | 89 | 249 | 2 | 11 |
| Myelitis transverse | 1 | 1 | | | | | 1 | 1 |
| Myocardial infarction | 5 | 8 | | | | | 5 | 8 |
| Myocardial necrosis marker increased | | 1 | | | | | | 1 |
| Myocarditis | | 1 | | | | | | 1 |
| Myositis | | 1 | | | | | | 1 |
| Nasal congestion | 12 | 39 | | | 12 | 36 | | 3 |
| Nasal discomfort | 2 | 5 | | | 2 | 3 | | 2 |
| Nasal disorder | 1 | 1 | | | 1 | 1 | | |
| Nasal dryness | | 1 | | | | 1 | | |
| Nasal oedema | 1 | 2 | | | 1 | 1 | | 1 |
| Nasopharyngitis | 7 | 13 | | | 7 | 12 | | 1 |
| Nausea | 123 | 379 | | | 116 | 347 | 7 | 32 |
| Neck injury | | 1 | | | | 1 | | |
| Neck mass | 1 | 2 | | | 1 | 2 | | |
| Neck pain | 25 | 66 | | | 23 | 61 | 2 | 5 |
| Nephrolithiasis | | 1 | | | | | | 1 |
| Nephropathy | 1 | 1 | | | 1 | 1 | | |
| Nerve compression | 1 | 3 | | | 1 | 3 | | |
| Nerve injury | 1 | 1 | | | 1 | 1 | | |
| Nervousness | 14 | 20 | | | 14 | 19 | | 1 |
| Nervous system disorder | 2 | 3 | | | 2 | 2 | | 1 |
| Neuralgia | 7 | 18 | | | 7 | 18 | | |
| Neuralgic amyotrophy | 1 | 1 | | | 1 | 1 | | |
| Neurological examination normal | 1 | 1 | | | 1 | 1 | | |
| Neurological symptom | | 1 | | | | | | 1 |
| Neuropathy peripheral | 2 | 8 | | | | | 2 | 8 |
| Neutropenia | 1 | 1 | | | | | 1 | 1 |
| Neutrophil count decreased | 1 | 2 | | | 1 | 2 | | |
| Neutrophil count increased | | 1 | | | | | | 1 |
| Nightmare | 2 | 2 | | | 2 | 2 | | |
| Night sweats | 4 | 9 | | | 4 | 9 | | |
| Nipple pain | | 2 | | | | 2 | | |

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| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Nipple swelling | | 1 | | | | 1 | | | |
| No adverse event | 1 | 1 | | | 1 | 1 | | | |
| Nocturia | | 1 | | | | 1 | | | |
| Noninfective encephalitis | 2 | 3 | | | | | 2 | 3 | |
| Normocytic anaemia | 1 | 1 | | | 1 | 1 | | | |
| Nuchal rigidity | | 1 | | | | 1 | | | |
| Nystagmus | | 2 | | | | 1 | | 1 | |
| Obstructive airways disorder | | 1 | | | | | | 1 | |
| Occipital neuralgia | 1 | 1 | | | | | 1 | 1 | |
| Ocular discomfort | 2 | 8 | | | 2 | 6 | | 2 | |
| Ocular hyperaemia | 5 | 14 | | | 5 | 14 | | | |
| Odynophagia | 3 | 6 | | | 3 | 5 | | 1 | |
| Oedema | | 3 | | | | 2 | | 1 | |
| Oedema peripheral | | 1 | | | | 1 | | | |
| Off label use | 58 | 108 | | | 57 | 107 | 1 | 1 | |
| Oligodipsia | | 1 | | | | | | 1 | |
| Oral discomfort | 3 | 8 | | | 3 | 7 | | 1 | |
| Oral disorder | 1 | 2 | | | 1 | 2 | | | |
| Oral herpes | 3 | 5 | | | 3 | 5 | | | |
| Oral mucosal erythema | | 2 | | | | 2 | | | |
| Oral mucosal exfoliation | 1 | 1 | | | 1 | 1 | | | |
| Oral pain | 2 | 5 | | | 2 | 5 | | | |
| Oral pruritus | | 1 | | | | 1 | | | |
| Oral viral infection | | 1 | | | | 1 | | | |
| Organising pneumonia | | 1 | | | | | | 1 | |
| Oropharyngeal discomfort | 4 | 7 | | | 3 | 5 | 1 | 2 | |
| Oropharyngeal pain | 20 | 65 | | | 19 | 58 | 1 | 7 | |
| Oropharyngeal spasm | 1 | 2 | | | | | 1 | 2 | |
| Orthopnoea | | 1 | | | | | | 1 | |
| Orthostatic hypotension | 1 | 1 | | | | | 1 | 1 | |
| Osteoarthritis | 1 | 1 | | | 1 | 1 | | | |
| Osteochondritis | | 1 | | | | 1 | | | |
| Overdose | 2 | 4 | | | 2 | 3 | | 1 | |

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| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Overweight | | 1 | | | | 1 | | | |
| Oxygen consumption | | 1 | | | | 1 | | | |
| Oxygen saturation abnormal | 2 | 2 | | | 2 | 2 | | | |
| Oxygen saturation decreased | 9 | 13 | | | 2 | 5 | 7 | 8 | |
| Pain | 145 | 436 | | | 132 | 404 | 13 | 32 | |
| Painful respiration | 2 | 2 | | | 2 | 2 | | | |
| Pain in extremity | 119 | 314 | | | 110 | 299 | 9 | 15 | |
| Pain in jaw | 5 | 11 | | | 3 | 8 | 2 | 3 | |
| Pain of skin | 4 | 9 | | | 3 | 8 | 1 | 1 | |
| Palatal disorder | | 1 | | | | 1 | | | |
| Palatal swelling | | 1 | | | | | | | 1 |
| Pallor | 3 | 10 | | | 1 | 7 | 2 | 3 | |
| Palmar erythema | | 2 | | | | 1 | | | 1 |
| Palpable purpura | 1 | 1 | | | 1 | 1 | | | |
| Palpitations | 26 | 62 | | | 21 | 45 | 5 | 17 | |
| Pancreatitis acute | 1 | 1 | | | | | 1 | 1 | |
| Panic attack | 1 | 1 | | | 1 | 1 | | | |
| Panic reaction | 2 | 3 | | | 2 | 2 | | 1 | |
| Paraesthesia | 45 | 130 | | | 39 | 106 | 6 | 24 | |
| Paraesthesia oral | 12 | 40 | | | 6 | 28 | 6 | 12 | |
| Paranasal sinus discomfort | 1 | 3 | | | 1 | 3 | | | |
| Paranoia | | 1 | | | | 1 | | | |
| Parkinson's disease | 1 | 1 | | | | | 1 | 1 | |
| Parosmia | 3 | 8 | | | 3 | 7 | | 1 | |
| Pelvic pain | 1 | 1 | | | 1 | 1 | | | |
| Penile haemorrhage | | 1 | | | | | | | 1 |
| Periarthritis | | 1 | | | | | | | 1 |
| Pericardial effusion | | 1 | | | | | | | 1 |
| Pericarditis | | 1 | | | | | | | 1 |
| Periorbital cellulitis | 1 | 1 | | | | | 1 | 1 | |
| Periorbital discomfort | | 1 | | | | 1 | | | |
| Periorbital swelling | 4 | 6 | | | 4 | 6 | | | |
| Peripheral coldness | 1 | 12 | | | 1 | 11 | | | 1 |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Peripheral nerve injury | 1 | 1 | | | | | 1 | 1 |
| Peripheral swelling | 28 | 62 | | | 26 | 57 | 2 | 5 |
| Peroneal nerve palsy | | 2 | | | | 1 | | 1 |
| Petechiae | 2 | 5 | | | | 2 | 2 | 3 |
| Pharyngeal disorder | | 2 | | | | 2 | | |
| Pharyngeal erythema | 1 | 1 | | | 1 | 1 | | |
| Pharyngeal hypoaesthesia | 1 | 4 | | | 1 | 2 | | 2 |
| Pharyngeal inflammation | | 1 | | | | 1 | | |
| Pharyngeal mass | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Pharyngeal oedema | | 1 | | | | | | 1 |
| Pharyngeal paraesthesia | 2 | 10 | | | 2 | 5 | | 5 |
| Pharyngeal swelling | 16 | 33 | | | 11 | 15 | 5 | 18 |
| Pharyngitis streptococcal | 1 | 1 | | | 1 | 1 | | |
| Phlebitis | | 1 | | | | 1 | | |
| Photophobia | 4 | 11 | | | 4 | 10 | | 1 |
| Photopsia | | 1 | | | | 1 | | |
| Photosensitivity reaction | | 1 | | | | 1 | | |
| Physical deconditioning | | 1 | | | | 1 | | |
| Pigmentation disorder | 1 | 1 | | | | | 1 | 1 |
| Piloerection | | 1 | | | | 1 | | |
| Platelet count abnormal | 1 | 1 | | | | | 1 | 1 |
| Platelet count decreased | 2 | 3 | | | | | 2 | 3 |
| Platelet count increased | | 3 | | | | 1 | | 2 |
| Pleural effusion | | 1 | | | | | | 1 |
| Pleurisy | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Plicated tongue | | 1 | | | | 1 | | |
| Pneumonia | 4 | 11 | | | | | 4 | 11 |
| Pneumonia aspiration | 1 | 1 | | | | | 1 | 1 |
| PO2 decreased | | 1 | | | | | | 1 |
| Pollakiuria | 3 | 6 | | | 3 | 6 | | |
| Polychondritis | 1 | 1 | | | | | 1 | 1 |
| Polycythaemia | 1 | 1 | | | 1 | 1 | | |
| Polydipsia | | 1 | | | | 1 | | |

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| | | | I | C | I | C | I | C |
| Polymyalgia rheumatica | 2 | 2 | | | | | 2 | 2 |
| Polyuria | | 1 | | | | 1 | | |
| Poor peripheral circulation | | 1 | | | | | | 1 |
| Poor quality sleep | 2 | 7 | | | 2 | 7 | | |
| Post herpetic neuralgia | 1 | 1 | | | 1 | 1 | | |
| Posturing | | 1 | | | | | | 1 |
| Pressure of speech | 1 | 1 | | | 1 | 1 | | |
| Presyncope | 12 | 25 | | | 10 | 18 | 2 | 7 |
| Procedural pain | | 2 | | | | 1 | | 1 |
| Procedural site reaction | 1 | 1 | | | | | 1 | 1 |
| Product administered at inappropriate site | 1 | 3 | | | 1 | 2 | | 1 |
| Product administration error | 1 | 1 | | | | | 1 | 1 |
| Product confusion | | 1 | | | | 1 | | |
| Productive cough | 3 | 5 | | | 3 | 4 | | 1 |
| Product preparation error | | 2 | | | | 2 | | |
| Product preparation issue | 1 | 1 | | | 1 | 1 | | |
| Product use issue | 58 | 105 | | | 57 | 103 | 1 | 2 |
| Pruritus | 49 | 127 | | | 44 | 109 | 5 | 18 |
| Pruritus genital | | 1 | | | | | | 1 |
| Psoriasis | 1 | 1 | | | 1 | 1 | | |
| Psoriatic arthropathy | | 1 | | | | | | 1 |
| Psychomotor hyperactivity | | 1 | | | | | | 1 |
| Pulmonary congestion | | 1 | | | | | | 1 |
| Pulmonary oedema | 1 | 2 | | | | | 1 | 2 |
| Pulmonary pain | 3 | 3 | | | 3 | 3 | | |
| Pulse abnormal | 2 | 5 | | | 1 | 2 | 1 | 3 |
| Pupillary disorder | | 1 | | | | 1 | | |
| Pyrexia | 158 | 471 | | | 143 | 430 | 15 | 41 |
| Rash | 48 | 129 | | | 42 | 106 | 6 | 23 |
| Rash erythematous | 12 | 27 | | | 12 | 22 | | 5 |
| Rash macular | 7 | 14 | | | 4 | 11 | 3 | 3 |
| Rash maculo-papular | 1 | 4 | | | 1 | 4 | | |
| Rash morbilliform | 2 | 2 | | | 1 | 1 | 1 | 1 |

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| | | | I | C | I | C | I | C |
| Rash papular | 6 | 11 | | | 6 | 11 | | |
| Rash pruritic | 5 | 24 | | | 5 | 22 | | 2 |
| Rash vesicular | 1 | 2 | | | 1 | 2 | | |
| Raynaud's phenomenon | | 2 | | | | 2 | | |
| Reaction to excipient | 1 | 3 | | | | 1 | 1 | 2 |
| Red blood cell count decreased | | 1 | | | | 1 | | |
| Red blood cell sedimentation rate abnormal | 1 | 1 | | | 1 | 1 | | |
| Red blood cell sedimentation rate increased | 1 | 2 | | | | 1 | 1 | 1 |
| Red ear syndrome | 1 | 1 | | | 1 | 1 | | |
| Reduced facial expression | | 1 | | | | 1 | | |
| Renal atrophy | 1 | 1 | | | | | 1 | 1 |
| Renal disorder | 1 | 1 | | | 1 | 1 | | |
| Renal failure | 1 | 2 | | | | | 1 | 2 |
| Renal haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Renal impairment | 1 | 1 | | | | | 1 | 1 |
| Renal pain | 2 | 4 | | | 2 | 4 | | |
| Respiration abnormal | 1 | 1 | | | 1 | 1 | | |
| Respiratory arrest | 1 | 1 | | | | | 1 | 1 |
| Respiratory disorder | 5 | 7 | | | 3 | 4 | 2 | 3 |
| Respiratory distress | 1 | 4 | | | 1 | 1 | | 3 |
| Respiratory failure | | 2 | | | | | | 2 |
| Respiratory rate decreased | | 1 | | | | | | 1 |
| Respiratory rate increased | 1 | 4 | | | | | 1 | 4 |
| Respiratory symptom | 1 | 1 | | | 1 | 1 | | |
| Respiratory tract congestion | 1 | 3 | | | 1 | 3 | | |
| Respiratory tract infection | 1 | 1 | | | | | 1 | 1 |
| Restlessness | 3 | 9 | | | 3 | 6 | | 3 |
| Retching | 4 | 9 | | | 3 | 8 | 1 | 1 |
| Retinitis | 1 | 1 | | | | | 1 | 1 |
| Rheumatoid arthritis | 4 | 5 | | | | | 4 | 5 |
| Rhinalgia | 1 | 3 | | | 1 | 3 | | |
| Rhinitis | 1 | 2 | | | 1 | 2 | | |
| Rhinitis allergic | | 1 | | | | 1 | | |

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| | | | I | C | I | C | I | C |
| Rhinorrhoea | 12 | 33 | | | 11 | 29 | 1 | 4 |
| Rosacea | | 1 | | | | 1 | | |
| Salivary hypersecretion | 1 | 2 | | | 1 | 2 | | |
| SARS-CoV-1 test positive | | 1 | | | | | | 1 |
| SARS-CoV-2 ant body test negative | 2 | 6 | | | 2 | 6 | | |
| SARS-CoV-2 test positive | 3 | 20 | | | 3 | 3 | | 17 |
| Scab | | 1 | | | | 1 | | |
| Sciatica | 1 | 2 | | | 1 | 2 | | |
| Scratch | | 1 | | | | 1 | | |
| Screaming | | 1 | | | | 1 | | |
| Sedation | | 1 | | | | 1 | | |
| Seizure | 6 | 9 | | | | | 6 | 9 |
| Sensation of foreign body | 5 | 11 | | | 5 | 10 | | 1 |
| Sensitive skin | 1 | 4 | | | 1 | 4 | | |
| Sensitivity to weather change | 1 | 1 | | | 1 | 1 | | |
| Sensory disturbance | 3 | 3 | | | 3 | 3 | | |
| Sensory loss | 1 | 2 | | | | 1 | 1 | 1 |
| Sepsis | 2 | 3 | | | | | 2 | 3 |
| Shock symptom | 1 | 1 | | | | | 1 | 1 |
| Sialoadenitis | 1 | 1 | | | | | 1 | 1 |
| Sinus congestion | | 2 | | | | 2 | | |
| Sinus disorder | 1 | 2 | | | 1 | 2 | | |
| Sinus headache | 1 | 2 | | | 1 | 2 | | |
| Sinusitis | 2 | 4 | | | 2 | 4 | | |
| Sinus pain | 1 | 4 | | | 1 | 4 | | |
| Sinus tachycardia | 1 | 2 | | | 1 | 1 | | 1 |
| Sjogren's syndrome | 1 | 1 | | | | | 1 | 1 |
| Skin burning sensation | 4 | 6 | | | 4 | 6 | | |
| Skin discolouration | 3 | 8 | | | 3 | 8 | | |
| Skin disorder | 3 | 5 | | | 2 | 3 | 1 | 2 |
| Skin exfoliation | | 1 | | | | 1 | | |
| Skin fissures | 1 | 1 | | | | | 1 | 1 |
| Skin injury | | 2 | | | | 2 | | |

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| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Skin irritation | 1 | 2 | | | 1 | 2 | | |
| Skin laceration | 1 | 1 | | | | | 1 | 1 |
| Skin laxity | 1 | 1 | | | 1 | 1 | | |
| Skin lesion | 1 | 2 | | | 1 | 2 | | |
| Skin swelling | 1 | 2 | | | 1 | 2 | | |
| Sleep disorder | 4 | 9 | | | 4 | 8 | | 1 |
| Sleep disorder due to a general medical condition | | 1 | | | | 1 | | |
| Sleep disorder due to general medical condition, insomnia type | | 1 | | | | 1 | | |
| Sleep paralysis | | 1 | | | | 1 | | |
| Sleep talking | | 1 | | | | 1 | | |
| Sleep terror | 1 | 1 | | | 1 | 1 | | |
| Sluggishness | 1 | 2 | | | 1 | 2 | | |
| Small intestinal obstruction | 1 | 2 | | | | | 1 | 2 |
| Sneezing | 5 | 11 | | | 5 | 11 | | |
| Snoring | 1 | 2 | | | 1 | 2 | | |
| Somnolence | 17 | 43 | | | 15 | 37 | 2 | 6 |
| Speech disorder | 2 | 11 | | | 1 | 6 | 1 | 5 |
| Spinal disorder | | 1 | | | | 1 | | |
| Spinal fusion surgery | | 1 | | | | | | 1 |
| Spinal pain | 2 | 2 | | | 2 | 2 | | |
| Splenomegaly | 1 | 1 | | | | | 1 | 1 |
| Sputum discoloured | | 1 | | | | | | 1 |
| Staphylococcal infection | 1 | 1 | | | | | 1 | 1 |
| Staring | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Status asthmaticus | | 1 | | | | | | 1 |
| Stiff tongue | | 1 | | | | | | 1 |
| Stoma site haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Stomatitis | 2 | 6 | | | 2 | 5 | | 1 |
| Stress | 3 | 4 | | | 3 | 4 | | |
| Stridor | 1 | 3 | | | | | 1 | 3 |
| Subarachnoid haemorrhage | 1 | 1 | | | | | 1 | 1 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Subdural haemorrhage | 1 | 1 | | | | | 1 | 1 |
| Sudden death | | 1 | | | | | | 1 |
| Supraventricular tachycardia | 1 | 1 | | | | | 1 | 1 |
| Suspected COVID-19 | | 6 | | | | 1 | | 5 |
| Suture related complication | | 1 | | | | | | 1 |
| Swelling | 18 | 45 | | | 17 | 39 | 1 | 6 |
| Swelling face | 22 | 52 | | | 19 | 39 | 3 | 13 |
| Swelling of eyelid | 1 | 8 | | | | 7 | 1 | 1 |
| Swollen tongue | 11 | 31 | | | 7 | 18 | 4 | 13 |
| Syncope | 13 | 18 | | | | | 13 | 18 |
| Synovial cyst | 1 | 1 | | | 1 | 1 | | |
| Systemic lupus erythematosus | | 1 | | | | | | 1 |
| Systemic scleroderma | | 1 | | | | | | 1 |
| Tachycardia | 12 | 53 | | | 7 | 32 | 5 | 21 |
| Tachyphrenia | | 1 | | | | 1 | | |
| Tachypnoea | 1 | 3 | | | 1 | 2 | | 1 |
| Taste disorder | 7 | 16 | | | 6 | 14 | 1 | 2 |
| Temperature intolerance | 1 | 1 | | | 1 | 1 | | |
| Temperature regulation disorder | 1 | 1 | | | 1 | 1 | | |
| Tenderness | | 4 | | | | 4 | | |
| Tension | 1 | 1 | | | 1 | 1 | | |
| Tension headache | | 1 | | | | 1 | | |
| Tetany | | 1 | | | | | | 1 |
| Therapeutic response unexpected | 7 | 11 | | | 7 | 11 | | |
| Thinking abnormal | 1 | 1 | | | 1 | 1 | | |
| Thirst | 4 | 9 | | | 4 | 8 | | 1 |
| Throat clearing | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Throat irritation | 10 | 27 | | | 8 | 20 | 2 | 7 |
| Throat tightness | 9 | 36 | | | 5 | 12 | 4 | 24 |
| Thrombocytopenia | 2 | 2 | | | | | 2 | 2 |
| Thrombosis | 3 | 3 | | | | | 3 | 3 |
| Thyroid disorder | 1 | 3 | | | 1 | 3 | | |
| Thyroid pain | | 1 | | | | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Tinnitus | 12 | 32 | | | 8 | 22 | 4 | 10 |
| Tongue blistering | | 1 | | | | 1 | | |
| Tongue discolouration | 1 | 1 | | | 1 | 1 | | |
| Tongue discomfort | 3 | 5 | | | 3 | 5 | | |
| Tongue disorder | | 2 | | | | 1 | | 1 |
| Tongue erythema | | 3 | | | | 3 | | |
| Tongue oedema | | 1 | | | | | | 1 |
| Tongue pruritus | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Tongue ulceration | | 1 | | | | 1 | | |
| Tonic clonic movements | 1 | 1 | | | | | 1 | 1 |
| Tonsillar hypertrophy | 1 | 1 | | | 1 | 1 | | |
| Toothache | 2 | 6 | | | 1 | 5 | 1 | 1 |
| Tooth disorder | 1 | 1 | | | 1 | 1 | | |
| Torsade de pointes | 1 | 1 | | | | | 1 | 1 |
| Tracheomalacia | | 1 | | | | | | 1 |
| Transient ischaemic attack | 1 | 3 | | | | | 1 | 3 |
| Tremor | 21 | 46 | | | 18 | 38 | 3 | 8 |
| Trigeminal nerve disorder | | 1 | | | | 1 | | |
| Trigeminal neuralgia | 1 | 2 | | | 1 | 1 | | 1 |
| Trismus | | 1 | | | | 1 | | |
| Troponin increased | | 2 | | | | | | 2 |
| Tryptase increased | | 1 | | | | 1 | | |
| Tunnel vision | 1 | 1 | | | | | 1 | 1 |
| Type III immune complex mediated reaction | | 1 | | | | | | 1 |
| Ulcer | 1 | 1 | | | 1 | 1 | | |
| Underdose | 4 | 8 | | | 4 | 8 | | |
| Undifferentiated connective tissue disease | | 1 | | | | | | 1 |
| Unresponsive to stimuli | 5 | 8 | | | | | 5 | 8 |
| Upper-airway cough syndrome | 2 | 6 | | | 2 | 6 | | |
| Upper respiratory tract congestion | | 4 | | | | 3 | | 1 |
| Upper respiratory tract infection | 1 | 3 | | | 1 | 3 | | |
| Urethral disorder | 1 | 1 | | | 1 | 1 | | |
| Urinary assistance device user | 1 | 1 | | | 1 | 1 | | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|--|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Urinary incontinence | | 1 | | | | 1 | | | |
| Urinary retention | 1 | 1 | | | | | 1 | 1 | |
| Urinary tract infection | 8 | 9 | | | 5 | 5 | 3 | 4 | |
| Urinary tract infection bacterial | 1 | 1 | | | | | 1 | 1 | |
| Urine output increased | 1 | 1 | | | 1 | 1 | | | |
| Urticaria | 28 | 93 | | | 22 | 69 | 6 | 24 | |
| Use of accessory respiratory muscles | 1 | 1 | | | 1 | 1 | | | |
| Uterine inflammation | 1 | 1 | | | 1 | 1 | | | |
| Uveitis | | 1 | | | | 1 | | | |
| Vaccination failure | 2 | 2 | | | | | 2 | 2 | |
| Vaccination site bruising | 5 | 11 | | | 5 | 11 | | | |
| Vaccination site cellulitis | 1 | 2 | | | 1 | 2 | | | |
| Vaccination site discolouration | 4 | 8 | | | 4 | 8 | | | |
| Vaccination site discomfort | 4 | 5 | | | 4 | 4 | | 1 | |
| Vaccination site erythema | 29 | 88 | | | 27 | 82 | 2 | 6 | |
| Vaccination site haemorrhage | 2 | 4 | | | 2 | 4 | | | |
| Vaccination site hypoaesthesia | | 1 | | | | 1 | | | |
| Vaccination site induration | 3 | 9 | | | 3 | 9 | | | |
| Vaccination site infection | | 1 | | | | 1 | | | |
| Vaccination site inflammation | 2 | 5 | | | 2 | 5 | | | |
| Vaccination site joint movement impairment | | 2 | | | | 2 | | | |
| Vaccination site joint pain | | 1 | | | | 1 | | | |
| Vaccination site lymphadenopathy | 1 | 2 | | | 1 | 2 | | | |
| Vaccination site macule | | 1 | | | | 1 | | | |
| Vaccination site mass | 4 | 9 | | | 4 | 7 | | 2 | |
| Vaccination site movement impairment | 3 | 10 | | | 3 | 10 | | | |
| Vaccination site nodule | | 1 | | | | 1 | | | |
| Vaccination site oedema | | 1 | | | | 1 | | | |
| Vaccination site pain | 126 | 372 | | | 124 | 358 | 2 | 14 | |
| Vaccination site pallor | | 1 | | | | 1 | | | |
| Vaccination site papule | 1 | 2 | | | 1 | 2 | | | |
| Vaccination site paraesthesia | 1 | 2 | | | 1 | 1 | | 1 | |
| Vaccination site pruritus | 15 | 49 | | | 15 | 45 | | 4 | |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vaccination site rash | 8 | 15 | | | 7 | 14 | 1 | 1 |
| Vaccination site reaction | 2 | 2 | | | 2 | 2 | | |
| Vaccination site scab | | 1 | | | | 1 | | |
| Vaccination site swelling | 35 | 91 | | | 34 | 88 | 1 | 3 |
| Vaccination site urticaria | 3 | 9 | | | 3 | 9 | | |
| Vaccination site vesicles | | 1 | | | | 1 | | |
| Vaccination site warmth | 12 | 35 | | | 10 | 32 | 2 | 3 |
| Vaginal discharge | 1 | 1 | | | 1 | 1 | | |
| Vaginal haemorrhage | | 3 | | | | 1 | | 2 |
| Varicella | | 1 | | | | 1 | | |
| Varicella zoster virus infection | | 1 | | | | 1 | | |
| Vascular dementia | 1 | 1 | | | | | 1 | 1 |
| Vasculitic rash | 1 | 1 | | | 1 | 1 | | |
| Vein discolouration | 1 | 1 | | | 1 | 1 | | |
| Ventricular arrhythmia | 1 | 1 | | | | | 1 | 1 |
| Ventricular extrasystoles | 3 | 5 | | | 1 | 2 | 2 | 3 |
| Vertigo | 9 | 26 | | | 7 | 22 | 2 | 4 |
| Viral upper respiratory tract infection | 1 | 1 | | | 1 | 1 | | |
| Vision blurred | 11 | 29 | | | 10 | 23 | 1 | 6 |
| Visual field defect | 1 | 2 | | | 1 | 2 | | |
| Visual impairment | 9 | 17 | | | 6 | 12 | 3 | 5 |
| Vitamin B12 decreased | 1 | 1 | | | | | 1 | 1 |
| Vlth nerve paralysis | 1 | 1 | | | | | 1 | 1 |
| Vocal cord disorder | 3 | 3 | | | | | 3 | 3 |
| Vomiting | 47 | 110 | | | 38 | 97 | 9 | 13 |
| Vomiting projectile | 1 | 1 | | | 1 | 1 | | |
| Vulvovaginal pruritus | | 1 | | | | | | 1 |
| Vulvovaginal rash | | 1 | | | | | | 1 |
| Vulvovaginal swelling | | 1 | | | | | | 1 |
| Weight decreased | 6 | 14 | | | 6 | 13 | | 1 |
| Weight fluctuation | 1 | 1 | | | 1 | 1 | | |
| Weight increased | | 1 | | | | 1 | | |
| Wheezing | 7 | 24 | | | 5 | 14 | 2 | 10 |

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| Preferred Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| White blood cell count decreased | 2 | 3 | | | 2 | 3 | | |
| White blood cell count increased | 3 | 5 | | | 1 | 2 | 2 | 3 |
| White matter lesion | 1 | 1 | | | | | 1 | 1 |
| Winged scapula | 1 | 1 | | | 1 | 1 | | |
| Wound | 1 | 2 | | | 1 | 2 | | |
| Wrong technique in device usage process | 1 | 1 | | | 1 | 1 | | |
| Wrong technique in product usage process | 1 | 2 | | | 1 | 2 | | |
| Yellow skin | 2 | 2 | | | 1 | 1 | 1 | 1 |
| | 4,834 | 12,339 | 2 | 2 | 3891 | 10045 | 943 | 2294 |

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APPENDIX 2.6: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Sources Organized per MedDRA System Organ Class by High Level Term

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval) / 42,086 (Cumulative)

Total Number of Adverse Events (PT): 91,739 (Interval) / 158,648 (Cumulative)

MedDRA Version: v.23.1J

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Anaemia deficiencies | 1 | 1 | | | | | 1 | 1 |
| Anaemias haemolytic immune | 4 | 4 | | | | | 4 | 4 |
| Anaemias haemolytic NEC | 1 | 3 | | | | | 1 | 3 |
| Anaemias NEC | 14 | 14 | | | 6 | 6 | 8 | 8 |
| Bleeding tendencies | 5 | 5 | | | 2 | 2 | 3 | 3 |
| Coagulopathies | 5 | 6 | | | 1 | 1 | 4 | 5 |
| Eosinophilic disorders | 1 | 3 | | | | 2 | 1 | 1 |
| Haematological disorders | 1 | 3 | | | | 1 | 1 | 2 |
| Leukocytoses NEC | 18 | 27 | | | 5 | 9 | 13 | 18 |
| Leukopenias NEC | 14 | 18 | | | 4 | 5 | 10 | 13 |
| Lymphatic system disorders NEC | 1,359 | 2,431 | 3 | 3 | 582 | 1398 | 777 | 1033 |
| Marrow depression and hypoplastic anaemias | 7 | 9 | | | | | 7 | 9 |
| Neutropenias | 16 | 18 | | | | | 16 | 18 |
| Platelet disorders NEC | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Polycythaemia (excl rubra vera) | 1 | 1 | | | 1 | 1 | | |
| Red blood cell abnormal findings NEC | 1 | 1 | | | | | 1 | 1 |
| Spleen disorders | 4 | 5 | | | 1 | 1 | 3 | 4 |
| Thrombocytopenias | 44 | 57 | | | 1 | 1 | 43 | 56 |
| Thrombocytoses | | 1 | | | | | | 1 |
| | 1,498 | 2,609 | 3 | 3 | 604 | 1428 | 894 | 1181 |

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System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Cardiac conduction disorders | 21 | 23 | | | 3 | 4 | 18 | 19 |
| Cardiac disorders NEC | 46 | 72 | | | 17 | 29 | 29 | 43 |
| Cardiac signs and symptoms NEC | 381 | 697 | 4 | 4 | 140 | 340 | 241 | 357 |
| Cardiac valve disorders NEC | | 2 | | | | | | 2 |
| Cardiomyopathies | 3 | 3 | | | | | 3 | 3 |
| Coronary artery disorders NEC | 6 | 11 | | | | | 6 | 11 |
| Heart failures NEC | 88 | 116 | | | | | 88 | 116 |
| Ischaemic coronary artery disorders | 127 | 199 | | | | | 127 | 199 |
| Left ventricular failures | 5 | 5 | | | | | 5 | 5 |
| Mitral valvular disorders | 1 | 1 | | | | | 1 | 1 |
| Myocardial disorders NEC | 6 | 11 | | | | 1 | 6 | 10 |
| Noninfectious myocarditis | 20 | 25 | | | | | 20 | 25 |
| Noninfectious pericarditis | 23 | 32 | | | | | 23 | 32 |
| Pericardial disorders NEC | 4 | 7 | | | | | 4 | 7 |
| Rate and rhythm disorders NEC | 907 | 1,350 | 12 | 12 | 296 | 518 | 611 | 832 |
| Right ventricular failures | 2 | 2 | | | | | 2 | 2 |
| Supraventricular arrhythmias | 166 | 238 | | | 15 | 30 | 151 | 208 |
| Ventricular arrhythmias and cardiac arrest | 92 | 163 | | | 4 | 10 | 88 | 153 |
| | 1,898 | 2,957 | 16 | 16 | 475 | 932 | 1423 | 2025 |

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System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coagulation disorders congenital | | 1 | | | | 1 |
| Inborn errors of amino acid metabolism | 1 | 1 | | | 1 | 1 |
| Musculoskeletal disorders congenital NEC | 1 | 1 | | | 1 | 1 |
| Neurological disorders congenital NEC | 2 | 6 | | | 2 | 6 |
| Skin and subcutaneous tissue disorders congenital NEC | 1 | 1 | 1 | 1 | | |
| Tongue disorders congenital | 5 | 5 | | | 5 | 5 |
| | 10 | 15 | 1 | 1 | 9 | 14 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ear disorders NEC | 203 | 361 | | | 97 | 227 | 106 | 134 |
| Eustachian tube disorders | 2 | 2 | | | 1 | 1 | 1 | 1 |
| External ear disorders NEC | 9 | 12 | | | 6 | 8 | 3 | 4 |
| External ear infections and inflammations | 1 | 1 | | | 1 | 1 | | |
| Hearing disorders NEC | 2 | 2 | | | | | 2 | 2 |
| Hearing losses | 109 | 159 | | | 20 | 37 | 89 | 122 |
| Hyperacusia | 11 | 19 | | | 5 | 10 | 6 | 9 |
| Inner ear disorders NEC | 12 | 13 | | | | 1 | 12 | 12 |
| Inner ear signs and symptoms | 484 | 753 | 2 | 2 | 187 | 373 | 297 | 380 |
| Mastoid disorders | 1 | 1 | | | | | 1 | 1 |
| Middle ear infections and inflammations | | 1 | | | | | | 1 |
| Tympanic membrane disorders (excl infections) | 2 | 2 | | | 2 | 2 | | |
| | 836 | 1,326 | 2 | 2 | 319 | 660 | 517 | 666 |

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System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic thyroiditis | 6 | 7 | | | 6 | 7 |
| Adrenal cortical hypofunctions | 3 | 3 | | | 3 | 3 |
| Adrenal gland disorders NEC | 1 | 1 | | | 1 | 1 |
| Female gonadal function disorders | 1 | 1 | | | 1 | 1 |
| Hypothalamic and pituitary disorders NEC | 1 | 1 | | | 1 | 1 |
| Thyroid disorders NEC | 8 | 12 | 3 | 6 | 5 | 6 |
| Thyroid hyperfunction disorders | 2 | 2 | | | 2 | 2 |
| Thyroid hypofunction disorders | 3 | 6 | | | 3 | 6 |
| | 25 | 33 | 3 | 6 | 22 | 27 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Amblyopic vision impairment | | 1 |
| Cataract conditions | 2 | 2 |
| Chambers (anterior and posterior) and lens infections and inflammations | 1 | 1 |
| Choroid and vitreous haemorrhages and vascular disorders | 2 | 2 |
| Choroid and vitreous structural change, deposit and degeneration | 15 | 17 |
| Colour blindness (incl acquired) | 2 | 2 |
| Conjunctival and corneal bleeding and vascular disorders | 24 | 30 |
| Conjunctival infections, irritations and inflammations | 9 | 14 |
| Corneal disorders NEC | 2 | 2 |
| Corneal infections, oedemas and inflammations | 2 | 3 |
| Corneal structural change, deposit and degeneration | 1 | 1 |
| Eyelid movement disorders | 27 | 42 |
| Glaucomas (excl congenital) | 4 | 7 |
| Iris and ciliary body structural change, deposit and degeneration | 1 | 1 |
| Iris and uveal tract infections, irritations and inflammations | 13 | 17 |
| Lacrimation disorders | 72 | 116 |
| Lid bleeding and vascular disorders | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 74 | 126 |
| Lid, lash and lacrimal structural disorders | 1 | 2 |
| Ocular bleeding and vascular disorders NEC | 18 | 27 |
| Ocular disorders NEC | 362 | 645 |
| Ocular infections, inflammations and associated manifestations | 145 | 285 |
| Ocular nerve and muscle disorders | 17 | 25 |
| Ocular sensation disorders | 105 | 196 |
| Optic disc abnormalities NEC | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | | 2 | 2 |
| | | 4 | 6 | 11 | 11 |
| | | 2 | 2 | | |
| | | | | 24 | 30 |
| | | 3 | 8 | 6 | 6 |
| | | | | 2 | 2 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 7 | 16 | 20 | 26 |
| | | | | 4 | 7 |
| | | | | 1 | 1 |
| | | 1 | 3 | 12 | 14 |
| | | 32 | 61 | 40 | 55 |
| | | 1 | 1 | | |
| 1 | 1 | 24 | 66 | 50 | 60 |
| | | | | 1 | 2 |
| | | | 1 | 18 | 26 |
| 2 | 2 | 144 | 333 | 218 | 312 |
| 3 | 3 | 72 | 168 | 73 | 117 |
| | | 2 | 4 | 15 | 21 |
| | | 35 | 92 | 70 | 104 |
| | | | | 2 | 2 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Optic nerve bleeding and vascular disorders | 1 | 1 |
| Orbital structural change, deposit and degeneration | 1 | 1 |
| Pupil disorders | 14 | 22 |
| Refractive and accommodative disorders | 2 | 3 |
| Retinal bleeding and vascular disorders (excl retinopathy) | 6 | 6 |
| Retinal, choroid and vitreous infections and inflammations | 2 | 2 |
| Retinal structural change, deposit and degeneration | 8 | 10 |
| Retinopathies NEC | 1 | 1 |
| Scleral infections, irritations and inflammations | 2 | 8 |
| Scleral structural change, deposit and degeneration | 2 | 2 |
| Structural change, deposit and degeneration of eye NEC | 1 | 2 |
| Visual colour distortions | 2 | 2 |
| Visual disorders NEC | 221 | 384 |
| Visual impairment and blindness (excl colour blindness) | 132 | 186 |
| Visual pathway disorders | 4 | 4 |
| | 1,301 | 2,201 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 5 | 7 | 9 | 15 |
| | | 1 | 2 | 1 | 1 |
| | | | | 6 | 6 |
| | | | | 2 | 2 |
| | | | | 8 | 10 |
| | | | | 1 | 1 |
| | | | 4 | 2 | 4 |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 1 | | 1 |
| | | 1 | 1 | 1 | 1 |
| | | 86 | 194 | 135 | 190 |
| | | 38 | 64 | 94 | 122 |
| | | | | 4 | 4 |
| 6 | 6 | 460 | 1037 | 841 | 1164 |

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System Organ Class

Gastrointestinal disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Abdominal findings abnormal | 4 | 7 |
| Abdominal wall conditions NEC | 3 | 3 |
| Acute and chronic pancreatitis | 13 | 18 |
| Anal and rectal disorders NEC | 4 | 4 |
| Anal and rectal pains | 2 | 2 |
| Anal and rectal signs and symptoms | 4 | 4 |
| Benign oral cavity neoplasms | | 1 |
| Colitis (excl infective) | 20 | 22 |
| Dental disorders NEC | 2 | 2 |
| Dental pain and sensation disorders | 30 | 59 |
| Diarrhoea (excl infective) | 1,131 | 1,880 |
| Diverticula | 1 | 1 |
| Duodenal and small intestinal stenosis and obstruction | 1 | 3 |
| Dyspeptic signs and symptoms | 67 | 114 |
| Faecal abnormalities NEC | 32 | 48 |
| Flatulence, bloating and distension | 75 | 115 |
| Gastric and oesophageal haemorrhages | 5 | 5 |
| Gastric and pyloric stenosis and obstruction | 2 | 2 |
| Gastric ulcers and perforation | 1 | 1 |
| Gastritis (excl infective) | 6 | 14 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 729 | 1,139 |
| Gastrointestinal atonic and hypomotility disorders NEC | 57 | 82 |
| Gastrointestinal disorders NEC | 39 | 71 |
| Gastrointestinal dyskinetic disorders | 6 | 11 |
| Gastrointestinal inflammatory disorders NEC | 3 | 4 |
| Gastrointestinal mucosal dystrophies and secretion disorders | 3 | 4 |
| Gastrointestinal necrosis and gangrene (excl gangrenous hernia) | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 315 | 512 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 4 | 3 | 3 |
| | | | | 3 | 3 |
| | | | | 13 | 18 |
| | | 1 | 1 | 3 | 3 |
| | | 2 | 2 | | |
| | | 4 | 4 | | |
| | | | 1 | | |
| | | 2 | 2 | 18 | 20 |
| | | 2 | 2 | | |
| | | 21 | 47 | 9 | 12 |
| 11 | 11 | 445 | 1002 | 686 | 878 |
| | | | | 1 | 1 |
| | | | | 1 | 3 |
| | | 29 | 68 | 38 | 46 |
| | | 21 | 35 | 11 | 13 |
| 1 | 1 | 34 | 64 | 41 | 51 |
| | | | | 5 | 5 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 7 | 5 | 7 |
| 2 | 2 | 296 | 588 | 433 | 551 |
| | | 26 | 42 | 31 | 40 |
| | | 28 | 54 | 11 | 17 |
| | | 3 | 8 | 3 | 3 |
| | | 1 | 2 | 2 | 2 |
| | | 1 | 2 | 2 | 2 |
| | | | | 1 | 1 |
| 5 | 5 | 126 | 251 | 189 | 261 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Gastrointestinal spastic and hypermotility disorders | 24 | 46 |
| Gastrointestinal stenosis and obstruction NEC | 11 | 12 |
| Gastrointestinal vascular malformations | 1 | 1 |
| Gastrointestinal vascular occlusion and infarction | 3 | 8 |
| Gingival disorders, signs and symptoms NEC | 27 | 61 |
| Gingival haemorrhages | 2 | 10 |
| Haemorrhoids and gastrointestinal varices (excl oesophageal) | 4 | 5 |
| Intestinal haemorrhages | 24 | 31 |
| Intestinal ulcers and perforation NEC | 2 | 2 |
| Nausea and vomiting symptoms | 3,980 | 6,913 |
| Non-mechanical ileus | 2 | 2 |
| Non-site specific gastrointestinal haemorrhages | 61 | 84 |
| Oesophageal disorders NEC | 1 | 1 |
| Oesophageal stenosis and obstruction | 2 | 2 |
| Oesophagitis (excl infective) | | 1 |
| Oral dryness and saliva altered | 151 | 274 |
| Oral soft tissue disorders NEC | 33 | 69 |
| Oral soft tissue haemorrhages | 9 | 11 |
| Oral soft tissue infections | | 1 |
| Oral soft tissue signs and symptoms | 646 | 1,210 |
| Oral soft tissue swelling and oedema | 267 | 445 |
| Peritoneal and retroperitoneal disorders | 3 | 4 |
| Peritoneal and retroperitoneal fibrosis and adhesions | | 1 |
| Rectal inflammations NEC | | 1 |
| Salivary gland disorders NEC | | 2 |
| Salivary gland enlargements | | 4 |
| Salivary gland stenosis and obstruction | 1 | 1 |
| Stomatitis and ulceration | 62 | 109 |
| Tongue disorders | 26 | 59 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 7 | 19 | 17 | 27 |
| | | | | 11 | 12 |
| | | | | 1 | 1 |
| | | | | 3 | 8 |
| | | 13 | 38 | 14 | 23 |
| | | 2 | 8 | | 2 |
| | | 1 | 2 | 3 | 3 |
| | | 1 | 2 | 23 | 29 |
| | | | | 2 | 2 |
| 54 | 58 | 1606 | 3641 | 2374 | 3272 |
| | | | | 2 | 2 |
| | | | | 61 | 84 |
| | | | | 1 | 1 |
| | | | 1 | | |
| 2 | 2 | 58 | 144 | 93 | 130 |
| | | 14 | 39 | 19 | 30 |
| | | 5 | 6 | 4 | 5 |
| | | | 1 | | |
| 4 | 4 | 247 | 647 | 399 | 563 |
| | | 53 | 147 | 214 | 298 |
| | | | | 3 | 4 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | 1 |
| | | | 4 | | |
| | | | | 1 | 1 |
| 1 | 1 | 22 | 58 | 40 | 51 |
| | | 8 | 33 | 18 | 26 |

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System Organ Class

Gastrointestinal disorders

High Level Term

Tongue signs and symptoms

Interval Total #
Spontaneous AE

287

8,185

Cumulative Total #
Spontaneous AE

500

13,999

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 80 | 84 | 71 | 180 | 216 | 320 |
| | | 3152 | 7157 | 5033 | 6842 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-------|---------|-------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Administration site reactions NEC | 7 | 11 | | | 2 | 5 | 5 | 6 |
| Adverse effect absent | 31 | 42 | | | 31 | 42 | | |
| Application and instillation site reactions | 5 | 6 | | | 3 | 4 | 2 | 2 |
| Asthenic conditions | 7,317 | 12,365 | 142 | 150 | 3393 | 7132 | 3924 | 5233 |
| Body temperature altered | 86 | 103 | | | 22 | 28 | 64 | 75 |
| Complications associated with device NEC | 1 | 2 | | | 1 | 2 | | |
| Death and sudden death | 319 | 510 | | | | | 319 | 510 |
| Eye complications associated with device | 1 | 1 | | | | | 1 | 1 |
| Febrile disorders | 4,392 | 7,786 | 36 | 41 | 1821 | 4278 | 2571 | 3508 |
| Feelings and sensations NEC | 4,244 | 8,054 | 37 | 41 | 2154 | 5072 | 2090 | 2982 |
| Gait disturbances | 224 | 335 | 1 | 1 | 92 | 167 | 132 | 168 |
| General signs and symptoms NEC | 2,032 | 3,556 | 8 | 8 | 735 | 1772 | 1297 | 1784 |
| Healing abnormal NEC | 1 | 1 | | | | | 1 | 1 |
| Inflamations | 95 | 139 | | | 53 | 78 | 42 | 61 |
| Injection site reactions | 77 | 222 | | | 44 | 180 | 33 | 42 |
| Interactions | 7 | 22 | | | 3 | 14 | 4 | 8 |
| Mass conditions NEC | 67 | 82 | | | 58 | 71 | 9 | 11 |
| Mucosal findings abnormal | 13 | 19 | | | 3 | 7 | 10 | 12 |
| Necrosis NEC | 2 | 2 | | | | | 2 | 2 |
| Oedema NEC | 258 | 309 | | | 107 | 140 | 151 | 169 |
| Pain and discomfort NEC | 3,038 | 5,759 | 18 | 18 | 1552 | 3624 | 1486 | 2135 |
| Therapeutic and nontherapeutic responses | 1,068 | 2,253 | 4 | 5 | 39 | 76 | 1029 | 2177 |
| Trophic disorders | | 1 | | | | | | 1 |
| Ulcers NEC | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Vaccination site reactions | 4,732 | 9,319 | 75 | 80 | 2939 | 6770 | 1793 | 2549 |
| Withdrawal and rebound effects | 1 | 1 | | | | | 1 | 1 |
| | 28,020 | 50,903 | 321 | 344 | 13053 | 29464 | 14967 | 21439 |

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System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholecystitis and cholelithiasis | 1 | 3 | | 1 | 1 | 2 |
| Cholestasis and jaundice | 11 | 16 | 1 | 5 | 10 | 11 |
| Gal bladder disorders NEC | 1 | 4 | 1 | 3 | | 1 |
| Hepatic and hepatobiliary disorders NEC | 1 | 1 | 1 | 1 | | |
| Hepatic enzymes and function abnormalities | 4 | 4 | 1 | 1 | 3 | 3 |
| Hepatic failure and associated disorders | 2 | 3 | | | 2 | 3 |
| Hepatic fibrosis and cirrhosis | 1 | 2 | | | 1 | 2 |
| Hepatic vascular disorders | | 1 | | | | 1 |
| Hepatobiliary signs and symptoms | 9 | 11 | 5 | 6 | 4 | 5 |
| Hepatocellular damage and hepatitis NEC | 15 | 20 | | | 15 | 20 |
| Obstructive bile duct disorders (excl neoplasms) | | 1 | | | | 1 |
| | 45 | 66 | 9 | 17 | 36 | 49 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute and chronic sarcoidosis | 2 | 2 | | | | | 2 | 2 |
| Allergic conditions NEC | 410 | 644 | 5 | 5 | 120 | 245 | 290 | 399 |
| Allergies to foods, food additives, drugs and other chemicals | 93 | 190 | | | 33 | 93 | 60 | 97 |
| Amyloidoses | 1 | 1 | | | | | 1 | 1 |
| Anaphylactic and anaphylactoid responses | 448 | 722 | 1 | 1 | 1 | 4 | 447 | 718 |
| Atopic disorders | 5 | 9 | | | 2 | 6 | 3 | 3 |
| Autoimmune disorders NEC | 7 | 11 | | | | | 7 | 11 |
| Immune and associated conditions NEC | 19 | 28 | | | 8 | 14 | 11 | 14 |
| Immunodeficiency disorders NEC | 4 | 6 | | | | | 4 | 6 |
| Transplant rejections | 1 | 1 | | | | | 1 | 1 |
| | 990 | 1,614 | 6 | 6 | 164 | 362 | 826 | 1252 |

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System Organ Class

Infections and infestations

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Abdominal and gastrointestinal infections | 130 | 142 |
| Aspergillus infections | 1 | 1 |
| Bacterial infections NEC | 105 | 148 |
| Bone and joint infections | 1 | 1 |
| Bordetella infections | 2 | 3 |
| Breast infections | 7 | 12 |
| Candida infections | 12 | 20 |
| Cardiac infections | 2 | 2 |
| Central nervous system and spinal infections | 28 | 30 |
| Clostridia infections | 1 | 2 |
| Coccidioides infections | 1 | 1 |
| Coronavirus infections | 1,300 | 2,285 |
| Coxiella infections | 10 | 11 |
| Cytomegaloviral infections | 1 | 1 |
| Dental and oral soft tissue infections | 20 | 29 |
| Ear infections | 26 | 40 |
| Ectoparasitic infestations | 1 | 2 |
| Epstein-Barr viral infections | 4 | 4 |
| Escherichia infections | 4 | 6 |
| Eye and eyelid infections | 34 | 52 |
| Female reproductive tract infections | 1 | 3 |
| Fungal infections NEC | 4 | 8 |
| Helicobacter infections | 1 | 1 |
| Hepatobiliary and spleen infections | | 2 |
| Herpes viral infections | 283 | 417 |
| Infections NEC | 67 | 110 |
| Influenza viral infections | 198 | 290 |
| Klebsiella infections | 1 | 1 |
| Listeria infections | 1 | 1 |
| Lower respiratory tract and lung infections | 146 | 207 |
| Male reproductive tract infections | 3 | 4 |
| Moraxella infections | 1 | 1 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 2 | 2 | 3 | 5 | 127 | 137 |
| | | | | 1 | 1 |
| | | 4 | 9 | 101 | 139 |
| | | | | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 7 | 12 |
| | | 3 | 9 | 9 | 11 |
| | | | | 2 | 2 |
| | | | | 28 | 30 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| 4 | 5 | 163 | 222 | 1137 | 2063 |
| | | | | 10 | 11 |
| | | | | 1 | 1 |
| | | 9 | 16 | 11 | 13 |
| | | 8 | 16 | 18 | 24 |
| | | | 1 | 1 | 1 |
| | | | | 4 | 4 |
| | | | | 4 | 6 |
| | | 14 | 26 | 20 | 26 |
| | | | 2 | 1 | 1 |
| | | 3 | 7 | 1 | 1 |
| | | | | 1 | 1 |
| | | | | | 2 |
| | | 90 | 198 | 193 | 219 |
| 1 | 1 | 14 | 29 | 53 | 81 |
| | | 51 | 110 | 147 | 180 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 3 | 7 | 143 | 200 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 1 |

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System Organ Class

Infections and infestations

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Muscle and soft tissue infections | 4 | 4 |
| Neisseria infections | 2 | 2 |
| Prion-associated disorders | 1 | 1 |
| Rhinoviral infections | | 1 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 34 | 56 |
| Skin structures and soft tissue infections | 24 | 33 |
| Staphylococcal infections | 6 | 11 |
| Streptococcal infections | 15 | 20 |
| Trypanosomal infections | | 1 |
| Tuberculous infections | 1 | 3 |
| Upper respiratory tract infections | 225 | 400 |
| Urinary tract infections | 87 | 110 |
| Vascular infections | 9 | 10 |
| Viral infections NEC | 53 | 89 |
| | 2,857 | 4,578 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|-----------|-------------|-------------|-------------|-------------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 4 | 4 |
| | | | | 2 | 2 |
| | | | | 1 | 1 |
| | | | 1 | | |
| | | 1 | 1 | 33 | 55 |
| 1 | 1 | 10 | 15 | 14 | 18 |
| | | 1 | 3 | 5 | 8 |
| | | 3 | 4 | 12 | 16 |
| | | | | | 1 |
| | | | | 1 | 3 |
| 1 | 1 | 119 | 261 | 106 | 139 |
| | | 27 | 39 | 60 | 71 |
| | | | | 9 | 10 |
| | | 9 | 21 | 44 | 68 |
| 9 | 10 | 535 | 1003 | 2322 | 3575 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|------|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal and gastrointestinal injuries NEC | 3 | 7 | | | 1 | 4 | 2 | 3 |
| Accidental exposures to product | 14 | 30 | | | 14 | 29 | | 1 |
| Atmospheric pressure injuries | 1 | 1 | | | 1 | 1 | | |
| Bone and joint injuries NEC | 6 | 9 | | | 2 | 5 | 4 | 4 |
| Cardiac and vascular procedural complications | 1 | 1 | | | | | 1 | 1 |
| Cerebral injuries NEC | 3 | 3 | | | | | 3 | 3 |
| Chest and respiratory tract injuries NEC | 7 | 8 | | | 2 | 2 | 5 | 6 |
| Conditions caused by cold | 6 | 10 | | | 3 | 6 | 3 | 4 |
| Exposures associated with pregnancy, delivery and lactation | 136 | 387 | | | 121 | 368 | 15 | 19 |
| Exposures to agents or circumstances NEC | 17 | 60 | | 1 | 13 | 45 | 4 | 15 |
| Eye injuries NEC | 16 | 26 | 1 | 1 | 7 | 12 | 9 | 14 |
| Fractures and dislocations NEC | 5 | 8 | | | | | 5 | 8 |
| Gastrointestinal and hepatobiliary procedural complications | 2 | 6 | | | | 2 | 2 | 4 |
| Heat injuries (excl thermal burns) | 1 | 4 | | | | 2 | 1 | 2 |
| Intentional product misuses | | 1 | | | | 1 | | |
| Intentional product use issues | | 1 | | | | 1 | | |
| Limb fractures and dislocations | 10 | 15 | | | | | 10 | 15 |
| Medication errors, product use errors and issues NEC | 533 | 1,079 | | | 522 | 1061 | 11 | 18 |
| Muscle, tendon and ligament injuries | 13 | 25 | 1 | 1 | 4 | 12 | 9 | 13 |
| Musculoskeletal procedural complications | 1 | 1 | | | | | 1 | 1 |
| Nerve injuries NEC | 7 | 9 | | | 2 | 4 | 5 | 5 |
| Neurological and psychiatric procedural complications | 1 | 2 | | | | | 1 | 2 |
| Non-site specific injuries NEC | 163 | 236 | | | 58 | 92 | 105 | 144 |
| Non-site specific procedural complications | 13 | 22 | | | | 3 | 13 | 19 |
| Occupational exposures | 7 | 20 | | | 6 | 18 | 1 | 2 |
| Off label uses | 508 | 880 | | | 498 | 865 | 10 | 15 |
| Overdoses NEC | 68 | 143 | | | 66 | 140 | 2 | 3 |
| Pathways and sources of exposure | 13 | 29 | | | 13 | 28 | | 1 |
| Pelvic fractures and dislocations | | 1 | | | | | | 1 |

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System Organ Class

Injury, poisoning and procedural complications

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Peripheral nerve injuries | 7 | 8 |
| Poisoning and toxicity | 1 | 2 |
| Product administration errors and issues | 718 | 1,629 |
| Product confusion errors and issues | | 6 |
| Product preparation errors and issues | 152 | 361 |
| Product prescribing errors and issues | 2 | 7 |
| Product storage errors and issues in the product use system | 4 | 4 |
| Product transcribing errors and communication issues | 2 | 2 |
| Radiation injuries | 1 | 3 |
| Site specific injuries NEC | 38 | 70 |
| Skin injuries NEC | 88 | 143 |
| Skull fractures, facial bone fractures and dislocations | 5 | 5 |
| Spinal cord injuries NEC | 2 | 2 |
| Stoma complications | 3 | 7 |
| Thermal burns | 9 | 11 |
| Thoracic cage fractures and dislocations | 1 | 2 |
| Underdoses NEC | 75 | 229 |
| Vaccination related complications | 49 | 63 |
| | 2,712 | 5,578 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 7 | 8 |
| | | | | 1 | 2 |
| 1 | 1 | 699 | 1596 | 19 | 33 |
| | | | 6 | | |
| | | 150 | 357 | 2 | 4 |
| | | 2 | 7 | | |
| | | 4 | 4 | | |
| | | 2 | 2 | | |
| | | | 2 | 1 | 1 |
| | | 14 | 34 | 24 | 36 |
| | | 46 | 84 | 42 | 59 |
| | | | | 5 | 5 |
| | | | | 2 | 2 |
| | | 1 | 2 | 2 | 5 |
| | | 2 | 3 | 7 | 8 |
| | | | | 1 | 2 |
| | | 74 | 228 | 1 | 1 |
| 2 | 2 | 10 | 19 | 39 | 44 |
| 5 | 6 | 2337 | 5045 | 375 | 533 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Adrenal cortex tests | | 1 |
| Adrenal medulla tests | | 1 |
| Auditory function diagnostic procedures | 2 | 2 |
| Autoimmunity analyses | 4 | 4 |
| Bacteria identification and serology (excl mycobacteria) | 2 | 3 |
| Blood counts NEC | 3 | 4 |
| Blood gas and acid base analyses | 212 | 276 |
| Bone marrow and immune tissue imaging procedures | 1 | 1 |
| Carbohydrate tolerance analyses (incl diabetes) | 47 | 89 |
| Cardiac auscultatory investigations | 2 | 2 |
| Cardiac function diagnostic procedures | 2 | 3 |
| Cerebrospinal fluid tests (excl microbiology) | 1 | 1 |
| Chemistry analyses NEC | 4 | 8 |
| Cholesterol analyses | 4 | 4 |
| Coagulation and bleeding analyses | 31 | 46 |
| Digestive enzymes | 5 | 5 |
| ECG investigations | 17 | 23 |
| Endocrine analyses and imaging NEC | 3 | 3 |
| Gastrointestinal function diagnostic procedures | | 1 |
| Haematological analyses NEC | 9 | 13 |
| Haem metabolism analyses | 1 | 1 |
| Heart rate and pulse investigations | 385 | 783 |
| Imaging procedures NEC | 1 | 1 |
| Immune response protein analyses NEC | 2 | 2 |
| Immunoglobulin analyses | 1 | 4 |
| Immunology analyses NEC | 21 | 27 |
| Investigations NEC | 8 | 11 |
| Lipoprotein and lipid tests NEC | | 1 |
| Liver function analyses | 45 | 61 |
| Metabolism tests NEC | 4 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | | 1 |
| | | | 1 | | |
| | | 2 | 2 | | |
| | | 3 | 3 | 1 | 1 |
| | | 2 | 3 | | |
| | | 2 | 3 | 1 | 1 |
| | | 38 | 58 | 174 | 218 |
| | | | | 1 | 1 |
| | | 21 | 46 | 26 | 43 |
| | | | | 2 | 2 |
| | | | 1 | 2 | 2 |
| | | | | 1 | 1 |
| | | 1 | 2 | 3 | 6 |
| | | 4 | 4 | | |
| | | 11 | 16 | 20 | 30 |
| | | 1 | 1 | 4 | 4 |
| | | 3 | 6 | 14 | 17 |
| | | 1 | 1 | 2 | 2 |
| | | | 1 | | |
| | | 7 | 10 | 2 | 3 |
| | | | | 1 | 1 |
| | | 178 | 454 | 207 | 329 |
| | | 1 | 1 | | |
| | | 1 | 1 | 1 | 1 |
| | | 1 | 4 | | |
| | | 21 | 27 | | |
| | | 5 | 5 | 3 | 6 |
| | | | 1 | | |
| | | 23 | 29 | 22 | 32 |
| | | | 1 | 4 | 5 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Microbiology and serology tests NEC | | 2 |
| Mineral and electrolyte analyses | 18 | 35 |
| Musculoskeletal and soft tissue histopathology procedures | 1 | 1 |
| Musculoskeletal and soft tissue tests NEC | 1 | 1 |
| Mycobacteria identification and serology | 1 | 1 |
| Neurologic diagnostic procedures | 2 | 6 |
| Ophthalmic function diagnostic procedures | 4 | 7 |
| Physical examination procedures and organ system status | 385 | 648 |
| Pituitary analyses anterior | 1 | 5 |
| Platelet analyses | 20 | 29 |
| Protein analyses NEC | 73 | 89 |
| Red blood cell analyses | 19 | 40 |
| Renal function analyses | 11 | 17 |
| Reproductive hormone analyses | 1 | 2 |
| Respiratory and pulmonary function diagnostic procedures | 5 | 6 |
| Respiratory tract and thoracic histopathology procedures | 2 | 2 |
| Respiratory tract and thoracic imaging procedures | 3 | 3 |
| Skeletal and cardiac muscle analyses | 16 | 27 |
| Therapeutic drug monitoring analyses | | 1 |
| Thyroid analyses | 2 | 4 |
| Tissue enzyme analyses NEC | 7 | 9 |
| Triglyceride analyses | | 1 |
| Urinalysis NEC | 15 | 30 |
| Urinary tract function analyses NEC | 4 | 7 |
| Vascular auscultatory investigations | 2 | 2 |
| Vascular tests NEC (incl blood pressure) | 412 | 667 |
| Virus identification and serology | 231 | 573 |
| Vitamin analyses | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | 1 | | 1 |
| | | 12 | 26 | 6 | 9 |
| | | | | 1 | 1 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | | | 2 | 6 |
| | | 1 | 2 | 3 | 5 |
| | 1 | 228 | 405 | 157 | 243 |
| | | 1 | 4 | | 1 |
| | | 7 | 12 | 13 | 17 |
| | | 29 | 40 | 44 | 49 |
| | | 7 | 25 | 12 | 15 |
| | | 4 | 9 | 7 | 8 |
| | | 1 | 2 | | |
| | | 1 | 2 | 4 | 4 |
| | | | | 2 | 2 |
| | | 1 | 1 | 2 | 2 |
| | | 2 | 5 | 14 | 22 |
| | | | | | 1 |
| | | | 1 | 2 | 3 |
| | | 4 | 5 | 3 | 4 |
| | | | | | 1 |
| | | 7 | 20 | 8 | 10 |
| | | 1 | 3 | 3 | 4 |
| | | | | 2 | 2 |
| 5 | 5 | 166 | 309 | 246 | 358 |
| | | 140 | 209 | 91 | 364 |
| | | 1 | 1 | 1 | 1 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|------|---------|------|--|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Water and electrolyte analyses NEC | | 1 | | | | 1 | | | |
| White blood cell analyses | 54 | 73 | | | 28 | 37 | 26 | 36 | |
| | 2,109 | 3,678 | 5 | 6 | 968 | 1802 | 1141 | 1876 | |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Appetite disorders | 419 | 672 | 3 | 3 | 183 | 330 | 236 | 342 |
| Calcium metabolism disorders | 4 | 9 | | | 1 | 1 | 3 | 8 |
| Diabetes mellitus (incl subtypes) | 22 | 31 | | | | | 22 | 31 |
| Diabetic complications NEC | 8 | 12 | | | | | 8 | 12 |
| Disorders of purine metabolism | 16 | 24 | | | 4 | 10 | 12 | 14 |
| Electrolyte imbalance NEC | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Fluid intake decreased | 1 | 6 | | | | 2 | 1 | 4 |
| Fluid intake increased | 7 | 10 | | | 3 | 6 | 4 | 4 |
| Food malabsorption and intolerance syndromes (excl sugar intolerance) | 3 | 3 | | | 1 | 1 | 2 | 2 |
| General nutritional disorders NEC | 48 | 70 | | | 21 | 39 | 27 | 31 |
| Hyperglycaemic conditions NEC | 21 | 35 | | | 6 | 10 | 15 | 25 |
| Hyperlipidaemias NEC | 1 | 1 | | | | | 1 | 1 |
| Hypervitaminoses NEC | 1 | 1 | | | | | 1 | 1 |
| Hypoglycaemic conditions NEC | 34 | 49 | | | 6 | 14 | 28 | 35 |
| Iron deficiencies | 1 | 1 | | | 1 | 1 | | |
| Lipid metabolism and deposit disorders NEC | 1 | 1 | | | 1 | 1 | | |
| Magnesium metabolism disorders | | 1 | | | | | | 1 |
| Metabolic acidoses (excl diabetic acidoses) | 6 | 8 | | | | 1 | 6 | 7 |
| Mixed acid-base disorders | 1 | 3 | | | | 1 | 1 | 2 |
| Phosphorus metabolism disorders | 1 | 1 | | | 1 | 1 | | |
| Potassium imbalance | 22 | 25 | | | | | 22 | 25 |
| Sodium imbalance | 14 | 17 | | | 4 | 4 | 10 | 13 |
| Total fluid volume decreased | 52 | 98 | | | 17 | 47 | 35 | 51 |
| Total fluid volume increased | 10 | 12 | | | 5 | 7 | 5 | 5 |
| | 695 | 1,093 | 3 | 3 | 255 | 477 | 440 | 616 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Arthropathies NEC | 64 | 108 | | | 25 | 56 | 39 | 52 |
| Bone disorders NEC | 6 | 10 | | | 4 | 8 | 2 | 2 |
| Bone related signs and symptoms | 220 | 386 | | | 113 | 242 | 107 | 144 |
| Bursal disorders | 13 | 14 | 1 | 1 | 6 | 7 | 7 | 7 |
| Cartilage disorders | 8 | 12 | | | 3 | 4 | 5 | 8 |
| Connective tissue disorders NEC | 10 | 16 | | | | | 10 | 16 |
| Crystal arthropathic disorders | 1 | 1 | | | | | 1 | 1 |
| Epiphyseal disorders | 1 | 1 | | | | | 1 | 1 |
| Extremity deformities | 2 | 2 | | | 2 | 2 | | |
| Intervertebral disc disorders NEC | 1 | 2 | | | | 1 | 1 | 1 |
| Joint related disorders NEC | 15 | 29 | | | 6 | 13 | 9 | 16 |
| Joint related signs and symptoms | 2,253 | 3,812 | 31 | 32 | 1052 | 2147 | 1201 | 1665 |
| Ligament disorders | | 2 | | | | 1 | | 1 |
| Lupus erythematosus (incl subtypes) | 4 | 6 | | | | | 4 | 6 |
| Metabolic bone disorders | 1 | 1 | | | | | 1 | 1 |
| Muscle infections and inflammations | 6 | 9 | 1 | 1 | 3 | 4 | 3 | 5 |
| Muscle pains | 2,870 | 4,885 | 43 | 47 | 1236 | 2662 | 1634 | 2223 |
| Muscle related signs and symptoms NEC | 313 | 555 | 1 | 1 | 122 | 309 | 191 | 246 |
| Muscle tone abnormalities | 30 | 48 | | | 12 | 20 | 18 | 28 |
| Muscle weakness conditions | 245 | 398 | | | 96 | 190 | 149 | 208 |
| Musculoskeletal and connective tissue conditions NEC | 384 | 637 | 3 | 3 | 172 | 343 | 212 | 294 |
| Musculoskeletal and connective tissue deformities of skull, face and buccal cavity | 1 | 3 | | | 1 | 3 | | |
| Musculoskeletal and connective tissue infections and inflammations NEC | 3 | 3 | | | | | 3 | 3 |
| Musculoskeletal and connective tissue pain and discomfort | 3,190 | 6,037 | 23 | 26 | 1535 | 3767 | 1655 | 2270 |
| Myopathies | 4 | 7 | | | | | 4 | 7 |
| Osteoarthropathies | 6 | 8 | | | 3 | 5 | 3 | 3 |
| Psoriatic arthropathies | 1 | 3 | | | | | 1 | 3 |
| Rheumatoid arthropathies | 20 | 26 | | | | | 20 | 26 |
| Soft tissue disorders NEC | 34 | 74 | 1 | 1 | 13 | 42 | 21 | 32 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|--------------------------|-----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Spine and neck deformities | 1 | 1 | | | 1 | 1 | | |
| Spondyloarthropathies | 13 | 17 | | | | | 13 | 17 |
| Synovial disorders | 12 | 15 | | | 3 | 5 | 9 | 10 |
| Tendon disorders | 15 | 23 | | | 10 | 16 | 5 | 7 |
| | 9,747 | 17,151 | 104 | 112 | 4418 | 9848 | 5329 | 7303 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aural neoplasms malignant and unspecified | | 1 | | 1 | | |
| B-cell lymphomas NEC | 1 | 1 | | | 1 | 1 |
| Bone neoplasms unspecified malignancy | | 1 | | 1 | | |
| Breast and nipple neoplasms benign | 1 | 1 | 1 | 1 | | |
| Breast and nipple neoplasms malignant | 2 | 2 | | | 2 | 2 |
| Cardiovascular neoplasms malignant and unspecified | | 1 | | | | 1 |
| Colorectal neoplasms malignant | 1 | 1 | | | 1 | 1 |
| Endocrine neoplasms malignant and unspecified NEC | 1 | 1 | | | 1 | 1 |
| Islet cell neoplasms and APUDoma NEC | 1 | 1 | | | 1 | 1 |
| Leukaemias acute lymphocytic | 1 | 1 | | | 1 | 1 |
| Leukaemias acute myeloid | 2 | 2 | | | 2 | 2 |
| Leukaemias acute NEC | 2 | 2 | | | 2 | 2 |
| Leukaemias chronic myeloid | 1 | 1 | | | 1 | 1 |
| Leukaemias NEC | 1 | 2 | | | 1 | 2 |
| Lymphomas unspecified NEC | 6 | 6 | | | 6 | 6 |
| Mediastinal neoplasms malignancy unspecified NEC | 1 | 1 | | | 1 | 1 |
| Metastases to specified sites | 7 | 8 | | | 7 | 8 |
| Neoplasms malignant site unspecified NEC | 3 | 3 | | | 3 | 3 |
| Neoplasms unspecified malignancy and site unspecified NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Nervous system neoplasms unspecified malignancy NEC | 1 | 1 | | | 1 | 1 |
| Oncologic complications and emergencies | 1 | 1 | | | 1 | 1 |
| Plasma cell myelomas | 1 | 1 | | | 1 | 1 |
| Respiratory tract and pleural neoplasms malignant cell type unspecified NEC | 1 | 2 | | | 1 | 2 |
| Skin neoplasms benign | 2 | 2 | | | 2 | 2 |
| Skin neoplasms malignant and unspecified (excl melanoma) | 1 | 3 | 1 | 2 | | 1 |
| Soft tissue neoplasms benign NEC | 1 | 1 | | | 1 | 1 |
| Soft tissue sarcomas histology unspecified | 1 | 1 | | | 1 | 1 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Thyroid neoplasms malignant | 1 | 1 | | | | |
| | 43 | 52 | 3 | 6 | 40 | 46 |

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System Organ Class

Nervous system disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Abnormal reflexes | 12 | 14 |
| Abnormal sleep-related events | 5 | 6 |
| Absence seizures | 6 | 9 |
| Acute polyneuropathies | 20 | 24 |
| Alzheimer's disease (incl subtypes) | 1 | 3 |
| Auditory nerve disorders | | 1 |
| Autonomic nervous system disorders | 8 | 12 |
| Central nervous system aneurysms and dissections | 2 | 2 |
| Central nervous system haemorrhages and cerebrovascular accidents | 206 | 296 |
| Central nervous system inflammatory disorders NEC | 1 | 1 |
| Central nervous system vascular disorders NEC | 5 | 5 |
| Cerebrovascular venous and sinus thrombosis | 2 | 3 |
| Cervical spinal cord and nerve root disorders | 5 | 5 |
| Choreiform movements | 2 | 2 |
| Chronic polyneuropathies | 2 | 3 |
| Coma states | 11 | 14 |
| Coordination and balance disturbances | 189 | 285 |
| Cortical dysfunction NEC | 44 | 58 |
| Cranial nerve disorders NEC | 5 | 8 |
| Dementia (excl Alzheimer's type) | 17 | 20 |
| Demyelinating disorders NEC | 2 | 5 |
| Disturbances in consciousness NEC | 1,512 | 2,262 |
| Disturbances in sleep phase rhythm | 1 | 2 |
| Dyskinesias and movement disorders NEC | 118 | 193 |
| Dystonias | 6 | 9 |
| Encephalitis NEC | 4 | 6 |
| Encephalopathies NEC | 8 | 10 |
| Eye movement disorders | 14 | 15 |
| Facial cranial nerve disorders | 367 | 525 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 3 | 9 | 11 |
| | | 3 | 4 | 2 | 2 |
| | | | | 6 | 9 |
| | | 1 | 1 | 19 | 23 |
| | | | | 1 | 3 |
| | | | | | 1 |
| | | 1 | 1 | 7 | 11 |
| | | | | 2 | 2 |
| | | | | 206 | 296 |
| | | | | 1 | 1 |
| | | | | 5 | 5 |
| | | | | 2 | 3 |
| | | 2 | 2 | 3 | 3 |
| | | 1 | 1 | 1 | 1 |
| | | | | 2 | 3 |
| | | | | 11 | 14 |
| | 1 | 57 | 109 | 132 | 176 |
| | | 15 | 21 | 29 | 37 |
| | | 2 | 3 | 3 | 5 |
| | | | | 17 | 20 |
| | | | | 2 | 5 |
| 7 | 7 | 236 | 538 | 1276 | 1724 |
| | | 1 | 2 | | |
| | | 46 | 99 | 72 | 94 |
| | | | | 6 | 9 |
| | | | | 4 | 6 |
| | | | | 8 | 10 |
| | | | | 14 | 15 |
| 1 | 1 | 7 | 19 | 360 | 506 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Generalised tonic-clonic seizures | 26 | 33 |
| Headaches NEC | 5,716 | 10,206 |
| Hypoglossal nerve disorders | 1 | 1 |
| Increased intracranial pressure disorders | 5 | 9 |
| Lumbar spinal cord and nerve root disorders | 12 | 18 |
| Memory loss (excl dementia) | 64 | 94 |
| Meningitis NEC | 1 | 1 |
| Mental impairment (excl dementia and memory loss) | 157 | 239 |
| Migraine headaches | 341 | 612 |
| Mononeuropathies | 16 | 29 |
| Motor neurone diseases | 1 | 1 |
| Multiple sclerosis acute and progressive | 8 | 17 |
| Muscle tone abnormal | 19 | 31 |
| Myelitis (incl infective) | 9 | 11 |
| Narcolepsy and hypersomnia | 68 | 117 |
| Nervous system disorders NEC | 36 | 44 |
| Neurological signs and symptoms NEC | 2,622 | 4,430 |
| Neurologic visual problems NEC | 25 | 34 |
| Neuromuscular disorders NEC | 29 | 40 |
| Neuromuscular junction dysfunction | 4 | 4 |
| Olfactory nerve disorders | 135 | 273 |
| Optic nerve disorders NEC | 8 | 10 |
| Paraesthesias and dysaesthesias | 1,648 | 2,909 |
| Paralysis and paresis (excl cranial nerve) | 149 | 195 |
| Parkinson's disease and parkinsonism | 8 | 13 |
| Partial complex seizures | 2 | 2 |
| Peripheral neuropathies NEC | 51 | 80 |
| Seizures and seizure disorders NEC | 280 | 340 |
| Sensory abnormalities NEC | 562 | 1,069 |
| Sleep disturbances NEC | 44 | 84 |
| Speech and language abnormalities | 133 | 190 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 26 | 33 |
| 77 | 84 | 2559 | 5876 | 3157 | 4330 |
| | | | | 1 | 1 |
| | | | | 5 | 9 |
| | | 7 | 10 | 5 | 8 |
| | | 21 | 40 | 43 | 54 |
| | | | | 1 | 1 |
| | | 50 | 88 | 107 | 151 |
| | | 101 | 273 | 240 | 339 |
| | | 6 | 13 | 10 | 16 |
| | | | | 1 | 1 |
| | | | 1 | 8 | 16 |
| | | 6 | 10 | 13 | 21 |
| | | | | 9 | 11 |
| | | 31 | 66 | 37 | 51 |
| | | 11 | 14 | 25 | 30 |
| 46 | 47 | 1123 | 2368 | 1499 | 2062 |
| | | 5 | 8 | 20 | 26 |
| | | 11 | 17 | 18 | 23 |
| | | | | 4 | 4 |
| | | 80 | 192 | 55 | 81 |
| | | | | 8 | 10 |
| 9 | 9 | 715 | 1661 | 933 | 1248 |
| | | 1 | 5 | 148 | 190 |
| | | 2 | 5 | 6 | 8 |
| | | | | 2 | 2 |
| 1 | 1 | 4 | 10 | 47 | 70 |
| | | 4 | 4 | 276 | 336 |
| | | 264 | 676 | 298 | 393 |
| | | 19 | 50 | 25 | 34 |
| 1 | 1 | 42 | 72 | 91 | 118 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-------|---------|-------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Spinal cord and nerve root disorders NEC | 3 | 7 | | | | | 3 | 7 |
| Structural brain disorders NEC | 3 | 6 | | | | | 3 | 6 |
| Transient cerebrovascular events | 41 | 52 | | | | | 41 | 52 |
| Tremor (excl congenital) | 445 | 741 | 3 | 3 | 149 | 321 | 296 | 420 |
| Trigeminal disorders | 27 | 33 | | | 6 | 10 | 21 | 23 |
| Vagus nerve disorders | | 1 | | | | 1 | | |
| | 15,274 | 25,774 | 145 | 154 | 5592 | 12594 | 9682 | 13180 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abortions not specified as induced or spontaneous | 3 | 3 | | | 3 | 3 |
| Abortions spontaneous | 17 | 24 | | | 17 | 24 |
| Foetal growth complications | 2 | 2 | | | 2 | 2 |
| Gestational age and weight conditions | 2 | 2 | | | 2 | 2 |
| Labour onset and length abnormalities | | 1 | | | | 1 |
| Maternal complications of pregnancy NEC | 2 | 3 | | | 2 | 3 |
| Normal pregnancy, labour and delivery | | 1 | | 1 | | |
| Stillbirth and foetal death | 1 | 1 | | | 1 | 1 |
| | 27 | 37 | | 1 | 27 | 36 |

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System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Counterfeit, falsified and substandard products | | 1 | | 1 | | |
| Device malfunction events NEC | 3 | 4 | | 1 | 3 | 3 |
| Device physical property and chemical issues | 4 | 16 | 3 | 14 | 1 | 2 |
| Product distribution and storage issues | 165 | 280 | 164 | 279 | 1 | 1 |
| Product label issues | 1 | 1 | 1 | 1 | | |
| Product packaging issues | 3 | 23 | 3 | 23 | | |
| Product physical issues | 10 | 81 | 10 | 81 | | |
| Product quality issues NEC | 6 | 18 | 5 | 16 | 1 | 2 |
| Product supply and availability issues | 3 | 4 | 3 | 4 | | |
| | 195 | 428 | 189 | 420 | 6 | 8 |

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System Organ Class

Psychiatric disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Abnormal behaviour NEC | 13 | 17 |
| Affect alterations NEC | 2 | 3 |
| Anxiety disorders NEC | 1 | 1 |
| Anxiety symptoms | 311 | 542 |
| Behaviour and socialisation disturbances | 21 | 30 |
| Bipolar disorders | 1 | 1 |
| Cognitive and attention disorders and disturbances NEC | 22 | 31 |
| Communications disorders | 10 | 13 |
| Confusion and disorientation | 303 | 418 |
| Decreased physical activity levels | 1 | 1 |
| Deliria | 36 | 57 |
| Delusional disorders | 1 | 1 |
| Delusional symptoms | 2 | 3 |
| Dementia NEC | 1 | 1 |
| Depressive disorders | 21 | 34 |
| Dissociative states | 7 | 14 |
| Disturbances in initiating and maintaining sleep | 370 | 624 |
| Eating disorders NEC | 16 | 28 |
| Emotional and mood disturbances NEC | 78 | 118 |
| Fear symptoms and phobic disorders (incl social phobia) | 13 | 36 |
| Fluctuating mood symptoms | 6 | 6 |
| Hallucinations (excl sleep-related) | 73 | 107 |
| Impulse control disorders | | 1 |
| Increased physical activity levels | 50 | 91 |
| Learning disorders | 1 | 1 |
| Mental disorders due to a general medical condition NEC | 1 | 1 |
| Mental disorders NEC | 10 | 20 |
| Mood alterations with depressive symptoms | 40 | 63 |
| Mood alterations with manic symptoms | 1 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 4 | 5 | 9 | 12 |
| | | 2 | 3 | | |
| | | 1 | 1 | | |
| | | 164 | 339 | 147 | 203 |
| | | 1 | 6 | 20 | 24 |
| | | | | 1 | 1 |
| | | 5 | 10 | 17 | 21 |
| | | 6 | 7 | 4 | 6 |
| | | 84 | 138 | 219 | 280 |
| | | | | 1 | 1 |
| | | | | 36 | 57 |
| | | | | 1 | 1 |
| | | 1 | 1 | 1 | 2 |
| | | | | 1 | 1 |
| | | 7 | 14 | 14 | 20 |
| | | 4 | 9 | 3 | 5 |
| 1 | 1 | 181 | 381 | 189 | 243 |
| | | 10 | 19 | 6 | 9 |
| | | 44 | 75 | 34 | 43 |
| | | 8 | 26 | 5 | 10 |
| | | 3 | 3 | 3 | 3 |
| | | 1 | 1 | 72 | 106 |
| | | | 1 | | |
| | | 21 | 50 | 29 | 41 |
| | | | | 1 | 1 |
| | | 1 | 1 | | |
| | | 9 | 16 | 1 | 4 |
| | | 13 | 28 | 27 | 35 |
| | | 1 | 1 | | 1 |

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System Organ Class

Psychiatric disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Mood disorders NEC | 23 | 30 |
| Narcolepsy and associated conditions | 1 | 3 |
| Obsessive-compulsive disorders and symptoms | 1 | 2 |
| Orgasmic disorders and disturbances | | 1 |
| Panic attacks and disorders | 35 | 54 |
| Parasomnias | 46 | 86 |
| Perception disturbances NEC | 11 | 17 |
| Psychiatric elimination disorders | | 3 |
| Psychiatric symptoms NEC | 2 | 5 |
| Psychotic disorder NEC | 7 | 8 |
| Sexual desire disorders | 3 | 3 |
| Sleep disorders NEC | 87 | 165 |
| Somatic symptom disorders | 2 | 6 |
| Speech and language usage disturbances | 7 | 8 |
| Speech articulation and rhythm disturbances | 8 | 10 |
| Stereotypies and automatisms | 4 | 6 |
| Stress disorders | | 2 |
| Substance related and addictive disorders | | 1 |
| Suicidal and self-injurious behaviour | 8 | 9 |
| Thinking disturbances | 27 | 42 |
| Tic disorders | 1 | 3 |
| | 1,685 | 2,729 |

| Non Interventional Study | | Spontaneous | | | | | |
|--------------------------|---|-------------|-----|---------|------|-----|------|
| Serious | | Nonserious | | Serious | | | |
| I | C | I | C | I | C | | |
| | | 10 | 12 | 13 | 18 | | |
| | | 1 | 1 | | 2 | | |
| | | | | 1 | 2 | | |
| | | | | | 1 | | |
| | | 13 | 25 | 22 | 29 | | |
| | | 27 | 58 | 19 | 28 | | |
| | | 5 | 9 | 6 | 8 | | |
| | | | 1 | | 2 | | |
| | | | 2 | 2 | 3 | | |
| | | 2 | 2 | 1 | 1 | | |
| | | 46 | 104 | 41 | 61 | | |
| | | | 2 | 2 | 4 | | |
| | | 3 | 4 | 4 | 4 | | |
| | | 3 | 4 | 5 | 6 | | |
| | | 2 | 3 | 2 | 3 | | |
| | | | 2 | | | | |
| | | | | | 1 | | |
| | | | | 8 | 9 | | |
| | | 13 | 24 | 14 | 18 | | |
| | | | 2 | 1 | 1 | | |
| | | 1 | 1 | 698 | 1392 | 987 | 1337 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 91 | 142 | 29 | 60 | 62 | 82 |
| Bladder disorders NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Bladder infections and inflammations | 4 | 4 | | | 4 | 4 |
| Genital and urinary tract disorders NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Genitourinary tract infections and inflammations NEC | 1 | 1 | | | 1 | 1 |
| Glomerulonephritis and nephrotic syndrome | 4 | 5 | | | 4 | 5 |
| Myoneurogenic bladder disorders | 3 | 4 | 1 | 2 | 2 | 2 |
| Nephritis NEC | 1 | 1 | | | 1 | 1 |
| Nephropathies and tubular disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Renal disorders NEC | 7 | 10 | 2 | 4 | 5 | 6 |
| Renal failure and impairment | 52 | 80 | | | 52 | 80 |
| Renal failure complications | 1 | 1 | | | 1 | 1 |
| Renal lithiasis | 2 | 3 | | | 2 | 3 |
| Renal obstructive disorders | 1 | 1 | | | 1 | 1 |
| Renal structural abnormalities and trauma | 1 | 1 | | | 1 | 1 |
| Urethral disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Urinary abnormalities | 32 | 45 | 19 | 28 | 13 | 17 |
| Urinary tract signs and symptoms NEC | 44 | 77 | 17 | 44 | 27 | 33 |
| | 255 | 387 | 72 | 142 | 183 | 245 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Benign and malignant breast neoplasms | 2 | 2 | | | | | 2 | 2 |
| Breast disorders NEC | 7 | 9 | | | 3 | 4 | 4 | 5 |
| Breast infections and inflammations | 2 | 2 | | | 2 | 2 | | |
| Breast signs and symptoms | 76 | 125 | 1 | 1 | 36 | 72 | 40 | 53 |
| Cervix disorders NEC | | 1 | | | | 1 | | |
| Erection and ejaculation conditions and disorders | 10 | 12 | | | | | 10 | 12 |
| Lactation disorders | | 5 | | | | 4 | | 1 |
| Menopausal effects NEC | 1 | 3 | | | 1 | 3 | | |
| Menopausal effects on the genitourinary tract | 3 | 3 | | | | | 3 | 3 |
| Menstruation and uterine bleeding NEC | 41 | 74 | | | 27 | 58 | 14 | 16 |
| Menstruation with decreased bleeding | 14 | 15 | | | 3 | 4 | 11 | 11 |
| Menstruation with increased bleeding | 20 | 30 | | | 8 | 14 | 12 | 16 |
| Ovarian and fallopian tube disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Pelvis and broad ligament disorders NEC | 5 | 6 | | | 1 | 2 | 4 | 4 |
| Penile and scrotal infections and inflammations | 1 | 1 | | | 1 | 1 | | |
| Penile disorders NEC (excl erection and ejaculation) | | 2 | | | | | | 2 |
| Prostate and seminal vesicles infections and inflammations | 1 | 1 | | | | | 1 | 1 |
| Prostatic signs, symptoms and disorders NEC | 1 | 2 | | | 1 | 2 | | |
| Reproductive tract disorders NEC (excl neoplasms) | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Reproductive tract signs and symptoms NEC | 13 | 20 | | | 3 | 9 | 10 | 11 |
| Scrotal disorders NEC | 4 | 9 | | | 3 | 4 | 1 | 5 |
| Sexual function and fertility disorders NEC | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Testicular and epididymal disorders NEC | 4 | 5 | | | 2 | 3 | 2 | 2 |
| Uterine disorders NEC | 4 | 5 | | | | | 4 | 5 |
| Uterine infections and inflammations (excl cervix) | 1 | 1 | | | 1 | 1 | | |
| Vulvovaginal disorders NEC | 19 | 32 | | | 7 | 11 | 12 | 21 |
| Vulvovaginal signs and symptoms | 8 | 14 | | | 6 | 9 | 2 | 5 |
| | 244 | 386 | 1 | 1 | 108 | 207 | 136 | 179 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Breathing abnormalities | 1,985 | 2,757 | 6 | 7 | 535 | 875 | 1450 | 1882 |
| Bronchial conditions NEC | 5 | 6 | | | 1 | 2 | 4 | 4 |
| Bronchospasm and obstruction | 324 | 458 | 1 | 1 | 63 | 121 | 261 | 337 |
| Conditions associated with abnormal gas exchange | 47 | 57 | | | 2 | 2 | 45 | 55 |
| Coughing and associated symptoms | 739 | 1,249 | 3 | 3 | 355 | 698 | 384 | 551 |
| Diaphragmatic disorders | 3 | 3 | | | | | 3 | 3 |
| Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) | 11 | 12 | | | | | 11 | 12 |
| Laryngeal spasm, oedema and obstruction | 99 | 134 | | | 1 | 2 | 98 | 132 |
| Lower respiratory tract inflammatory and immunologic conditions | 32 | 43 | | | | 1 | 32 | 42 |
| Lower respiratory tract signs and symptoms | 60 | 88 | | | 22 | 33 | 38 | 55 |
| Nasal congestion and inflammations | 116 | 276 | | | 76 | 220 | 40 | 56 |
| Nasal disorders NEC | 102 | 177 | 1 | 1 | 41 | 96 | 61 | 81 |
| Paranasal sinus disorders (excl infections and neoplasms) | 31 | 66 | | | 23 | 53 | 8 | 13 |
| Parenchymal lung disorders NEC | 16 | 23 | | | 2 | 3 | 14 | 20 |
| Pharyngeal disorders (excl infections and neoplasms) | 232 | 429 | 1 | 1 | 68 | 166 | 164 | 263 |
| Pleural infections and inflammations | 7 | 10 | | | 1 | 1 | 6 | 9 |
| Pneumothorax and pleural effusions NEC | 9 | 15 | | | | | 9 | 15 |
| Pulmonary hypertensions | 2 | 2 | | | | | 2 | 2 |
| Pulmonary oedemas | 42 | 58 | 1 | 1 | | | 42 | 58 |
| Pulmonary thrombotic and embolic conditions | 61 | 75 | 1 | 1 | | | 61 | 75 |
| Respiratory failures (excl neonatal) | 52 | 72 | | | | 1 | 52 | 71 |
| Respiratory signs and symptoms NEC | 37 | 51 | 1 | 1 | 16 | 25 | 21 | 26 |
| Respiratory tract disorders NEC | 63 | 95 | | | 14 | 32 | 49 | 63 |
| Tracheal disorders (excl infections and neoplasms) | 4 | 5 | | | 2 | 2 | 2 | 3 |
| Upper respiratory tract signs and symptoms | 1,470 | 2,651 | 5 | 5 | 743 | 1579 | 727 | 1072 |
| | 5,549 | 8,812 | 20 | 21 | 1965 | 3912 | 3584 | 4900 |

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System Organ Class

Skin and subcutaneous tissue disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|---|--|--|
| Acnes | 9 | 15 |
| Alopecias | 9 | 15 |
| Angioedemas | 155 | 214 |
| Apocrine and eccrine gland disorders | 755 | 1,321 |
| Bullous conditions | 82 | 118 |
| Dermal and epidermal conditions NEC | 443 | 657 |
| Dermatitis and eczema | 98 | 166 |
| Dermatitis ascribed to specific agent | 5 | 13 |
| Erythemas | 643 | 1,051 |
| Exfoliative conditions | 19 | 32 |
| Hypopigmentation disorders | 1 | 1 |
| Lipodystrophies | 1 | 1 |
| Nail and nail bed conditions (excl infections and infestations) | 2 | 4 |
| Panniculitides | 6 | 7 |
| Papulosquamous conditions | 3 | 4 |
| Photosensitivity and photodermatitis conditions | 17 | 27 |
| Pigmentation changes NEC | 1 | 1 |
| Pilar disorders NEC | 7 | 16 |
| Pruritus NEC | 808 | 1,444 |
| Psoriatic conditions | 11 | 14 |
| Purpura and related conditions | 49 | 71 |
| Rashes, eruptions and exanthems NEC | 1,254 | 2,289 |
| Rosaceas | 3 | 5 |
| Scaly conditions | 2 | 2 |
| Skin and subcutaneous conditions NEC | 10 | 14 |
| Skin and subcutaneous tissue ulcerations | 9 | 13 |
| Skin haemorrhages | 5 | 6 |
| Skin hyperplasias and hypertrophies | 1 | 1 |
| Skin injuries and mechanical dermatoses | | 1 |
| Skin preneoplastic conditions NEC | | 1 |
| Skin vascular conditions NEC | 2 | 2 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 7 | 13 | 2 | 2 |
| | | 5 | 10 | 4 | 5 |
| | | | 2 | 155 | 212 |
| 6 | 6 | 319 | 707 | 436 | 614 |
| 1 | 1 | 14 | 41 | 68 | 77 |
| | | 248 | 391 | 195 | 266 |
| | | 35 | 82 | 63 | 84 |
| | | 2 | 5 | 3 | 8 |
| 2 | 2 | 301 | 599 | 342 | 452 |
| | | 8 | 12 | 11 | 20 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| | | | | 2 | 4 |
| | | | 1 | 6 | 6 |
| | | | 1 | 3 | 3 |
| | | 9 | 18 | 8 | 9 |
| | | | | 1 | 1 |
| | | 1 | 6 | 6 | 10 |
| 4 | 4 | 351 | 827 | 457 | 617 |
| 1 | 1 | 6 | 8 | 5 | 6 |
| | | 16 | 31 | 33 | 40 |
| 7 | 7 | 500 | 1241 | 754 | 1048 |
| | | 2 | 3 | 1 | 2 |
| | | 2 | 2 | | |
| | | 2 | 5 | 8 | 9 |
| | | 1 | 2 | 8 | 11 |
| | | 2 | 2 | 3 | 4 |
| | | 1 | 1 | | |
| | | | 1 | | |
| | | | 1 | | |
| | | 2 | 2 | | |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Skin vasculitides | 10 | 11 | | | 4 | 4 | 6 | 7 |
| Skin vasomotor conditions | 20 | 26 | | | 4 | 7 | 16 | 19 |
| Urticarias | 449 | 882 | 3 | 3 | 149 | 468 | 300 | 414 |
| | 4,889 | 8,445 | 24 | 24 | 1992 | 4494 | 2897 | 3951 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disability issues | 110 | 175 | 42 | 87 | 68 | 88 |
| Social issues NEC | 1 | 4 | 1 | 4 | | |
| | 111 | 179 | 43 | 91 | 68 | 88 |

System Organ Class

SOC Not Yet Coded

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| | 6 | 15 | 6 | 15 |
| | 6 | 15 | 6 | 15 |

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System Organ Class

Surgical and medical procedures

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dental and gingival therapeutic procedures | 1 | 1 | 1 | 1 | | |
| Dietary and nutritional therapies | 1 | 2 | | | 1 | 2 |
| Gastrointestinal therapeutic procedures NEC | 1 | 1 | | | 1 | 1 |
| Immunisations | | 1 | | 1 | | |
| Limb therapeutic procedures | 3 | 4 | 2 | 3 | 1 | 1 |
| Nervous system therapeutic procedures NEC | 1 | 1 | | | 1 | 1 |
| Respiratory tract therapeutic procedures NEC | | 1 | | | | 1 |
| Spine and spinal cord therapeutic procedures | | 1 | | | | 1 |
| Therapeutic procedures NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 9 | 14 | 4 | 6 | 5 | 8 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Accelerated and malignant hypertension | 116 | 136 | | | | | 116 | 136 |
| Aneurysms and dissections non-site specific | 2 | 2 | | | | | 2 | 2 |
| Aortic aneurysms and dissections | 4 | 8 | | | | | 4 | 8 |
| Aortic necrosis and vascular insufficiency | 1 | 1 | | | | | 1 | 1 |
| Arterial infections and inflammations | 4 | 5 | | | | 1 | 4 | 4 |
| Blood pressure disorders NEC | 18 | 25 | | | 10 | 14 | 8 | 11 |
| Circulatory collapse and shock | 81 | 120 | 1 | 1 | 1 | 1 | 80 | 119 |
| Haemorrhages NEC | 56 | 71 | 1 | 1 | 5 | 11 | 51 | 60 |
| Lymphoedemas | 15 | 33 | | | 5 | 18 | 10 | 15 |
| Non-site specific embolism and thrombosis | 34 | 48 | 1 | 1 | | | 34 | 48 |
| Non-site specific necrosis and vascular insufficiency NEC | 7 | 11 | | | 1 | 1 | 6 | 10 |
| Non-site specific vascular disorders NEC | 21 | 34 | | | 11 | 19 | 10 | 15 |
| Peripheral embolism and thrombosis | 44 | 57 | | | 2 | 3 | 42 | 54 |
| Peripheral vascular disorders NEC | 405 | 812 | 1 | 1 | 154 | 431 | 251 | 381 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 102 | 182 | 1 | 1 | 47 | 103 | 55 | 79 |
| Phlebitis NEC | 3 | 5 | | | 1 | 2 | 2 | 3 |
| Site specific vascular disorders NEC | 118 | 189 | | | 31 | 70 | 87 | 119 |
| Varicose veins NEC | 1 | 3 | | | 1 | 3 | | |
| Vascular hypertensive disorders NEC | 448 | 646 | 4 | 4 | 133 | 229 | 315 | 417 |
| Vascular hypotensive disorders | 269 | 374 | 1 | 1 | 60 | 99 | 209 | 275 |
| Vasculitides NEC | 14 | 16 | | | 3 | 4 | 11 | 12 |
| Vena caval embolism and thrombosis | | 2 | | | | | | 2 |
| | 1,763 | 2,780 | 10 | 10 | 465 | 1009 | 1298 | 1771 |

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APPENDIX 2.6.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by High Level Term per Country

Cumulative Reporting Period: Through 28-FEB-2021

Interval Reporting Period: 01-FEB-2021 Through 28-FEB-2021

Total Number of Cases: 23,558 (Interval) / 42,086 (Cumulative)

Total Number of Adverse Events (PT): 91,739 (Interval) / 158,648 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

AFGHANISTAN

System Organ Class

General disorders and administration site conditions

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|--------------------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Feelings and sensations NEC | | 2 | | 2 |
| General signs and symptoms NEC | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Musculoskeletal and connective tissue disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|---------------------------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle related signs and symptoms NEC | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Facial cranial nerve disorders | | 1 | | | | 1 |
| Paraesthesias and dysaesthesias | | 1 | | 1 | | |
| | | 2 | | 1 | | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Erythemas | | 1 | | 1 |
| Pruritus NEC | | 1 | | 1 |
| Rashes, eruptions and exanthems NEC | | 1 | | 1 |
| | | 3 | | 3 |

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 * AE=Adverse Event
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Country Where Event Occurred

ANDORRA

System Organ Class

Injury, poisoning and procedural complications

High Level Term

Product administration errors and issues

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous

Nonserious

I

C

1

1

1

1

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

ANGOLA

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Nausea and vomiting symptoms | 1 | 1 | 1 | 1 |
| Tongue signs and symptoms | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Febrile disorders | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Upper respiratory tract infections | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product administration errors and issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

AUSTRIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemias haemolytic immune | 1 | 1 | | | 1 | 1 |
| Coagulopathies | 1 | 1 | | | 1 | 1 |
| Leukocytoses NEC | 1 | 1 | | | 1 | 1 |
| Lymphatic system disorders NEC | 17 | 17 | 11 | 11 | 6 | 6 |
| Thrombocytopenias | 1 | 1 | | | 1 | 1 |
| | 21 | 21 | 11 | 11 | 10 | 10 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 1 | 1 | | | 1 | 1 |
| Cardiac disorders NEC | 7 | 8 | 6 | 7 | 1 | 1 |
| Cardiac signs and symptoms NEC | 5 | 5 | | | 5 | 5 |
| Heart failures NEC | 3 | 4 | | | 3 | 4 |
| Ischaemic coronary artery disorders | 4 | 5 | | | 4 | 5 |
| Left ventricular failures | 1 | 1 | | | 1 | 1 |
| Noninfectious myocarditis | 2 | 2 | | | 2 | 2 |
| Noninfectious pericarditis | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 10 | 10 | | | 10 | 10 |
| Supraventricular arrhythmias | 5 | 5 | | | 5 | 5 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 40 | 43 | 6 | 7 | 34 | 36 |

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 * AE=Adverse Event
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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 2 | 2 | 2 | 2 | | |
| Inner ear signs and symptoms | 11 | 11 | 6 | 6 | 5 | 5 |
| | 13 | 13 | 8 | 8 | 5 | 5 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid movement disorders | 1 | 1 | | | 1 | 1 |
| Lacrimation disorders | 1 | 1 | 1 | 1 | | |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 1 | | | 1 | 1 |
| Ocular disorders NEC | 2 | 2 | 2 | 2 | | |
| Ocular infections, inflammations and associated manifestations | 5 | 5 | 4 | 4 | 1 | 1 |
| Ocular nerve and muscle disorders | 1 | 1 | | | 1 | 1 |
| Ocular sensation disorders | 1 | 1 | 1 | 1 | | |
| Pupil disorders | 1 | 1 | | | 1 | 1 |
| Visual disorders NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Visual impairment and blindness (excl colour blindness) | 2 | 2 | | | 2 | 2 |
| | 19 | 19 | 10 | 10 | 9 | 9 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 11 | 13 | 7 | 9 | 4 | 4 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 3 | 3 | 1 | 1 | 2 | 2 |
| Gastrointestinal disorders NEC | 1 | 1 | 1 | 1 | | |
| Gastrointestinal signs and symptoms NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Nausea and vomiting symptoms | 36 | 43 | 21 | 28 | 15 | 15 |
| Oral dryness and saliva altered | 5 | 5 | 3 | 3 | 2 | 2 |
| Oral soft tissue disorders NEC | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 14 | 14 | 2 | 2 | 12 | 12 |
| Oral soft tissue swelling and oedema | 6 | 6 | | | 6 | 6 |
| Tongue signs and symptoms | 7 | 7 | 3 | 3 | 4 | 4 |
| | 87 | 96 | 40 | 49 | 47 | 47 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 65 | 72 | 54 | 58 | 11 | 14 |
| Complications associated with device NEC | 1 | 1 | 1 | 1 | | |
| Death and sudden death | 8 | 10 | | | 8 | 10 |
| Febrile disorders | 45 | 45 | 25 | 25 | 20 | 20 |
| Feelings and sensations NEC | 44 | 46 | 23 | 25 | 21 | 21 |
| Gait disturbances | 2 | 2 | 2 | 2 | | |
| General signs and symptoms NEC | 20 | 20 | 4 | 4 | 16 | 16 |
| Inflammatons | 2 | 2 | | | 2 | 2 |
| Injection site reactions | 1 | 1 | 1 | 1 | | |
| Mucosal findings abnormal | 1 | 1 | 1 | 1 | | |
| Oedema NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain and discomfort NEC | 13 | 13 | 9 | 9 | 4 | 4 |
| Therapeutic and nontherapeutic responses | 17 | 19 | | | 17 | 19 |
| Vaccination site reactions | 78 | 84 | 57 | 63 | 21 | 21 |
| | 299 | 318 | 178 | 190 | 121 | 128 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholestasis and jaundice | 1 | 1 | | | 1 | 1 |
| Hepatobiliary signs and symptoms | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 8 | 8 | 1 | 1 | 7 | 7 |
| Anaphylactic and anaphylactoid responses | 8 | 9 | | | 8 | 9 |
| | 16 | 17 | 1 | 1 | 15 | 16 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacterial infections NEC | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 21 | 22 | 4 | 4 | 17 | 18 |
| Ear infections | 1 | 1 | | | 1 | 1 |
| Escherichia infections | 1 | 1 | | | 1 | 1 |
| Eye and eyelid infections | 1 | 1 | | | 1 | 1 |
| Herpes viral infections | 1 | 1 | | | 1 | 1 |
| Influenza viral infections | | 1 | | 1 | | |
| Lower respiratory tract and lung infections | 3 | 3 | | | 3 | 3 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 1 | 1 | | | 1 | 1 |
| Skin structures and soft tissue infections | 4 | 4 | 2 | 2 | 2 | 2 |
| Upper respiratory tract infections | 1 | 1 | 1 | 1 | | |
| Viral infections NEC | 1 | 1 | | | 1 | 1 |
| | 36 | 38 | 7 | 8 | 29 | 30 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Medication errors, product use errors and issues NEC | 5 | 6 | 5 | 6 |
| Off label uses | 3 | 3 | 3 | 3 |
| Product administration errors and issues | 5 | 7 | 5 | 7 |
| Product preparation errors and issues | | 1 | | 1 |
| Underdoses NEC | 1 | 1 | 1 | 1 |
| | 14 | 18 | 14 | 18 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 3 | 3 | | | 3 | 3 |
| Coagulation and bleeding analyses | 1 | 1 | 1 | 1 | | |
| ECG investigations | 1 | 1 | 1 | 1 | | |
| Heart rate and pulse investigations | 2 | 2 | | | 2 | 2 |
| Immune response protein analyses NEC | 1 | 1 | | | 1 | 1 |
| Liver function analyses | 1 | 1 | 1 | 1 | | |
| Mineral and electrolyte analyses | 1 | 1 | 1 | 1 | | |
| Ophthalmic function diagnostic procedures | 1 | 1 | | | 1 | 1 |
| Physical examination procedures and organ system status | 9 | 9 | 7 | 7 | 2 | 2 |
| Protein analyses NEC | 2 | 2 | | | 2 | 2 |
| Skeletal and cardiac muscle analyses | 1 | 1 | | | 1 | 1 |
| Tissue enzyme analyses NEC | 1 | 1 | 1 | 1 | | |
| Vascular tests NEC (incl blood pressure) | 11 | 11 | 3 | 3 | 8 | 8 |
| Virus identification and serology | 2 | 3 | | | 2 | 3 |
| | 37 | 38 | 15 | 15 | 22 | 23 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Appetite disorders | 1 | 1 | 1 | 1 |
| Food malabsorption and intolerance syndromes (excl sugar intolerance) | 1 | 1 | 1 | 1 |
| General nutritional disorders NEC | 2 | 2 | 2 | 2 |
| Hyperglycaemic conditions NEC | 1 | 1 | 1 | 1 |
| Sodium imbalance | 1 | 1 | 1 | 1 |
| | 6 | 6 | 6 | 6 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 1 | 1 | 1 | 1 | | |
| Bursal disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Joint related signs and symptoms | 17 | 17 | 6 | 6 | 11 | 11 |
| Muscle pains | 11 | 12 | 3 | 4 | 8 | 8 |
| Muscle related signs and symptoms NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Muscle tone abnormalities | 1 | 1 | 1 | 1 | | |
| Muscle weakness conditions | 5 | 5 | 2 | 2 | 3 | 3 |
| Musculoskeletal and connective tissue pain and discomfort | 24 | 24 | 18 | 18 | 6 | 6 |
| Rheumatoid arthropathies | 1 | 1 | | | 1 | 1 |
| Soft tissue disorders NEC | 1 | 1 | 1 | 1 | | |
| Tendon disorders | 1 | 1 | 1 | 1 | | |
| | 68 | 69 | 36 | 37 | 32 | 32 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coordination and balance disturbances | 1 | 1 | | | 1 | 1 |
| Cortical dysfunction NEC | 2 | 2 | 2 | 2 | | |
| Disturbances in consciousness NEC | 20 | 21 | 6 | 6 | 14 | 15 |
| Dyskinesias and movement disorders NEC | 2 | 2 | 2 | 2 | | |
| Facial cranial nerve disorders | 7 | 7 | | | 7 | 7 |
| Generalised tonic-clonic seizures | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 65 | 67 | 48 | 50 | 17 | 17 |
| Memory loss (excl dementia) | 1 | 1 | 1 | 1 | | |
| Mental impairment (excl dementia and memory loss) | 2 | 2 | | | 2 | 2 |
| Migraine headaches | 2 | 4 | 2 | 4 | | |
| Muscle tone abnormal | 2 | 2 | 1 | 1 | 1 | 1 |
| Narcolepsy and hypersomnia | 2 | 2 | 1 | 1 | 1 | 1 |
| Neurological signs and symptoms NEC | 46 | 46 | 24 | 24 | 22 | 22 |
| Neurologic visual problems NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Olfactory nerve disorders | 3 | 3 | 2 | 2 | 1 | 1 |
| Paraesthesias and dysaesthesias | 37 | 38 | 14 | 15 | 23 | 23 |
| Paralysis and paresis (excl cranial nerve) | 2 | 2 | | | 2 | 2 |
| Parkinson's disease and parkinsonism | 1 | 1 | 1 | 1 | | |
| Peripheral neuropathies NEC | 3 | 3 | | | 3 | 3 |
| Seizures and seizure disorders NEC | 5 | 5 | | | 5 | 5 |
| Sensory abnormalities NEC | 10 | 10 | 5 | 5 | 5 | 5 |
| Speech and language abnormalities | 3 | 3 | 1 | 1 | 2 | 2 |
| Tremor (excl congenital) | 1 | 1 | 1 | 1 | | |
| Trigeminal disorders | 1 | 1 | | | 1 | 1 |
| | 221 | 227 | 112 | 117 | 109 | 110 |

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System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Device physical property and chemical issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusion and disorientation | 1 | 1 | 1 | 1 | | |
| Disturbances in initiating and maintaining sleep | 3 | 3 | 3 | 3 | | |
| Increased physical activity levels | 3 | 3 | 2 | 2 | 1 | 1 |
| Narcolepsy and associated conditions | 1 | 1 | 1 | 1 | | |
| Panic attacks and disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Sleep disorders NEC | 1 | 1 | 1 | 1 | | |
| Somatic symptom disorders | 1 | 1 | | | 1 | 1 |
| Speech and language usage disturbances | 1 | 1 | 1 | 1 | | |
| | 13 | 13 | 10 | 10 | 3 | 3 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Bladder and urethral symptoms | | 1 | | 1 |
| Renal failure and impairment | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 | | |
| Vulvovaginal disorders NEC | 1 | 1 | | | 1 | 1 |
| Vulvovaginal signs and symptoms | | 1 | | 1 | | |
| | 2 | 3 | 1 | 2 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 17 | 18 | 5 | 5 | 12 | 13 |
| Bronchospasm and obstruction | 2 | 2 | 1 | 1 | 1 | 1 |
| Coughing and associated symptoms | 3 | 3 | 3 | 3 | | |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract inflammatory and immunologic conditions | 2 | 2 | | | 2 | 2 |
| Lower respiratory tract signs and symptoms | 1 | 2 | 1 | 1 | | 1 |
| Nasal congestion and inflammations | 1 | 1 | | | 1 | 1 |
| Paranasal sinus disorders (excl infections and neoplasms) | 1 | 1 | 1 | 1 | | |
| Parenchymal lung disorders NEC | 2 | 2 | | | 2 | 2 |
| Pharyngeal disorders (excl infections and neoplasms) | 2 | 2 | 1 | 1 | 1 | 1 |
| Pneumothorax and pleural effusions NEC | 1 | 1 | | | 1 | 1 |
| Pulmonary oedemas | | 1 | | | | 1 |
| Pulmonary thrombotic and embolic conditions | 1 | 2 | | | 1 | 2 |
| Respiratory failures (excl neonatal) | 1 | 1 | | | 1 | 1 |
| Respiratory tract disorders NEC | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 11 | 11 | 4 | 4 | 7 | 7 |
| | 47 | 51 | 17 | 17 | 30 | 34 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alopecias | 1 | 1 | 1 | 1 | | |
| Apocrine and eccrine gland disorders | 1 | 1 | 1 | 1 | | |
| Bullous conditions | 1 | 1 | | | 1 | 1 |
| Dermal and epidermal conditions NEC | 4 | 4 | | | 4 | 4 |
| Dermatitis and eczema | 2 | 2 | | | 2 | 2 |
| Erythemas | 6 | 6 | 3 | 3 | 3 | 3 |
| Pruritus NEC | 19 | 21 | 3 | 5 | 16 | 16 |
| Purpura and related conditions | 1 | 1 | | | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 17 | 17 | 4 | 4 | 13 | 13 |
| Skin vasomotor conditions | 1 | 1 | 1 | 1 | | |
| Urticarias | 5 | 6 | | 1 | 5 | 5 |
| | 58 | 61 | 13 | 16 | 45 | 45 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disability issues | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 3 | 3 | | | 3 | 3 |
| Circulatory collapse and shock | 10 | 10 | | | 10 | 10 |
| Peripheral vascular disorders NEC | 11 | 11 | 2 | 2 | 9 | 9 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 2 | 2 | 2 | 2 | | |
| Site specific vascular disorders NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Vascular hypertensive disorders NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Vascular hypotensive disorders | 4 | 4 | 1 | 1 | 3 | 3 |
| | 39 | 39 | 7 | 7 | 32 | 32 |

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Country Where Event Occurred

BAHRAIN

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Nausea and vomiting symptoms | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Febrile disorders | 2 | 2 | 2 | 2 |
| Feelings and sensations NEC | 2 | 2 | 2 | 2 |
| Pain and discomfort NEC | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle pains | 1 | 1 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Pruritus NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Peripheral vascular disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

BELGIUM

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coagulopathies | 1 | 1 | | | 1 | 1 |
| Leukocytoses NEC | 1 | 2 | | | 1 | 2 |
| Lymphatic system disorders NEC | 3 | 4 | | 1 | 3 | 3 |
| Neutropenias | | 1 | | | | 1 |
| Thrombocytopenias | 1 | 1 | | | 1 | 1 |
| | 6 | 9 | | 1 | 6 | 8 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 1 | 1 | | | 1 | 1 |
| Cardiac disorders NEC | 9 | 13 | 1 | 1 | 8 | 12 |
| Cardiac signs and symptoms NEC | 3 | 4 | 2 | 3 | 1 | 1 |
| Heart failures NEC | 2 | 2 | | | 2 | 2 |
| Ischaemic coronary artery disorders | 2 | 2 | | | 2 | 2 |
| Rate and rhythm disorders NEC | 7 | 9 | 1 | 1 | 6 | 8 |
| Supraventricular arrhythmias | 2 | 2 | | | 2 | 2 |
| Ventricular arrhythmias and cardiac arrest | 3 | 4 | | | 3 | 4 |
| | 29 | 37 | 4 | 5 | 25 | 32 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 1 | 1 | | | 1 | 1 |
| Hearing losses | 1 | 1 | | | 1 | 1 |
| Inner ear disorders NEC | 1 | 1 | | | 1 | 1 |
| Inner ear signs and symptoms | 7 | 7 | 1 | 1 | 6 | 6 |
| | 10 | 10 | 1 | 1 | 9 | 9 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Glaucomas (excl congenital) | 2 | 2 | | | 2 | 2 |
| Lacrimation disorders | 1 | 1 | 1 | 1 | | |
| Ocular disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Ocular infections, inflammations and associated manifestations | 1 | 1 | 1 | 1 | | |
| Ocular nerve and muscle disorders | | 1 | | | | 1 |
| Visual disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 8 | 9 | 4 | 4 | 4 | 5 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 1 | | | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 4 | 5 | 1 | 1 | 3 | 4 |
| Gastrointestinal atonic and hypomotility disorders NEC | | 1 | | | | 1 |
| Gastrointestinal signs and symptoms NEC | 2 | 3 | 2 | 3 | | |
| Gastrointestinal vascular occlusion and infarction | | 2 | | | | 2 |
| Nausea and vomiting symptoms | 36 | 38 | 3 | 4 | 33 | 34 |
| Oral dryness and saliva altered | 3 | 3 | 2 | 2 | 1 | 1 |
| Oral soft tissue signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| Oral soft tissue swelling and oedema | 2 | 2 | 2 | 2 | | |
| Tongue signs and symptoms | 3 | 4 | 2 | 3 | 1 | 1 |
| | 53 | 61 | 13 | 16 | 40 | 45 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 81 | 92 | 12 | 19 | 69 | 73 |
| Death and sudden death | 8 | 10 | | | 8 | 10 |
| Febrile disorders | 37 | 38 | 3 | 3 | 34 | 35 |
| Feelings and sensations NEC | 41 | 41 | 6 | 6 | 35 | 35 |
| Gait disturbances | 2 | 2 | | | 2 | 2 |
| General signs and symptoms NEC | 18 | 20 | | 1 | 18 | 19 |
| Oedema NEC | 1 | 1 | | | 1 | 1 |
| Pain and discomfort NEC | 7 | 7 | 1 | 1 | 6 | 6 |
| Therapeutic and nontherapeutic responses | 31 | 36 | | | 31 | 36 |
| Vaccination site reactions | 39 | 46 | 12 | 19 | 27 | 27 |
| | 265 | 293 | 34 | 49 | 231 | 244 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Allergic conditions NEC | 1 | 1 | 1 | 1 |
| Anaphylactic and anaphylactoid responses | 12 | 12 | 12 | 12 |
| | 13 | 13 | 13 | 13 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 37 | 42 | | | 37 | 42 |
| Herpes viral infections | 5 | 5 | 2 | 2 | 3 | 3 |
| Infections NEC | 3 | 3 | | | 3 | 3 |
| Influenza viral infections | 1 | 1 | 1 | 1 | | |
| Lower respiratory tract and lung infections | 1 | 1 | | | 1 | 1 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 1 | 3 | | | 1 | 3 |
| Streptococcal infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 2 | 2 | 1 | 1 | 1 | 1 |
| | 51 | 58 | 4 | 4 | 47 | 54 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conditions caused by cold | 1 | 1 | | | 1 | 1 |
| Exposures associated with pregnancy, delivery and lactation | 1 | 1 | 1 | 1 | | |
| Medication errors, product use errors and issues NEC | 2 | 2 | 2 | 2 | | |
| Non-site specific injuries NEC | 4 | 5 | 1 | 1 | 3 | 4 |
| Occupational exposures | | 1 | | 1 | | |
| Off label uses | 2 | 2 | 2 | 2 | | |
| Pathways and sources of exposure | | 1 | | 1 | | |
| Product administration errors and issues | 2 | 2 | 2 | 2 | | |
| | 12 | 15 | 8 | 10 | 4 | 5 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 7 | 9 | | | 7 | 9 |
| Coagulation and bleeding analyses | 1 | 1 | | | 1 | 1 |
| Heart rate and pulse investigations | 3 | 3 | 1 | 1 | 2 | 2 |
| Liver function analyses | 2 | 3 | | | 2 | 3 |
| Physical examination procedures and organ system status | 3 | 3 | | | 3 | 3 |
| Protein analyses NEC | 2 | 2 | | | 2 | 2 |
| Skeletal and cardiac muscle analyses | 2 | 2 | | | 2 | 2 |
| Vascular tests NEC (incl blood pressure) | 4 | 4 | 2 | 2 | 2 | 2 |
| Virus identification and serology | 1 | 1 | | | 1 | 1 |
| | 25 | 28 | 3 | 3 | 22 | 25 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Diabetic complications NEC | 1 | 1 | 1 | 1 |
| Hypoglycaemic conditions NEC | 1 | 2 | 1 | 2 |
| Metabolic acidoses (excl diabetic acidoses) | | 1 | | 1 |
| Potassium imbalance | 1 | 1 | 1 | 1 |
| Sodium imbalance | 1 | 1 | 1 | 1 |
| | 4 | 6 | 4 | 6 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 1 | | | 1 | 1 |
| Joint related signs and symptoms | 19 | 19 | 1 | 1 | 18 | 18 |
| Muscle pains | 41 | 41 | 4 | 4 | 37 | 37 |
| Muscle related signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Musculoskeletal and connective tissue conditions NEC | 6 | 8 | 1 | 3 | 5 | 5 |
| Musculoskeletal and connective tissue pain and discomfort | 16 | 17 | 4 | 5 | 12 | 12 |
| | 84 | 87 | 10 | 13 | 74 | 74 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 2 | 3 | | | 2 | 3 |
| Coma states | 1 | 1 | | | 1 | 1 |
| Coordination and balance disturbances | 4 | 4 | | | 4 | 4 |
| Disturbances in consciousness NEC | 22 | 23 | | | 22 | 23 |
| Dystonias | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizures | 2 | 2 | | | 2 | 2 |
| Headaches NEC | 51 | 52 | 6 | 7 | 45 | 45 |
| Memory loss (excl dementia) | | 2 | | 1 | | 1 |
| Nervous system disorders NEC | 4 | 6 | | | 4 | 6 |
| Neurological signs and symptoms NEC | 12 | 16 | 1 | 1 | 11 | 15 |
| Paraesthesias and dysaesthesias | 4 | 4 | | | 4 | 4 |
| Paralysis and paresis (excl cranial nerve) | 3 | 3 | | | 3 | 3 |
| Peripheral neuropathies NEC | 2 | 2 | | | 2 | 2 |
| Seizures and seizure disorders NEC | 6 | 6 | | | 6 | 6 |
| Sensory abnormalities NEC | 3 | 4 | 2 | 3 | 1 | 1 |
| Sleep disturbances NEC | 1 | 2 | | 1 | 1 | 1 |
| Tremor (excl congenital) | 2 | 2 | | | 2 | 2 |
| | 121 | 134 | 9 | 13 | 112 | 121 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal behaviour NEC | | 1 | | | | 1 |
| Anxiety symptoms | 5 | 7 | | | 5 | 7 |
| Confusion and disorientation | | 3 | | | | 3 |
| Disturbances in initiating and maintaining sleep | 2 | 2 | | | 2 | 2 |
| Increased physical activity levels | 1 | 1 | 1 | 1 | | |
| Sleep disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 10 | 16 | 2 | 2 | 8 | 14 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Renal disorders NEC | | 1 | | 1 |
| Renal failure and impairment | 3 | 4 | 3 | 4 |
| | 3 | 5 | 3 | 5 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 13 | 15 | 1 | 1 | 12 | 14 |
| Bronchospasm and obstruction | 5 | 5 | | | 5 | 5 |
| Conditions associated with abnormal gas exchange | 1 | 1 | | | 1 | 1 |
| Coughing and associated symptoms | 3 | 3 | 1 | 1 | 2 | 2 |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract inflammatory and immunologic conditions | 1 | 2 | | | 1 | 2 |
| Lower respiratory tract signs and symptoms | 1 | 1 | | | 1 | 1 |
| Nasal congestion and inflammations | 1 | 1 | 1 | 1 | | |
| Parenchymal lung disorders NEC | | 1 | | | | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 |
| Pneumothorax and pleural effusions NEC | 1 | 1 | | | 1 | 1 |
| Pulmonary oedemas | 2 | 2 | | | 2 | 2 |
| Pulmonary thrombotic and embolic conditions | 1 | 2 | | | 1 | 2 |
| Respiratory failures (excl neonatal) | 3 | 4 | | | 3 | 4 |
| Respiratory tract disorders NEC | 5 | 7 | | | 5 | 7 |
| Upper respiratory tract signs and symptoms | 10 | 10 | 4 | 4 | 6 | 6 |
| | 49 | 57 | 7 | 7 | 42 | 50 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 3 | 3 | | | 3 | 3 |
| Apocrine and eccrine gland disorders | 3 | 3 | | | 3 | 3 |
| Dermal and epidermal conditions NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Erythemas | 5 | 5 | 2 | 2 | 3 | 3 |
| Pruritus NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Rashes, eruptions and exanthems NEC | 3 | 3 | | | 3 | 3 |
| Skin vasomotor conditions | 1 | 1 | | | 1 | 1 |
| Urticarias | 2 | 2 | | | 2 | 2 |
| | 26 | 26 | 4 | 4 | 22 | 22 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circulatory collapse and shock | 2 | 3 | | | 2 | 3 |
| Lymphoedemas | 1 | 1 | | | 1 | 1 |
| Non-site specific embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | | | 1 | 1 |
| Site specific vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Vascular hypertensive disorders NEC | 7 | 7 | 2 | 2 | 5 | 5 |
| Vascular hypotensive disorders | 5 | 6 | | | 5 | 6 |
| | 24 | 26 | 3 | 3 | 21 | 23 |

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Country Where Event Occurred

BERMUDA

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea (excl infective) | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

BULGARIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 4 | 8 | 3 | 7 | 1 | 1 |
| | 4 | 8 | 3 | 7 | 1 | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 1 | 2 | 1 | 2 | | |
| Rate and rhythm disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 4 | 5 | 2 | 3 | 2 | 2 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Inner ear signs and symptoms | 3 | 4 | 2 | 2 | 1 | 2 |
| | 3 | 4 | 2 | 2 | 1 | 2 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Conjunctival infections, irritations and inflammations | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dental pain and sensation disorders | 1 | 1 | 1 | 1 | | |
| Diarrhoea (excl infective) | | 2 | | 2 | | |
| Dyspeptic signs and symptoms | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 1 | 1 | 1 | 1 | | |
| Gastrointestinal disorders NEC | 1 | 1 | 1 | 1 | | |
| Gastrointestinal signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Nausea and vomiting symptoms | 4 | 8 | 4 | 7 | | 1 |
| Oral soft tissue signs and symptoms | | 1 | | 1 | | |
| Oral soft tissue swelling and oedema | 1 | 1 | | | 1 | 1 |
| Tongue signs and symptoms | 1 | 1 | | | 1 | 1 |
| | 11 | 18 | 9 | 15 | 2 | 3 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Application and instillation site reactions | 1 | 1 | 1 | 1 | | |
| Asthenic conditions | 18 | 22 | 16 | 20 | 2 | 2 |
| Body temperature altered | 1 | 1 | | | 1 | 1 |
| Febrile disorders | 10 | 12 | 8 | 10 | 2 | 2 |
| Feelings and sensations NEC | 11 | 14 | 9 | 11 | 2 | 3 |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | 1 | 3 | 1 | 3 | | |
| Injection site reactions | 1 | 1 | 1 | 1 | | |
| Pain and discomfort NEC | 2 | 3 | 2 | 3 | | |
| Therapeutic and nontherapeutic responses | | 4 | | | | 4 |
| Vaccination site reactions | 39 | 51 | 33 | 45 | 6 | 6 |
| | 85 | 113 | 72 | 95 | 13 | 18 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactic and anaphylactoid responses | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Coronavirus infections | | 4 | | 4 |
| Viral infections NEC | 1 | 1 | 1 | 1 |
| | 1 | 5 | 1 | 5 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| High Level Term | | | | | | | |
| Autoimmunity analyses | 1 | 1 | 1 | 1 | | | |
| Heart rate and pulse investigations | 1 | 1 | 1 | 1 | | | |
| Physical examination procedures and organ system status | 8 | 11 | 6 | 9 | 2 | 2 | |
| Thyroid analyses | 1 | 1 | | | 1 | 1 | |
| Vascular tests NEC (incl blood pressure) | 4 | 5 | 3 | 4 | 1 | 1 | |
| White blood cell analyses | | 1 | | 1 | | | |
| | 15 | 20 | 11 | 16 | 4 | 4 | |

System Organ Class

| Metabolism and nutrition disorders | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| High Level Term | | | | | | | |
| Appetite disorders | 2 | 2 | 1 | 1 | 1 | 1 | |
| | 2 | 2 | 1 | 1 | 1 | 1 | |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 1 | 1 | 1 | | |
| Bone related signs and symptoms | 1 | 1 | 1 | 1 | | |
| Joint related signs and symptoms | 8 | 11 | 8 | 11 | | |
| Muscle pains | 12 | 17 | 12 | 17 | | |
| Musculoskeletal and connective tissue conditions NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 3 | 6 | 3 | 6 | | |
| Rheumatoid arthropathies | 1 | 1 | | | 1 | 1 |
| | 29 | 40 | 27 | 38 | 2 | 2 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Facial cranial nerve disorders | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 12 | 17 | 10 | 14 | 2 | 3 |
| Neurological signs and symptoms NEC | 7 | 12 | 7 | 10 | | 2 |
| Olfactory nerve disorders | | 1 | | 1 | | |
| Paraesthesias and dysaesthesias | 2 | 3 | 1 | 2 | 1 | 1 |
| Parkinson's disease and parkinsonism | 1 | 1 | | | 1 | 1 |
| Peripheral neuropathies NEC | 1 | 1 | 1 | 1 | | |
| Seizures and seizure disorders NEC | 1 | 1 | | | 1 | 1 |
| Sensory abnormalities NEC | | 1 | | 1 | | |
| Tremor (excl congenital) | 2 | 2 | 2 | 2 | | |
| | 27 | 40 | 21 | 31 | 6 | 9 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Urinary tract signs and symptoms NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Erection and ejaculation conditions and disorders | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 1 | 2 | | | 1 | 2 |
| Upper respiratory tract signs and symptoms | 1 | 1 | 1 | 1 | | |
| | 2 | 3 | 1 | 1 | 1 | 2 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 4 | 6 | 3 | 4 | 1 | 2 |
| Erythemas | 2 | 3 | 2 | 3 | | |
| Rashes, eruptions and exanthems NEC | 1 | 4 | 1 | 4 | | |
| Urticarias | 1 | 1 | | | 1 | 1 |
| | 8 | 14 | 6 | 11 | 2 | 3 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure disorders NEC | 1 | 1 | 1 | 1 | | |
| Non-site specific necrosis and vascular insufficiency NEC | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | | 1 | | 1 | | |
| Site specific vascular disorders NEC | 1 | 2 | | 1 | 1 | 1 |
| Vascular hypertensive disorders NEC | 1 | 1 | 1 | 1 | | |
| | 5 | 7 | 3 | 5 | 2 | 2 |

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Country Where Event Occurred

CANADA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 8 | 15 | 7 | 14 | 1 | 1 |
| | 8 | 15 | 7 | 14 | 1 | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 1 | 2 | 1 | 2 | | |
| Rate and rhythm disorders NEC | 4 | 9 | | 3 | 4 | 6 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 6 | 12 | 1 | 5 | 5 | 7 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 1 | 2 | 1 | 2 | | |
| Hearing losses | 2 | 3 | 2 | 2 | | 1 |
| Inner ear signs and symptoms | 2 | 2 | 2 | 2 | | |
| | 5 | 7 | 5 | 6 | | 1 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid movement disorders | 1 | 1 | | | 1 | 1 |
| Ocular disorders NEC | 2 | 4 | 2 | 4 | | |
| Ocular infections, inflammations and associated manifestations | | 1 | | 1 | | |
| Ocular sensation disorders | 2 | 2 | 2 | 2 | | |
| Visual disorders NEC | 3 | 4 | 2 | 3 | 1 | 1 |
| Visual impairment and blindness (excl colour blindness) | 1 | 2 | | 1 | 1 | 1 |
| | 9 | 14 | 6 | 11 | 3 | 3 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 11 | 1 | 11 | | |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 2 | 6 | 2 | 6 | | |
| Gastrointestinal atonic and hypomotility disorders NEC | | 1 | | 1 | | |
| Gastrointestinal disorders NEC | 1 | 1 | 1 | 1 | | |
| Gastrointestinal signs and symptoms NEC | 1 | 4 | 1 | 4 | | |
| Nausea and vomiting symptoms | 11 | 31 | 11 | 31 | | |
| Oesophageal disorders NEC | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 4 | 11 | 2 | 7 | 2 | 4 |
| Oral soft tissue swelling and oedema | | 3 | | 1 | | 2 |
| Stomatitis and ulceration | | 1 | | 1 | | |
| Tongue disorders | | 1 | | | | 1 |
| Tongue signs and symptoms | 1 | 5 | 1 | 4 | | 1 |
| | 23 | 77 | 20 | 68 | 3 | 9 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse effect absent | 1 | 1 | 1 | 1 | | |
| Asthenic conditions | 29 | 61 | 26 | 57 | 3 | 4 |
| Febrile disorders | 15 | 33 | 15 | 33 | | |
| Feelings and sensations NEC | 17 | 35 | 17 | 34 | | 1 |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | 11 | 19 | 8 | 14 | 3 | 5 |
| Injection site reactions | | 1 | | 1 | | |
| Oedema NEC | | 2 | | 1 | | 1 |
| Pain and discomfort NEC | 17 | 30 | 16 | 27 | 1 | 3 |
| Therapeutic and nontherapeutic responses | 4 | 10 | 1 | 1 | 3 | 9 |
| Vaccination site reactions | 25 | 47 | 25 | 46 | | 1 |
| | 120 | 240 | 110 | 216 | 10 | 24 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 8 | 13 | 1 | 3 | 7 | 10 |
| Allergies to foods, food additives, drugs and other chemicals | | 1 | | 1 | | |
| Anaphylactic and anaphylactoid responses | 5 | 10 | | | 5 | 10 |
| | 13 | 24 | 1 | 4 | 12 | 20 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal infections | | 1 | | 1 | | |
| Bacterial infections NEC | | 1 | | | | 1 |
| Candida infections | 1 | 1 | 1 | 1 | | |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 3 | 9 | | 1 | 3 | 8 |
| Herpes viral infections | 1 | 6 | | 4 | 1 | 2 |
| Lower respiratory tract and lung infections | 1 | 1 | | | 1 | 1 |
| Skin structures and soft tissue infections | | 1 | | 1 | | |
| Streptococcal infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | | 1 | | 1 | | |
| | 8 | 23 | 1 | 9 | 7 | 14 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 7 | 30 | 5 | 28 | 2 | 2 |
| Medication errors, product use errors and issues NEC | 6 | 25 | 6 | 25 | | |
| Off label uses | 7 | 27 | 7 | 27 | | |
| Overdoses NEC | 2 | 8 | 2 | 8 | | |
| Product administration errors and issues | 15 | 22 | 15 | 22 | | |
| Product preparation errors and issues | 2 | 12 | 2 | 12 | | |
| Skin injuries NEC | | 1 | | 1 | | |
| Underdoses NEC | 2 | 6 | 2 | 6 | | |
| | 41 | 131 | 39 | 129 | 2 | 2 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Carbohydrate tolerance analyses (incl diabetes) | 2 | 2 | 1 | 1 | 1 | 1 |
| Heart rate and pulse investigations | | 1 | | 1 | | |
| Physical examination procedures and organ system status | 1 | 3 | 1 | 2 | | 1 |
| Vascular tests NEC (incl blood pressure) | 1 | 1 | 1 | 1 | | |
| Virus identification and serology | | 1 | | | | 1 |
| | 4 | 8 | 3 | 5 | 1 | 3 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 2 | 5 | 1 | 4 | 1 | 1 |
| Disorders of purine metabolism | | 1 | | 1 | | |
| Fluid intake increased | 1 | 1 | 1 | 1 | | |
| Total fluid volume decreased | 1 | 1 | 1 | 1 | | |
| Total fluid volume increased | 1 | 2 | 1 | 2 | | |
| | 5 | 10 | 4 | 9 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 2 | 2 | 2 | 2 | | |
| Bursal disorders | 1 | 1 | 1 | 1 | | |
| Joint related disorders NEC | 1 | 1 | 1 | 1 | | |
| Joint related signs and symptoms | 7 | 20 | 7 | 17 | | 3 |
| Lupus erythematosus (incl subtypes) | 1 | 1 | | | 1 | 1 |
| Muscle pains | 10 | 28 | 10 | 26 | | 2 |
| Muscle related signs and symptoms NEC | 1 | 3 | 1 | 3 | | |
| Muscle weakness conditions | 1 | 2 | 1 | 2 | | |
| Musculoskeletal and connective tissue conditions NEC | 1 | 4 | 1 | 4 | | |
| Musculoskeletal and connective tissue pain and discomfort | 13 | 35 | 10 | 32 | 3 | 3 |
| Rheumatoid arthropathies | | 1 | | | | 1 |
| Tendon disorders | 1 | 1 | 1 | 1 | | |
| | 39 | 99 | 35 | 89 | 4 | 10 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cortical dysfunction NEC | 1 | 1 | 1 | 1 | | |
| Disturbances in consciousness NEC | 1 | 7 | 1 | 5 | | 2 |
| Dyskinesias and movement disorders NEC | 1 | 2 | 1 | 2 | | |
| Eye movement disorders | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 3 | 4 | | | 3 | 4 |
| Generalised tonic-clonic seizures | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 17 | 49 | 17 | 49 | | |
| Mental impairment (excl dementia and memory loss) | 2 | 3 | 2 | 3 | | |
| Migraine headaches | 3 | 4 | 2 | 3 | 1 | 1 |
| Narcolepsy and hypersomnia | 1 | 2 | 1 | 2 | | |
| Neurological signs and symptoms NEC | 12 | 20 | 12 | 19 | | 1 |
| Paraesthesias and dysaesthesias | 10 | 21 | 9 | 16 | 1 | 5 |
| Sensory abnormalities NEC | 6 | 8 | 5 | 7 | 1 | 1 |
| Tremor (excl congenital) | | 2 | | 1 | | 1 |
| | 59 | 125 | 51 | 108 | 8 | 17 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortions spontaneous | 1 | 1 | 1 | 1 |
| Foetal growth complications | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product supply and availability issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Affect alterations NEC | | 1 | | 1 |
| Anxiety symptoms | 1 | 5 | 1 | 5 |
| Cognitive and attention disorders and disturbances NEC | | 1 | | 1 |
| Confusion and disorientation | 1 | 1 | 1 | 1 |
| Depressive disorders | | 1 | | 1 |
| Disturbances in initiating and maintaining sleep | | 2 | | 2 |
| Fear symptoms and phobic disorders (incl social phobia) | | 1 | | 1 |
| Psychotic disorder NEC | 1 | 1 | 1 | 1 |
| | 3 | 13 | 3 | 13 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Renal failure and impairment | 1 | 1 | | | 1 | 1 |
| Urinary tract signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Menstruation and uterine bleeding NEC | | 1 | | 1 | | |
| Menstruation with decreased bleeding | 1 | 1 | 1 | 1 | | |
| Vulvovaginal disorders NEC | | 1 | | | | 1 |
| | 1 | 3 | 1 | 2 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 8 | 12 | 5 | 8 | 3 | 4 |
| Bronchospasm and obstruction | 4 | 4 | 3 | 3 | 1 | 1 |
| Coughing and associated symptoms | 4 | 4 | 3 | 3 | 1 | 1 |
| Lower respiratory tract signs and symptoms | | 1 | | | | 1 |
| Nasal congestion and inflammations | | 1 | | 1 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 4 | 1 | 3 | | 1 |
| Pulmonary thrombotic and embolic conditions | 3 | 3 | | | 3 | 3 |
| Respiratory tract disorders NEC | | 1 | | | | 1 |
| Upper respiratory tract signs and symptoms | 4 | 13 | 4 | 12 | | 1 |
| | 24 | 43 | 16 | 30 | 8 | 13 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acnes | 1 | 1 | 1 | 1 | | |
| Angioedemas | | 1 | | | | 1 |
| Apocrine and eccrine gland disorders | 2 | 4 | 2 | 4 | | |
| Bullous conditions | 1 | 1 | | | 1 | 1 |
| Dermal and epidermal conditions NEC | | 3 | | 3 | | |
| Dermatitis and eczema | | 1 | | 1 | | |
| Erythemas | 1 | 3 | 1 | 2 | | 1 |
| Pruritus NEC | 1 | 7 | 1 | 6 | | 1 |
| Purpura and related conditions | | 1 | | 1 | | |
| Rashes, eruptions and exanthems NEC | 8 | 14 | 4 | 9 | 4 | 5 |
| Skin preneoplastic conditions NEC | | 1 | | 1 | | |
| Urticarias | 2 | 7 | 2 | 7 | | |
| | 16 | 44 | 11 | 35 | 5 | 9 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disability issues | 3 | 4 | 3 | 4 |
| | 3 | 4 | 3 | 4 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 1 | 1 | | | 1 | 1 |
| Lymphoedemas | | 1 | | 1 | | |
| Peripheral vascular disorders NEC | | 2 | | 1 | | 1 |
| Vascular hypertensive disorders NEC | 5 | 8 | 3 | 4 | 2 | 4 |
| Vascular hypotensive disorders | 1 | 3 | 1 | 1 | | 2 |
| | 7 | 15 | 4 | 7 | 3 | 8 |

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Country Where Event Occurred

CHILE

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 2 | 8 | 2 | 7 | | 1 |
| | 2 | 8 | 2 | 7 | | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Rate and rhythm disorders NEC | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Ocular disorders NEC | | 1 | | 1 |
| Ocular infections, inflammations and associated manifestations | | 2 | | 2 |
| Ocular sensation disorders | | 1 | | 1 |
| | | 4 | | 4 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | | 1 | | | | 1 |
| Diarrhoea (excl infective) | 1 | 6 | 1 | 6 | | |
| Faecal abnormalities NEC | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | | 2 | | 1 | | 1 |
| Gastrointestinal disorders NEC | | 1 | | | | 1 |
| Nausea and vomiting symptoms | 1 | 4 | 1 | 3 | | 1 |
| Oral dryness and saliva altered | | 1 | | | | 1 |
| | 3 | 16 | 3 | 11 | | 5 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 4 | 10 | 4 | 10 | | |
| Febrile disorders | 1 | 6 | 1 | 5 | | 1 |
| Feelings and sensations NEC | 1 | 5 | 1 | 4 | | 1 |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | | 4 | | 2 | | 2 |
| Oedema NEC | 3 | 3 | | | 3 | 3 |
| Pain and discomfort NEC | 3 | 5 | 1 | 3 | 2 | 2 |
| Vaccination site reactions | 2 | 5 | 1 | 3 | 1 | 2 |
| | 15 | 39 | 9 | 28 | 6 | 11 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 1 | 2 | 1 | 2 | | |
| Anaphylactic and anaphylactoid responses | 2 | 3 | | | 2 | 3 |
| | 3 | 5 | 1 | 2 | 2 | 3 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Exposures associated with pregnancy, delivery and lactation | | 1 | | 1 |
| Medication errors, product use errors and issues NEC | | 1 | | 1 |
| Off label uses | | 2 | | 2 |
| Product administration errors and issues | 7 | 9 | 7 | 9 |
| | 7 | 13 | 7 | 13 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Immune response protein analyses NEC | 1 | 1 | 1 | 1 | | |
| Protein analyses NEC | 1 | 1 | 1 | 1 | | |
| Urinalysis NEC | | 1 | | | | 1 |
| Virus identification and serology | 1 | 1 | 1 | 1 | | |
| White blood cell analyses | 1 | 1 | 1 | 1 | | |
| | 4 | 5 | 4 | 4 | | 1 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Fluid intake increased | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | | 1 | | | | 1 |
| Joint related signs and symptoms | 1 | 5 | 1 | 3 | | 2 |
| Muscle pains | 2 | 5 | 2 | 4 | | 1 |
| Muscle related signs and symptoms NEC | | 1 | | 1 | | |
| Muscle weakness conditions | 1 | 1 | 1 | 1 | | |
| Musculoskeletal and connective tissue pain and discomfort | 2 | 4 | 2 | 4 | | |
| Myopathies | 1 | 1 | | | 1 | 1 |
| Synovial disorders | | 1 | | 1 | | |
| | 7 | 19 | 6 | 14 | 1 | 5 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute polyneuropathies | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 1 | 7 | 1 | 6 | | 1 |
| Neurological signs and symptoms NEC | 1 | 2 | | 1 | 1 | 1 |
| Paraesthesias and dysaesthesias | 3 | 6 | 1 | 3 | 2 | 3 |
| Paralysis and paresis (excl cranial nerve) | 1 | 1 | | | 1 | 1 |
| Sensory abnormalities NEC | 1 | 2 | | 1 | 1 | 1 |
| | 9 | 20 | 2 | 11 | 7 | 9 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Mental disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 3 | 5 | | | 3 | 5 |
| Nasal congestion and inflammations | | 1 | | 1 | | |
| Respiratory tract disorders NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 1 | 1 | | | 1 | 1 |
| | 5 | 8 | | 1 | 5 | 7 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 1 | 2 | | | 1 | 2 |
| Apocrine and eccrine gland disorders | | 1 | | 1 | | |
| Dermatitis and eczema | | 4 | | 4 | | |
| Erythemas | | 1 | | 1 | | |
| Rashes, eruptions and exanthems NEC | 2 | 2 | | | 2 | 2 |
| Urticarias | 1 | 1 | | | 1 | 1 |
| | 4 | 11 | | 6 | 4 | 5 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disability issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Non-site specific embolism and thrombosis | 1 | 1 | 1 | 1 |
| Site specific vascular disorders NEC | 1 | 1 | 1 | 1 |
| Vascular hypotensive disorders | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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Country Where Event Occurred

COLOMBIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Leukocytoses NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Stomatitis and ulceration | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Febrile disorders | | 1 | | 1 |
| Feelings and sensations NEC | | 1 | | 1 |
| | | 2 | | 2 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Allergic conditions NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Candida infections | | 2 | | 2 |
| Dental and oral soft tissue infections | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Medication errors, product use errors and issues NEC | | 1 | | 1 |
| Off label uses | | 1 | | 1 |
| | | 2 | | 2 |

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Country Where Event Occurred

COSTA RICA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | | 1 | | 1 | | |
| Spleen disorders | | 1 | | | | 1 |
| | | 2 | | 1 | | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Rate and rhythm disorders NEC | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ocular disorders NEC | 1 | 1 | 1 | 1 | | |
| Ocular infections, inflammations and associated manifestations | 2 | 4 | 2 | 4 | | |
| Pupil disorders | 1 | 1 | | | 1 | 1 |
| | 4 | 6 | 3 | 5 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 1 | | | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | | 1 | | 1 | | |
| Nausea and vomiting symptoms | 1 | 1 | | | 1 | 1 |
| Oral dryness and saliva altered | 1 | 1 | | | 1 | 1 |
| | 3 | 4 | | 1 | 3 | 3 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 10 | 14 | 8 | 11 | 2 | 3 |
| Body temperature altered | 1 | 1 | | | 1 | 1 |
| Febrile disorders | 3 | 6 | 3 | 5 | | 1 |
| Feelings and sensations NEC | 7 | 11 | 5 | 9 | 2 | 2 |
| General signs and symptoms NEC | 2 | 3 | 1 | 2 | 1 | 1 |
| Pain and discomfort NEC | 7 | 8 | 4 | 5 | 3 | 3 |
| Therapeutic and nontherapeutic responses | 1 | 1 | | | 1 | 1 |
| Vaccination site reactions | 6 | 10 | 6 | 10 | | |
| | 37 | 54 | 27 | 42 | 10 | 12 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 3 | 3 | 1 | 1 | 2 | 2 |
| Vascular infections | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product administration errors and issues | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 1 | 1 | | | 1 | 1 |
| Coagulation and bleeding analyses | 1 | 1 | 1 | 1 | | |
| Haematological analyses NEC | | 1 | | 1 | | |
| Heart rate and pulse investigations | 1 | 2 | | 1 | 1 | 1 |
| Liver function analyses | | 1 | | | | 1 |
| | 3 | 6 | 1 | 3 | 2 | 3 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 1 | 1 | 1 | 1 | | |
| Joint related signs and symptoms | 2 | 3 | 2 | 2 | | 1 |
| Muscle pains | 6 | 8 | 5 | 6 | 1 | 2 |
| Musculoskeletal and connective tissue conditions NEC | 1 | 2 | 1 | 1 | | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 5 | 8 | 5 | 8 | | |
| | 15 | 22 | 14 | 18 | 1 | 4 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Headaches NEC | 8 | 14 | 7 | 13 | 1 | 1 |
| Migraine headaches | 1 | 1 | 1 | 1 | | |
| Neurological signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Sensory abnormalities NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Tremor (excl congenital) | 1 | 1 | 1 | 1 | | |
| | 13 | 19 | 10 | 16 | 3 | 3 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Communications disorders | 1 | 1 | 1 | 1 |
| Depressive disorders | 1 | 1 | 1 | 1 |
| Disturbances in initiating and maintaining sleep | | 1 | | 1 |
| Emotional and mood disturbances NEC | | 1 | | 1 |
| Sleep disorders NEC | | 1 | | 1 |
| | 2 | 5 | 2 | 5 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 6 | 6 | 4 | 4 | 2 | 2 |
| Lower respiratory tract inflammatory and immunologic conditions | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 1 | 1 | 1 | 1 | | |
| Pneumothorax and pleural effusions NEC | 1 | 1 | | | 1 | 1 |
| Respiratory tract disorders NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 2 | 2 | 2 | 2 | | |
| | 12 | 12 | 7 | 7 | 5 | 5 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 1 | 1 | | | 1 | 1 |
| Dermal and epidermal conditions NEC | 1 | 1 | 1 | 1 | | |
| Pruritus NEC | | 1 | | 1 | | |
| Rashes, eruptions and exanthems NEC | | 1 | | 1 | | |
| | 2 | 4 | 1 | 3 | 1 | 1 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disability issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 1 | 1 | | | 1 | 1 |
| Vascular hypertensive disorders NEC | 1 | 1 | | | 1 | 1 |
| Vasculitides NEC | | 1 | | 1 | | |
| | 2 | 3 | | 1 | 2 | 2 |

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Country Where Event Occurred

CROATIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukopenias NEC | 1 | 1 | 1 | 1 | | |
| Lymphatic system disorders NEC | 6 | 6 | 5 | 5 | 1 | 1 |
| | 7 | 7 | 6 | 6 | 1 | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 6 | 6 | 3 | 3 | 3 | 3 |
| Heart failures NEC | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 6 | 6 | 4 | 4 | 2 | 2 |
| | 13 | 13 | 7 | 7 | 6 | 6 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 3 | 3 | | | 3 | 3 |
| Hearing losses | 2 | 2 | 1 | 1 | 1 | 1 |
| Inner ear signs and symptoms | 6 | 6 | 4 | 4 | 2 | 2 |
| | 11 | 11 | 5 | 5 | 6 | 6 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Choroid and vitreous structural change, deposit and degeneration | 1 | 1 | | | 1 | 1 |
| Conjunctival infections, irritations and inflammations | 1 | 1 | | | 1 | 1 |
| Eyelid movement disorders | 1 | 2 | | | 1 | 2 |
| Lacrimation disorders | 1 | 1 | 1 | 1 | | |
| Lid, lash and lacrimal infections, irritations and inflammations | 2 | 2 | 1 | 1 | 1 | 1 |
| Ocular bleeding and vascular disorders NEC | 2 | 2 | | | 2 | 2 |
| Ocular disorders NEC | | 1 | | 1 | | |
| Ocular infections, inflammations and associated manifestations | 1 | 1 | 1 | 1 | | |
| Structural change, deposit and degeneration of eye NEC | 1 | 1 | 1 | 1 | | |
| Visual disorders NEC | 1 | 1 | | | 1 | 1 |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | | | 1 | 1 |
| | 12 | 14 | 4 | 5 | 8 | 9 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 2 | 3 | 2 | 3 | | |
| Gastrointestinal signs and symptoms NEC | 2 | 2 | | | 2 | 2 |
| Gingival haemorrhages | 1 | 1 | 1 | 1 | | |
| Nausea and vomiting symptoms | 18 | 18 | 14 | 14 | 4 | 4 |
| Oral dryness and saliva altered | 3 | 3 | 1 | 1 | 2 | 2 |
| Oral soft tissue disorders NEC | | 1 | | | | 1 |
| Oral soft tissue signs and symptoms | 6 | 7 | 3 | 3 | 3 | 4 |
| Oral soft tissue swelling and oedema | 3 | 3 | | | 3 | 3 |
| Stomatitis and ulceration | 1 | 1 | 1 | 1 | | |
| Tongue signs and symptoms | 3 | 5 | | | 3 | 5 |
| | 40 | 45 | 23 | 24 | 17 | 21 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 32 | 37 | 27 | 32 | 5 | 5 |
| Death and sudden death | 2 | 2 | | | 2 | 2 |
| Febrile disorders | 34 | 42 | 25 | 33 | 9 | 9 |
| Feelings and sensations NEC | 28 | 33 | 21 | 26 | 7 | 7 |
| General signs and symptoms NEC | 6 | 9 | 2 | 3 | 4 | 6 |
| Oedema NEC | 1 | 1 | 1 | 1 | | |
| Pain and discomfort NEC | 7 | 9 | 3 | 5 | 4 | 4 |
| Vaccination site reactions | 111 | 124 | 76 | 87 | 35 | 37 |
| | 221 | 257 | 155 | 187 | 66 | 70 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 21 | 22 | | | 21 | 22 |
| Allergies to foods, food additives, drugs and other chemicals | | 1 | | 1 | | |
| Anaphylactic and anaphylactoid responses | | 2 | | | | 2 |
| Immune and associated conditions NEC | 1 | 1 | 1 | 1 | | |
| | 22 | 26 | 1 | 2 | 21 | 24 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Coronavirus infections | 1 | 1 | 1 | 1 |
| Viral infections NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Medication errors, product use errors and issues NEC | 1 | 1 | 1 | 1 | | |
| Product administration errors and issues | 1 | 1 | | | 1 | 1 |
| Underdoses NEC | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autoimmunity analyses | 1 | 1 | 1 | 1 | | |
| Physical examination procedures and organ system status | 7 | 10 | 6 | 9 | 1 | 1 |
| Skeletal and cardiac muscle analyses | 1 | 1 | 1 | 1 | | |
| Vascular tests NEC (incl blood pressure) | 5 | 5 | 1 | 1 | 4 | 4 |
| | 14 | 17 | 9 | 12 | 5 | 5 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Appetite disorders | 2 | 2 | 2 | 2 |
| General nutritional disorders NEC | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 5 | 5 | 5 | 5 | | |
| Joint related signs and symptoms | 9 | 9 | 9 | 9 | | |
| Muscle pains | 23 | 25 | 21 | 23 | 2 | 2 |
| Muscle related signs and symptoms NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Muscle weakness conditions | 4 | 4 | 2 | 2 | 2 | 2 |
| Musculoskeletal and connective tissue pain and discomfort | 16 | 18 | 12 | 14 | 4 | 4 |
| | 60 | 64 | 50 | 54 | 10 | 10 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal sleep-related events | 1 | 1 | 1 | 1 | | |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 1 | | | 1 | 1 |
| Coordination and balance disturbances | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Dyskinesias and movement disorders NEC | 2 | 2 | | | 2 | 2 |
| Encephalitis NEC | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 4 | 5 | | | 4 | 5 |
| Headaches NEC | 43 | 51 | 30 | 37 | 13 | 14 |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | 1 | 1 | | |
| Migraine headaches | 1 | 1 | 1 | 1 | | |
| Neurological signs and symptoms NEC | 11 | 12 | 6 | 7 | 5 | 5 |
| Neuromuscular disorders NEC | 1 | 1 | | | 1 | 1 |
| Paraesthesias and dysaesthesias | 11 | 15 | 5 | 7 | 6 | 8 |
| Paralysis and paresis (excl cranial nerve) | 2 | 2 | | | 2 | 2 |
| Sensory abnormalities NEC | 4 | 5 | 2 | 2 | 2 | 3 |
| Speech and language abnormalities | 1 | 1 | | | 1 | 1 |
| Tremor (excl congenital) | 7 | 8 | 6 | 6 | 1 | 2 |
| | 95 | 111 | 53 | 63 | 42 | 48 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusion and disorientation | 1 | 1 | 1 | 1 | | |
| Disturbances in initiating and maintaining sleep | 1 | 2 | 1 | 2 | | |
| Fear symptoms and phobic disorders (incl social phobia) | 1 | 1 | | | 1 | 1 |
| Panic attacks and disorders | 2 | 2 | | | 2 | 2 |
| Parasomnias | 1 | 1 | 1 | 1 | | |
| | 6 | 7 | 3 | 4 | 3 | 3 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 8 | 10 | 1 | 1 | 7 | 9 |
| Bronchospasm and obstruction | 4 | 6 | 1 | 1 | 3 | 5 |
| Coughing and associated symptoms | 2 | 2 | | | 2 | 2 |
| Diaphragmatic disorders | 1 | 1 | | | 1 | 1 |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| Nasal congestion and inflammations | 1 | 1 | 1 | 1 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 2 | 1 | 1 | | 1 |
| Respiratory signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Respiratory tract disorders NEC | | 1 | | | | 1 |
| Upper respiratory tract signs and symptoms | 2 | 2 | 2 | 2 | | |
| | 23 | 29 | 7 | 7 | 16 | 22 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 1 | 2 | | | 1 | 2 |
| Apocrine and eccrine gland disorders | 5 | 5 | 3 | 3 | 2 | 2 |
| Bullous conditions | 1 | 1 | | | 1 | 1 |
| Dermal and epidermal conditions NEC | 2 | 2 | | | 2 | 2 |
| Dermatitis and eczema | 1 | 1 | | | 1 | 1 |
| Erythemas | 13 | 16 | | 2 | 13 | 14 |
| Pruritus NEC | 5 | 6 | | | 5 | 6 |
| Psoriatic conditions | 1 | 1 | 1 | 1 | | |
| Rashes, eruptions and exanthems NEC | 11 | 14 | | 1 | 11 | 13 |
| Skin vascular conditions NEC | 1 | 1 | 1 | 1 | | |
| Urticarias | 5 | 5 | | | 5 | 5 |
| | 46 | 54 | 5 | 8 | 41 | 46 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Site specific vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Vascular hypertensive disorders NEC | 1 | 1 | | | 1 | 1 |
| Vascular hypotensive disorders | 1 | 1 | 1 | 1 | | |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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Country Where Event Occurred

CYPRUS

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 4 | 5 | 4 | 4 | | 1 |
| | 4 | 5 | 4 | 4 | | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ischaemic coronary artery disorders | 1 | 2 | | | 1 | 2 |
| Rate and rhythm disorders NEC | 2 | 4 | 1 | 1 | 1 | 3 |
| | 3 | 6 | 1 | 1 | 2 | 5 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear disorders NEC | 2 | 2 | 2 | 2 |
| Hearing losses | 1 | 1 | 1 | 1 |
| Inner ear signs and symptoms | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid movement disorders | | 1 | | 1 | | |
| Ocular disorders NEC | 1 | 1 | 1 | 1 | | |
| Ocular sensation disorders | | 1 | | | | 1 |
| | 1 | 3 | 1 | 2 | | 1 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 1 | 1 | 1 | | |
| Gastrointestinal signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Nausea and vomiting symptoms | 7 | 7 | 7 | 7 | | |
| Oral soft tissue signs and symptoms | 1 | 2 | | | 1 | 2 |
| Tongue signs and symptoms | | 1 | | 1 | | |
| | 10 | 12 | 9 | 10 | 1 | 2 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 14 | 15 | 14 | 15 | | |
| Febrile disorders | 7 | 8 | 7 | 8 | | |
| Feelings and sensations NEC | 7 | 8 | 7 | 8 | | |
| Gait disturbances | 3 | 3 | 3 | 3 | | |
| General signs and symptoms NEC | | 1 | | 1 | | |
| Oedema NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Pain and discomfort NEC | 5 | 5 | 5 | 5 | | |
| Therapeutic and nontherapeutic responses | 1 | 1 | | | 1 | 1 |
| Vaccination site reactions | 12 | 14 | 12 | 14 | | |
| | 51 | 57 | 49 | 55 | 2 | 2 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | | 1 | | 1 | | |
| Anaphylactic and anaphylactoid responses | 2 | 2 | | | 2 | 2 |
| | 2 | 3 | | 1 | 2 | 2 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 2 | 2 | 1 | 1 | 1 | 1 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Medication errors, product use errors and issues NEC | 1 | 1 | 1 | 1 |
| Off label uses | 1 | 1 | 1 | 1 |
| Overdoses NEC | 1 | 1 | 1 | 1 |
| Product administration errors and issues | | 1 | | 1 |
| Skin injuries NEC | 1 | 1 | 1 | 1 |
| | 4 | 5 | 4 | 5 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 3 | 3 | 1 | 1 | 2 | 2 |
| Coagulation and bleeding analyses | 1 | 1 | 1 | 1 | | |
| Physical examination procedures and organ system status | 1 | 1 | 1 | 1 | | |
| Vascular tests NEC (incl blood pressure) | | 1 | | | | 1 |
| Virus identification and serology | | 1 | | | | 1 |
| | 5 | 7 | 3 | 3 | 2 | 4 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Sodium imbalance | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Bone related signs and symptoms | 1 | 1 | 1 | 1 |
| Joint related signs and symptoms | 8 | 8 | 8 | 8 |
| Muscle pains | 12 | 12 | 12 | 12 |
| Muscle weakness conditions | 1 | 1 | 1 | 1 |
| Musculoskeletal and connective tissue conditions NEC | 1 | 1 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 2 | 3 | 2 | 3 |
| | 25 | 26 | 25 | 26 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute polyneuropathies | 1 | 1 | 1 | 1 | | |
| Coordination and balance disturbances | 1 | 1 | 1 | 1 | | |
| Disturbances in consciousness NEC | 3 | 3 | | | 3 | 3 |
| Facial cranial nerve disorders | 5 | 8 | | | 5 | 8 |
| Generalised tonic-clonic seizures | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 7 | 9 | 7 | 9 | | |
| Migraine headaches | | 1 | | 1 | | |
| Neurological signs and symptoms NEC | 5 | 7 | 5 | 7 | | |
| Paraesthesias and dysaesthesias | 3 | 4 | 2 | 2 | 1 | 2 |
| Sensory abnormalities NEC | | 1 | | 1 | | |
| Tremor (excl congenital) | 2 | 2 | 2 | 2 | | |
| | 28 | 38 | 18 | 24 | 10 | 14 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Confusion and disorientation | 1 | 1 | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Cervix disorders NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 5 | 6 | 2 | 3 | 3 | 3 |
| Coughing and associated symptoms | | 1 | | 1 | | |
| Nasal congestion and inflammations | 1 | 1 | 1 | 1 | | |
| Nasal disorders NEC | 1 | 1 | | | 1 | 1 |
| Paranasal sinus disorders (excl infections and neoplasms) | | 1 | | 1 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 1 | 1 | 1 | | |
| Pulmonary thrombotic and embolic conditions | 2 | 2 | | | 2 | 2 |
| Respiratory tract disorders NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | | 2 | | 2 | | |
| | 11 | 16 | 4 | 9 | 7 | 7 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Apocrine and eccrine gland disorders | 1 | 1 | 1 | 1 |
| Dermatitis and eczema | 2 | 2 | 2 | 2 |
| Erythemas | 1 | 1 | 1 | 1 |
| Rashes, eruptions and exanthems NEC | | 1 | | 1 |
| | 4 | 5 | 4 | 5 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Site specific vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Vascular hypertensive disorders NEC | | 1 | | | | 1 |
| Vascular hypotensive disorders | 2 | 2 | | | 2 | 2 |
| Vasculitides NEC | 1 | 1 | 1 | 1 | | |
| | 4 | 5 | 2 | 2 | 2 | 3 |

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Country Where Event Occurred

CZECH REPUBLIC

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytoses NEC | 1 | 1 | 1 | 1 | | |
| Lymphatic system disorders NEC | 28 | 29 | 18 | 19 | 10 | 10 |
| | 29 | 30 | 19 | 20 | 10 | 10 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 7 | 7 | 2 | 2 | 5 | 5 |
| Ischaemic coronary artery disorders | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 12 | 13 | 5 | 6 | 7 | 7 |
| Supraventricular arrhythmias | 1 | 1 | | | 1 | 1 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 22 | 23 | 7 | 8 | 15 | 15 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Hearing losses | 2 | 2 | 1 | 1 | 1 | 1 |
| Inner ear disorders NEC | 1 | 1 | | | 1 | 1 |
| Inner ear signs and symptoms | 14 | 15 | 9 | 10 | 5 | 5 |
| | 21 | 22 | 11 | 12 | 10 | 10 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ocular disorders NEC | 2 | 2 | 2 | 2 | | |
| Ocular infections, inflammations and associated manifestations | 1 | 3 | 1 | 3 | | |
| Ocular sensation disorders | | 1 | | 1 | | |
| Visual disorders NEC | 3 | 4 | 3 | 4 | | |
| Visual impairment and blindness (excl colour blindness) | 2 | 2 | | | 2 | 2 |
| | 8 | 12 | 6 | 10 | 2 | 2 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dental pain and sensation disorders | 1 | 1 | 1 | 1 | | |
| Diarrhoea (excl infective) | 8 | 9 | 7 | 8 | 1 | 1 |
| Dyspeptic signs and symptoms | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 1 | 1 | 1 | 1 | | |
| Gastrointestinal signs and symptoms NEC | 2 | 3 | 1 | 2 | 1 | 1 |
| Gastrointestinal spastic and hypermotility disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Nausea and vomiting symptoms | 47 | 52 | 37 | 40 | 10 | 12 |
| Oral dryness and saliva altered | 2 | 2 | 2 | 2 | | |
| Oral soft tissue signs and symptoms | 8 | 9 | | 1 | 8 | 8 |
| Oral soft tissue swelling and oedema | 2 | 3 | | | 2 | 3 |
| Tongue signs and symptoms | 4 | 6 | 1 | 1 | 3 | 5 |
| | 78 | 89 | 52 | 58 | 26 | 31 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Application and instillation site reactions | 1 | 1 | | | 1 | 1 |
| Asthenic conditions | 78 | 90 | 63 | 75 | 15 | 15 |
| Febrile disorders | 71 | 75 | 51 | 55 | 20 | 20 |
| Feelings and sensations NEC | 60 | 63 | 52 | 54 | 8 | 9 |
| General signs and symptoms NEC | 25 | 28 | 9 | 9 | 16 | 19 |
| Injection site reactions | 1 | 1 | 1 | 1 | | |
| Mucosal findings abnormal | 2 | 2 | 1 | 1 | 1 | 1 |
| Oedema NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Pain and discomfort NEC | 18 | 19 | 11 | 12 | 7 | 7 |
| Therapeutic and nontherapeutic responses | 4 | 7 | | | 4 | 7 |
| Vaccination site reactions | 108 | 112 | 84 | 88 | 24 | 24 |
| | 372 | 402 | 274 | 297 | 98 | 105 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Cholestasis and jaundice | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 12 | 14 | 4 | 5 | 8 | 9 |
| Allergies to foods, food additives, drugs and other chemicals | 2 | 4 | 1 | 1 | 1 | 3 |
| Anaphylactic and anaphylactoid responses | 5 | 7 | | | 5 | 7 |
| | 19 | 25 | 5 | 6 | 14 | 19 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal infections | 1 | 1 | 1 | 1 | | |
| Bacterial infections NEC | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 13 | 15 | 4 | 4 | 9 | 11 |
| Influenza viral infections | 1 | 1 | 1 | 1 | | |
| Lower respiratory tract and lung infections | 2 | 2 | | | 2 | 2 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 1 | 1 | | | 1 | 1 |
| Skin structures and soft tissue infections | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract infections | | 1 | | 1 | | |
| | 20 | 23 | 7 | 8 | 13 | 15 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 2 | 2 | 2 | 2 | | |
| Medication errors, product use errors and issues NEC | 4 | 4 | 4 | 4 | | |
| Non-site specific injuries NEC | 1 | 1 | 1 | 1 | | |
| Off label uses | 4 | 4 | 4 | 4 | | |
| Product administration errors and issues | 87 | 87 | 87 | 87 | | |
| Product preparation errors and issues | 83 | 83 | 83 | 83 | | |
| Vaccination related complications | 2 | 2 | 1 | 1 | 1 | 1 |
| | 183 | 183 | 182 | 182 | 1 | 1 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 1 | 1 | 1 | 1 | | |
| Physical examination procedures and organ system status | 2 | 3 | 2 | 3 | | |
| Protein analyses NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Vascular tests NEC (incl blood pressure) | 6 | 7 | 5 | 5 | 1 | 2 |
| Virus identification and serology | 2 | 3 | 2 | 2 | | 1 |
| | 13 | 16 | 11 | 12 | 2 | 4 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 7 | 7 | 5 | 5 | 2 | 2 |
| Hyperglycaemic conditions NEC | 1 | 1 | 1 | 1 | | |
| Hypoglycaemic conditions NEC | 1 | 1 | 1 | 1 | | |
| Potassium imbalance | 2 | 2 | | | 2 | 2 |
| | 11 | 11 | 7 | 7 | 4 | 4 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 1 | | | 1 | 1 |
| Bone related signs and symptoms | 1 | 1 | | | 1 | 1 |
| Joint related disorders NEC | 1 | 1 | | | 1 | 1 |
| Joint related signs and symptoms | 33 | 36 | 27 | 30 | 6 | 6 |
| Muscle pains | 26 | 29 | 20 | 23 | 6 | 6 |
| Muscle related signs and symptoms NEC | 2 | 2 | | | 2 | 2 |
| Muscle weakness conditions | 3 | 3 | 3 | 3 | | |
| Musculoskeletal and connective tissue conditions NEC | 3 | 6 | 3 | 6 | | |
| Musculoskeletal and connective tissue pain and discomfort | 22 | 27 | 19 | 24 | 3 | 3 |
| | 92 | 106 | 72 | 86 | 20 | 20 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 1 | | | 1 | 1 |
| Cortical dysfunction NEC | 1 | 1 | 1 | 1 | | |
| Disturbances in consciousness NEC | 11 | 13 | 1 | 3 | 10 | 10 |
| Dyskinesias and movement disorders NEC | 1 | 1 | 1 | 1 | | |
| Facial cranial nerve disorders | 1 | 2 | | | 1 | 2 |
| Headaches NEC | 55 | 59 | 45 | 49 | 10 | 10 |
| Memory loss (excl dementia) | 2 | 2 | | | 2 | 2 |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | 1 | 1 | | |
| Migraine headaches | 1 | 1 | 1 | 1 | | |
| Narcolepsy and hypersomnia | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 19 | 21 | 8 | 9 | 11 | 12 |
| Neurologic visual problems NEC | 1 | 1 | | | 1 | 1 |
| Olfactory nerve disorders | 2 | 2 | 2 | 2 | | |
| Paraesthesias and dysaesthesias | 25 | 29 | 17 | 19 | 8 | 10 |
| Paralysis and paresis (excl cranial nerve) | 1 | 1 | | | 1 | 1 |
| Peripheral neuropathies NEC | 1 | 1 | | | 1 | 1 |
| Seizures and seizure disorders NEC | 2 | 2 | | | 2 | 2 |
| Sensory abnormalities NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Speech and language abnormalities | 3 | 3 | 1 | 1 | 2 | 2 |
| Transient cerebrovascular events | 1 | 1 | | | 1 | 1 |
| Tremor (excl congenital) | 6 | 6 | 4 | 4 | 2 | 2 |
| | 138 | 151 | 83 | 92 | 55 | 59 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 4 | 5 | 3 | 4 | 1 | 1 |
| Communications disorders | 1 | 1 | | | 1 | 1 |
| Confusion and disorientation | 4 | 4 | 1 | 1 | 3 | 3 |
| Deliria | 1 | 1 | | | 1 | 1 |
| Depressive disorders | 1 | 1 | 1 | 1 | | |
| Disturbances in initiating and maintaining sleep | 3 | 3 | 2 | 2 | 1 | 1 |
| Eating disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Emotional and mood disturbances NEC | 1 | 1 | 1 | 1 | | |
| Hallucinations (excl sleep-related) | 2 | 2 | | | 2 | 2 |
| Increased physical activity levels | 1 | 1 | 1 | 1 | | |
| Mood alterations with depressive symptoms | 1 | 1 | 1 | 1 | | |
| Mood disorders NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Perception disturbances NEC | 1 | 1 | 1 | 1 | | |
| Sleep disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Speech and language usage disturbances | 1 | 1 | 1 | 1 | | |
| | 28 | 29 | 15 | 16 | 13 | 13 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 16 | 22 | 5 | 7 | 11 | 15 |
| Bronchospasm and obstruction | 1 | 2 | 1 | 1 | | 1 |
| Conditions associated with abnormal gas exchange | 3 | 3 | 1 | 1 | 2 | 2 |
| Coughing and associated symptoms | 5 | 6 | 4 | 5 | 1 | 1 |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 1 | 1 | 1 | 1 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 2 | 4 | | 1 | 2 | 3 |
| Pulmonary thrombotic and embolic conditions | 1 | 1 | | | 1 | 1 |
| Respiratory failures (excl neonatal) | 1 | 1 | | | 1 | 1 |
| Respiratory tract disorders NEC | 2 | 2 | | | 2 | 2 |
| Upper respiratory tract signs and symptoms | 7 | 9 | 3 | 4 | 4 | 5 |
| | 40 | 52 | 15 | 20 | 25 | 32 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | | 1 | | | | 1 |
| Apocrine and eccrine gland disorders | 7 | 7 | 7 | 7 | | |
| Dermal and epidermal conditions NEC | 4 | 4 | 3 | 3 | 1 | 1 |
| Dermatitis and eczema | 2 | 2 | 1 | 1 | 1 | 1 |
| Erythemas | 13 | 15 | 7 | 9 | 6 | 6 |
| Photosensitivity and photodermatosis conditions | 1 | 1 | 1 | 1 | | |
| Pruritus NEC | 14 | 15 | 4 | 5 | 10 | 10 |
| Rashes, eruptions and exanthems NEC | 19 | 20 | 6 | 7 | 13 | 13 |
| Urticarias | 2 | 2 | 2 | 2 | | |
| | 62 | 67 | 31 | 35 | 31 | 32 |

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System Organ Class

Surgical and medical procedures

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Limb therapeutic procedures | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circulatory collapse and shock | 5 | 6 | | | 5 | 6 |
| Lymphoedemas | 1 | 1 | 1 | 1 | | |
| Peripheral vascular disorders NEC | 5 | 5 | 2 | 2 | 3 | 3 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 5 | 5 | 5 | 5 | | |
| Site specific vascular disorders NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Vascular hypertensive disorders NEC | 4 | 5 | 1 | 2 | 3 | 3 |
| Vascular hypotensive disorders | 8 | 9 | 3 | 3 | 5 | 6 |
| | 31 | 34 | 14 | 15 | 17 | 19 |

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Country Where Event Occurred

DENMARK

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemias NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Leukopenias NEC | 2 | 2 | | | 2 | 2 |
| Lymphatic system disorders NEC | 18 | 22 | 11 | 15 | 7 | 7 |
| | 22 | 26 | 12 | 16 | 10 | 10 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 7 | 17 | 5 | 10 | 2 | 7 |
| Heart failures NEC | 1 | 1 | | | 1 | 1 |
| Ischaemic coronary artery disorders | 2 | 2 | | | 2 | 2 |
| Rate and rhythm disorders NEC | 2 | 6 | | 1 | 2 | 5 |
| Supraventricular arrhythmias | 3 | 5 | 1 | 2 | 2 | 3 |
| Ventricular arrhythmias and cardiac arrest | | 1 | | | | 1 |
| | 15 | 32 | 6 | 13 | 9 | 19 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| External ear disorders NEC | 1 | 1 | 1 | 1 | | |
| Hearing losses | 2 | 2 | 2 | 2 | | |
| Hyperacusia | 2 | 2 | 1 | 1 | 1 | 1 |
| Inner ear signs and symptoms | 3 | 4 | 2 | 2 | 1 | 2 |
| | 10 | 11 | 7 | 7 | 3 | 4 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival and corneal bleeding and vascular disorders | 1 | 1 | | | 1 | 1 |
| Lacrimation disorders | 2 | 3 | 2 | 3 | | |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 3 | 1 | 2 | | 1 |
| Ocular disorders NEC | 4 | 7 | 3 | 6 | 1 | 1 |
| Ocular infections, inflammations and associated manifestations | 1 | 3 | | 2 | 1 | 1 |
| Ocular sensation disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual disorders NEC | 3 | 5 | | 1 | 3 | 4 |
| Visual impairment and blindness (excl colour blindness) | | 1 | | 1 | | |
| | 14 | 25 | 7 | 16 | 7 | 9 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 11 | 16 | 4 | 9 | 7 | 7 |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 7 | 9 | 3 | 5 | 4 | 4 |
| Gastrointestinal atonic and hypomotility disorders NEC | | 1 | | 1 | | |
| Gastrointestinal signs and symptoms NEC | 3 | 5 | 1 | 2 | 2 | 3 |
| Nausea and vomiting symptoms | 75 | 105 | 42 | 59 | 33 | 46 |
| Oral dryness and saliva altered | 4 | 4 | 3 | 3 | 1 | 1 |
| Oral soft tissue signs and symptoms | 14 | 16 | 9 | 10 | 5 | 6 |
| Oral soft tissue swelling and oedema | 2 | 2 | | | 2 | 2 |
| Stomatitis and ulceration | 1 | 1 | 1 | 1 | | |
| Tongue signs and symptoms | 5 | 9 | 1 | 2 | 4 | 7 |
| | 123 | 169 | 65 | 93 | 58 | 76 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 124 | 178 | 84 | 119 | 40 | 59 |
| Death and sudden death | 8 | 10 | | | 8 | 10 |
| Febrile disorders | 91 | 126 | 62 | 90 | 29 | 36 |
| Feelings and sensations NEC | 51 | 75 | 35 | 52 | 16 | 23 |
| Gait disturbances | 1 | 1 | | | 1 | 1 |
| General signs and symptoms NEC | 35 | 52 | 15 | 23 | 20 | 29 |
| Injection site reactions | 1 | 2 | 1 | 2 | | |
| Interactions | | 1 | | | | 1 |
| Oedema NEC | 2 | 3 | | 1 | 2 | 2 |
| Pain and discomfort NEC | 34 | 51 | 21 | 30 | 13 | 21 |
| Therapeutic and nontherapeutic responses | 9 | 10 | | | 9 | 10 |
| Vaccination site reactions | 125 | 199 | 110 | 178 | 15 | 21 |
| | 481 | 708 | 328 | 495 | 153 | 213 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 10 | 16 | 1 | 2 | 9 | 14 |
| Anaphylactic and anaphylactoid responses | 6 | 14 | | | 6 | 14 |
| Atopic disorders | 1 | 1 | 1 | 1 | | |
| | 17 | 31 | 2 | 3 | 15 | 28 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacterial infections NEC | 3 | 3 | | | 3 | 3 |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 14 | 16 | | | 14 | 16 |
| Eye and eyelid infections | 1 | 1 | | | 1 | 1 |
| Fungal infections NEC | 1 | 1 | 1 | 1 | | |
| Herpes viral infections | 1 | 1 | 1 | 1 | | |
| Infections NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Influenza viral infections | 5 | 5 | 4 | 4 | 1 | 1 |
| Lower respiratory tract and lung infections | 7 | 8 | | | 7 | 8 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | 2 | | | | 2 |
| Streptococcal infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 4 | 5 | 3 | 4 | 1 | 1 |
| Urinary tract infections | 2 | 2 | 1 | 1 | 1 | 1 |
| | 42 | 49 | 11 | 12 | 31 | 37 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accidental exposures to product | 1 | 1 | 1 | 1 | | |
| Exposures associated with pregnancy, delivery and lactation | 1 | 1 | 1 | 1 | | |
| Medication errors, product use errors and issues NEC | 6 | 6 | 6 | 6 | | |
| Non-site specific injuries NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Off label uses | 7 | 7 | 7 | 7 | | |
| Pathways and sources of exposure | 1 | 1 | 1 | 1 | | |
| Product administration errors and issues | 4 | 7 | 3 | 6 | 1 | 1 |
| Site specific injuries NEC | 1 | 1 | | | 1 | 1 |
| Underdoses NEC | 1 | 2 | 1 | 2 | | |
| Vaccination related complications | 1 | 2 | 1 | 1 | | 1 |
| | 26 | 31 | 22 | 26 | 4 | 5 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 1 | 2 | | | 1 | 2 |
| Carbohydrate tolerance analyses (incl diabetes) | | 1 | | 1 | | |
| ECG investigations | 2 | 2 | | | 2 | 2 |
| Heart rate and pulse investigations | 5 | 8 | 4 | 6 | 1 | 2 |
| Liver function analyses | 1 | 1 | 1 | 1 | | |
| Mineral and electrolyte analyses | 2 | 2 | 2 | 2 | | |
| Physical examination procedures and organ system status | 3 | 6 | 2 | 5 | 1 | 1 |
| Protein analyses NEC | 6 | 6 | 2 | 2 | 4 | 4 |
| Renal function analyses | 2 | 2 | | | 2 | 2 |
| Skeletal and cardiac muscle analyses | 2 | 2 | | | 2 | 2 |
| Tissue enzyme analyses NEC | 1 | 1 | 1 | 1 | | |
| Vascular tests NEC (incl blood pressure) | 5 | 10 | 2 | 3 | 3 | 7 |
| Virus identification and serology | 2 | 2 | 1 | 1 | 1 | 1 |
| White blood cell analyses | 1 | 1 | 1 | 1 | | |
| | 33 | 46 | 16 | 23 | 17 | 23 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 2 | 3 | 2 | 3 | | |
| Fluid intake decreased | | 1 | | 1 | | |
| Hypoglycaemic conditions NEC | 1 | 1 | 1 | 1 | | |
| Potassium imbalance | 1 | 1 | | | 1 | 1 |
| | 4 | 6 | 3 | 5 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint related disorders NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Joint related signs and symptoms | 16 | 27 | 8 | 19 | 8 | 8 |
| Muscle pains | 40 | 62 | 32 | 53 | 8 | 9 |
| Muscle related signs and symptoms NEC | 7 | 10 | 4 | 7 | 3 | 3 |
| Muscle weakness conditions | 4 | 4 | 1 | 1 | 3 | 3 |
| Musculoskeletal and connective tissue conditions NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Musculoskeletal and connective tissue pain and discomfort | 28 | 38 | 22 | 32 | 6 | 6 |
| Soft tissue disorders NEC | 1 | 1 | 1 | 1 | | |
| | 101 | 148 | 71 | 116 | 30 | 32 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Leukaemias acute NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 2 | 2 | | | 2 | 2 |
| Coma states | | 1 | | | | 1 |
| Coordination and balance disturbances | 3 | 3 | | | 3 | 3 |
| Disturbances in consciousness NEC | 22 | 29 | 6 | 6 | 16 | 23 |
| Dyskinesias and movement disorders NEC | 1 | 1 | | | 1 | 1 |
| Generalised tonic-clonic seizures | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 115 | 159 | 84 | 120 | 31 | 39 |
| Mental impairment (excl dementia and memory loss) | 1 | 3 | 1 | 2 | | 1 |
| Migraine headaches | 2 | 3 | 1 | 2 | 1 | 1 |
| Narcolepsy and hypersomnia | 1 | 1 | 1 | 1 | | |
| Neurological signs and symptoms NEC | 68 | 106 | 36 | 53 | 32 | 53 |
| Neurologic visual problems NEC | 1 | 1 | | | 1 | 1 |
| Olfactory nerve disorders | 1 | 1 | 1 | 1 | | |
| Paraesthesias and dysaesthesias | 25 | 34 | 17 | 22 | 8 | 12 |
| Paralysis and paresis (excl cranial nerve) | | 1 | | | | 1 |
| Seizures and seizure disorders NEC | 2 | 2 | | | 2 | 2 |
| Sensory abnormalities NEC | 9 | 11 | 5 | 7 | 4 | 4 |
| Tremor (excl congenital) | 6 | 9 | 3 | 3 | 3 | 6 |
| | 260 | 368 | 155 | 217 | 105 | 151 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 2 | 3 | 1 | 1 | 1 | 2 |
| Behaviour and socialisation disturbances | | 1 | | | | 1 |
| Confusion and disorientation | 4 | 5 | 1 | 1 | 3 | 4 |
| Deliria | 1 | 1 | | | 1 | 1 |
| Delusional symptoms | 1 | 1 | | | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 3 | 4 | 3 | 4 | | |
| Hallucinations (excl sleep-related) | 1 | 1 | | | 1 | 1 |
| Increased physical activity levels | 1 | 5 | 1 | 5 | | |
| Panic attacks and disorders | 1 | 1 | | | 1 | 1 |
| Perception disturbances NEC | 2 | 3 | 2 | 3 | | |
| Thinking disturbances | | 1 | | | | 1 |
| | 16 | 26 | 8 | 14 | 8 | 12 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 1 | 2 | | | 1 | 2 |
| Renal failure and impairment | 1 | 1 | | | 1 | 1 |
| Urinary tract signs and symptoms NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 4 | 5 | 1 | 1 | 3 | 4 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 | | |
| Menopausal effects on the genitourinary tract | 1 | 1 | | | 1 | 1 |
| Vulvovaginal disorders NEC | 1 | 1 | 1 | 1 | | |
| Vulvovaginal signs and symptoms | 3 | 3 | 3 | 3 | | |
| | 6 | 6 | 5 | 5 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 33 | 56 | 10 | 17 | 23 | 39 |
| Bronchospasm and obstruction | 6 | 9 | 1 | 1 | 5 | 8 |
| Conditions associated with abnormal gas exchange | 2 | 2 | | | 2 | 2 |
| Coughing and associated symptoms | 9 | 17 | 7 | 10 | 2 | 7 |
| Laryngeal spasm, oedema and obstruction | | 1 | | | | 1 |
| Lower respiratory tract inflammatory and immunologic conditions | | 1 | | | | 1 |
| Lower respiratory tract signs and symptoms | | 1 | | | | 1 |
| Nasal congestion and inflammations | 3 | 4 | 3 | 4 | | |
| Nasal disorders NEC | 1 | 2 | | 1 | 1 | 1 |
| Parenchymal lung disorders NEC | | 1 | | | | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 6 | 11 | 3 | 3 | 3 | 8 |
| Pneumothorax and pleural effusions NEC | 1 | 2 | | | 1 | 2 |
| Pulmonary hypertensions | 1 | 1 | | | 1 | 1 |
| Pulmonary oedemas | 2 | 3 | | | 2 | 3 |
| Pulmonary thrombotic and embolic conditions | 3 | 3 | | | 3 | 3 |
| Respiratory failures (excl neonatal) | 7 | 9 | | | 7 | 9 |
| Respiratory signs and symptoms NEC | 2 | 2 | 2 | 2 | | |
| Respiratory tract disorders NEC | | 1 | | | | 1 |
| Upper respiratory tract signs and symptoms | 32 | 46 | 27 | 37 | 5 | 9 |
| | 108 | 172 | 53 | 75 | 55 | 97 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 1 | 5 | | | 1 | 5 |
| Apocrine and eccrine gland disorders | 7 | 10 | 4 | 6 | 3 | 4 |
| Dermal and epidermal conditions NEC | 2 | 3 | 2 | 3 | | |
| Dermatitis and eczema | 2 | 3 | 1 | 1 | 1 | 2 |
| Erythemas | 21 | 27 | 12 | 16 | 9 | 11 |
| Pruritus NEC | 23 | 32 | 15 | 23 | 8 | 9 |
| Rashes, eruptions and exanthems NEC | 24 | 42 | 20 | 30 | 4 | 12 |
| Urticarias | 10 | 20 | 7 | 14 | 3 | 6 |
| | 90 | 142 | 61 | 93 | 29 | 49 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure disorders NEC | 1 | 1 | 1 | 1 | | |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Non-site specific embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Non-site specific vascular disorders NEC | | 1 | | | | 1 |
| Peripheral embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 6 | 14 | 6 | 10 | | 4 |
| Site specific vascular disorders NEC | 2 | 8 | | 3 | 2 | 5 |
| Vascular hypertensive disorders NEC | 9 | 11 | 4 | 5 | 5 | 6 |
| Vascular hypotensive disorders | 4 | 6 | 1 | 1 | 3 | 5 |
| | 25 | 44 | 12 | 20 | 13 | 24 |

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Country Where Event Occurred

ECUADOR

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vaccination site reactions | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Upper respiratory tract infections | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vascular tests NEC (incl blood pressure) | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Musculoskeletal and connective tissue conditions NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

ESTONIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | | 1 | | 1 | | |
| Rate and rhythm disorders NEC | 2 | 3 | 1 | 2 | 1 | 1 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | 1 | 3 | 2 | 2 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 1 | 1 | 1 | | |
| Nausea and vomiting symptoms | 10 | 10 | 5 | 5 | 5 | 5 |
| Oral soft tissue signs and symptoms | 3 | 3 | 3 | 3 | | |
| | 14 | 14 | 9 | 9 | 5 | 5 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 23 | 25 | 14 | 16 | 9 | 9 |
| Body temperature altered | 1 | 1 | | | 1 | 1 |
| Febrile disorders | 14 | 14 | 12 | 12 | 2 | 2 |
| Feelings and sensations NEC | 7 | 8 | 6 | 7 | 1 | 1 |
| Pain and discomfort NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Therapeutic and nontherapeutic responses | | 1 | | | | 1 |
| Vaccination site reactions | 30 | 31 | 30 | 31 | | |
| | 77 | 82 | 63 | 67 | 14 | 15 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Allergies to foods, food additives, drugs and other chemicals | 1 | 1 | | | 1 | 1 |
| Immune and associated conditions NEC | 1 | 1 | | | 1 | 1 |
| | 6 | 6 | 1 | 1 | 5 | 5 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | | 1 | | | | 1 |
| Herpes viral infections | 2 | 2 | 2 | 2 | | |
| Lower respiratory tract and lung infections | 1 | 1 | | | 1 | 1 |
| | 3 | 4 | 2 | 2 | 1 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 1 | 5 | 1 | 5 | | |
| Fractures and dislocations NEC | | 1 | | | | 1 |
| Medication errors, product use errors and issues NEC | 1 | 2 | 1 | 2 | | |
| Non-site specific injuries NEC | 1 | 1 | 1 | 1 | | |
| Off label uses | 1 | 2 | 1 | 2 | | |
| Underdoses NEC | | 1 | | 1 | | |
| | 4 | 12 | 4 | 11 | | 1 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Skeletal and cardiac muscle analyses | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Appetite disorders | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 1 | 1 | | | 1 | 1 |
| Joint related signs and symptoms | 5 | 6 | 5 | 6 | | |
| Muscle pains | 6 | 7 | 5 | 6 | 1 | 1 |
| Muscle related signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Muscle weakness conditions | 1 | 1 | 1 | 1 | | |
| Musculoskeletal and connective tissue pain and discomfort | 6 | 7 | 4 | 5 | 2 | 2 |
| | 20 | 23 | 16 | 19 | 4 | 4 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 2 | 2 | | | 2 | 2 |
| Disturbances in consciousness NEC | 7 | 7 | 4 | 4 | 3 | 3 |
| Facial cranial nerve disorders | | 1 | | 1 | | |
| Headaches NEC | 18 | 20 | 14 | 16 | 4 | 4 |
| Migraine headaches | 1 | 1 | 1 | 1 | | |
| Neurological signs and symptoms NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Paraesthesias and dysaesthesias | 11 | 17 | 9 | 15 | 2 | 2 |
| Sensory abnormalities NEC | 5 | 5 | 4 | 4 | 1 | 1 |
| Speech and language abnormalities | 1 | 1 | | | 1 | 1 |
| | 50 | 59 | 33 | 42 | 17 | 17 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Device physical property and chemical issues | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Anxiety symptoms | 5 | 7 | 5 | 7 |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 |
| Increased physical activity levels | | 1 | | 1 |
| | 6 | 9 | 6 | 9 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 4 | 4 | 2 | 2 | 2 | 2 |
| Coughing and associated symptoms | 2 | 2 | 2 | 2 | | |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Nasal disorders NEC | 1 | 1 | 1 | 1 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 1 | 1 | 1 | | |
| Pulmonary thrombotic and embolic conditions | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| | 12 | 12 | 7 | 7 | 5 | 5 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Apocrine and eccrine gland disorders | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Site specific vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Vascular hypertensive disorders NEC | 1 | 2 | 1 | 2 | | |
| Vascular hypotensive disorders | 2 | 2 | | | 2 | 2 |
| | 5 | 6 | 2 | 3 | 3 | 3 |

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Country Where Event Occurred

FINLAND

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 20 | 24 | 8 | 12 | 12 | 12 |
| | 20 | 24 | 8 | 12 | 12 | 12 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 9 | 10 | 2 | 3 | 7 | 7 |
| Cardiomyopathies | 1 | 1 | | | 1 | 1 |
| Ischaemic coronary artery disorders | 1 | 1 | | | 1 | 1 |
| Noninfectious myocarditis | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 10 | 13 | 1 | 3 | 9 | 10 |
| Supraventricular arrhythmias | 2 | 2 | | | 2 | 2 |
| | 24 | 28 | 3 | 6 | 21 | 22 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 4 | 4 | 4 | 4 | | |
| Inner ear signs and symptoms | 4 | 4 | 1 | 1 | 3 | 3 |
| Tympanic membrane disorders (excl infections) | 1 | 1 | 1 | 1 | | |
| | 9 | 9 | 6 | 6 | 3 | 3 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid movement disorders | 1 | 1 | | | 1 | 1 |
| Lacrimation disorders | 1 | 1 | | | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 6 | 6 | 1 | 1 | 5 | 5 |
| Ocular bleeding and vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Ocular disorders NEC | 5 | 5 | 2 | 2 | 3 | 3 |
| Ocular nerve and muscle disorders | 2 | 2 | | | 2 | 2 |
| Ocular sensation disorders | 2 | 2 | | | 2 | 2 |
| Pupil disorders | 1 | 1 | 1 | 1 | | |
| Visual disorders NEC | 2 | 2 | | | 2 | 2 |
| Visual impairment and blindness (excl colour blindness) | 2 | 2 | | | 2 | 2 |
| | 23 | 23 | 4 | 4 | 19 | 19 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dental pain and sensation disorders | 2 | 2 | 2 | 2 | | |
| Diarrhoea (excl infective) | 4 | 4 | 2 | 2 | 2 | 2 |
| Flatulence, bloating and distension | 2 | 2 | 2 | 2 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 10 | 10 | 3 | 3 | 7 | 7 |
| Gastrointestinal disorders NEC | 1 | 1 | 1 | 1 | | |
| Gastrointestinal signs and symptoms NEC | 8 | 8 | | | 8 | 8 |
| Gingival disorders, signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Nausea and vomiting symptoms | 37 | 40 | 12 | 13 | 25 | 27 |
| Oral dryness and saliva altered | 1 | 1 | | | 1 | 1 |
| Oral soft tissue disorders NEC | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 22 | 26 | 6 | 9 | 16 | 17 |
| Oral soft tissue swelling and oedema | 5 | 5 | 2 | 2 | 3 | 3 |
| Tongue disorders | 1 | 1 | | | 1 | 1 |
| Tongue signs and symptoms | 2 | 2 | | | 2 | 2 |
| | 97 | 104 | 31 | 35 | 66 | 69 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 83 | 91 | 25 | 31 | 58 | 60 |
| Death and sudden death | 5 | 5 | | | 5 | 5 |
| Febrile disorders | 45 | 48 | 6 | 9 | 39 | 39 |
| Feelings and sensations NEC | 32 | 34 | 8 | 10 | 24 | 24 |
| Gait disturbances | 3 | 4 | | 1 | 3 | 3 |
| General signs and symptoms NEC | 17 | 18 | 1 | 2 | 16 | 16 |
| Mass conditions NEC | | 1 | | 1 | | |
| Oedema NEC | 10 | 10 | 2 | 2 | 8 | 8 |
| Pain and discomfort NEC | 25 | 28 | 9 | 10 | 16 | 18 |
| Vaccination site reactions | 90 | 103 | 45 | 58 | 45 | 45 |
| | 310 | 342 | 96 | 124 | 214 | 218 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 7 | 9 | 1 | 2 | 6 | 7 |
| Allergies to foods, food additives, drugs and other chemicals | 1 | 1 | | | 1 | 1 |
| Anaphylactic and anaphylactoid responses | 9 | 12 | | | 9 | 12 |
| | 17 | 22 | 1 | 2 | 16 | 20 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal infections | 1 | 1 | | | 1 | 1 |
| Herpes viral infections | 4 | 4 | 2 | 2 | 2 | 2 |
| Infections NEC | 2 | 2 | | | 2 | 2 |
| Lower respiratory tract and lung infections | 2 | 2 | | | 2 | 2 |
| Skin structures and soft tissue infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 1 | 1 | | | 1 | 1 |
| Urinary tract infections | 2 | 2 | | | 2 | 2 |
| Viral infections NEC | 2 | 2 | | | 2 | 2 |
| | 15 | 15 | 2 | 2 | 13 | 13 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 1 | 1 | 1 | 1 | | |
| Medication errors, product use errors and issues NEC | 2 | 2 | 2 | 2 | | |
| Non-site specific injuries NEC | 1 | 1 | | | 1 | 1 |
| Off label uses | 1 | 1 | 1 | 1 | | |
| Product administration errors and issues | 20 | 20 | 20 | 20 | | |
| Product preparation errors and issues | 12 | 12 | 12 | 12 | | |
| | 37 | 37 | 36 | 36 | 1 | 1 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Auditory function diagnostic procedures | 2 | 2 | 2 | 2 | | |
| Blood gas and acid base analyses | 1 | 1 | | | 1 | 1 |
| Bone marrow and immune tissue imaging procedures | 1 | 1 | | | 1 | 1 |
| Chemistry analyses NEC | 1 | 1 | | | 1 | 1 |
| Heart rate and pulse investigations | 14 | 15 | 1 | 1 | 13 | 14 |
| Musculoskeletal and soft tissue histopathology procedures | 1 | 1 | | | 1 | 1 |
| Physical examination procedures and organ system status | 5 | 5 | 1 | 1 | 4 | 4 |
| Protein analyses NEC | 7 | 8 | | 1 | 7 | 7 |
| Vascular tests NEC (incl blood pressure) | 14 | 14 | 1 | 1 | 13 | 13 |
| | 46 | 48 | 5 | 6 | 41 | 42 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Appetite disorders | 1 | 1 | 1 | 1 |
| General nutritional disorders NEC | 1 | 1 | 1 | 1 |
| Potassium imbalance | 3 | 5 | 3 | 5 |
| | 5 | 7 | 5 | 7 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 1 | | | 1 | 1 |
| Bone related signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| Joint related signs and symptoms | 18 | 19 | 5 | 6 | 13 | 13 |
| Muscle pains | 27 | 30 | 3 | 6 | 24 | 24 |
| Muscle related signs and symptoms NEC | 6 | 6 | 1 | 1 | 5 | 5 |
| Muscle tone abnormalities | 1 | 2 | 1 | 2 | | |
| Muscle weakness conditions | 11 | 11 | 2 | 2 | 9 | 9 |
| Musculoskeletal and connective tissue conditions NEC | 3 | 4 | | 1 | 3 | 3 |
| Musculoskeletal and connective tissue pain and discomfort | 45 | 49 | 14 | 18 | 31 | 31 |
| Spondyloarthropathies | 2 | 2 | | | 2 | 2 |
| Tendon disorders | 1 | 1 | | | 1 | 1 |
| | 117 | 127 | 27 | 37 | 90 | 90 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Lymphomas unspecified NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alzheimer's disease (incl subtypes) | 1 | 2 | | | 1 | 2 |
| Central nervous system haemorrhages and cerebrovascular accidents | 2 | 2 | | | 2 | 2 |
| Coordination and balance disturbances | 2 | 2 | | | 2 | 2 |
| Cortical dysfunction NEC | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 8 | 10 | | 1 | 8 | 9 |
| Dyskinesias and movement disorders NEC | 1 | 1 | | | 1 | 1 |
| Dystonias | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 8 | 8 | | | 8 | 8 |
| Headaches NEC | 47 | 50 | 11 | 12 | 36 | 38 |
| Memory loss (excl dementia) | 1 | 1 | 1 | 1 | | |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | 1 | 1 | | |
| Migraine headaches | 2 | 3 | | | 2 | 3 |
| Muscle tone abnormal | 2 | 2 | | | 2 | 2 |
| Neurological signs and symptoms NEC | 19 | 21 | | 1 | 19 | 20 |
| Neuromuscular disorders NEC | 1 | 1 | | | 1 | 1 |
| Paraesthesias and dysaesthesias | 42 | 44 | 7 | 8 | 35 | 36 |
| Paralysis and paresis (excl cranial nerve) | 1 | 1 | | | 1 | 1 |
| Seizures and seizure disorders NEC | 3 | 4 | | | 3 | 4 |
| Sensory abnormalities NEC | 7 | 7 | 2 | 2 | 5 | 5 |
| Speech and language abnormalities | 5 | 5 | | | 5 | 5 |
| Transient cerebrovascular events | 1 | 1 | | | 1 | 1 |
| Tremor (excl congenital) | 4 | 5 | | | 4 | 5 |
| | 160 | 173 | 22 | 26 | 138 | 147 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusion and disorientation | 3 | 3 | 1 | 1 | 2 | 2 |
| Disturbances in initiating and maintaining sleep | 5 | 5 | 2 | 2 | 3 | 3 |
| Hallucinations (excl sleep-related) | 1 | 1 | | | 1 | 1 |
| Perception disturbances NEC | | 1 | | 1 | | |
| Suicidal and self-injurious behaviour | 1 | 1 | | | 1 | 1 |
| | 10 | 11 | 3 | 4 | 7 | 7 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Benign and malignant breast neoplasms | 1 | 1 | 1 | 1 |
| Menstruation and uterine bleeding NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 35 | 38 | 4 | 4 | 31 | 34 |
| Bronchospasm and obstruction | 4 | 4 | 1 | 1 | 3 | 3 |
| Coughing and associated symptoms | 8 | 9 | | | 8 | 9 |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract inflammatory and immunologic conditions | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 2 | 2 | | | 2 | 2 |
| Nasal congestion and inflammations | 2 | 2 | | | 2 | 2 |
| Nasal disorders NEC | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 10 | 12 | 3 | 3 | 7 | 9 |
| Pulmonary oedemas | 1 | 1 | | | 1 | 1 |
| Respiratory tract disorders NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 32 | 33 | 10 | 10 | 22 | 23 |
| | 98 | 105 | 18 | 18 | 80 | 87 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 7 | 7 | 2 | 2 | 5 | 5 |
| Bullous conditions | 1 | 1 | | | 1 | 1 |
| Dermal and epidermal conditions NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Dermatitis and eczema | 2 | 2 | | | 2 | 2 |
| Erythemas | 19 | 22 | 4 | 5 | 15 | 17 |
| Pruritus NEC | 7 | 7 | 5 | 5 | 2 | 2 |
| Rashes, eruptions and exanthems NEC | 8 | 11 | 3 | 4 | 5 | 7 |
| Urticarias | 15 | 16 | 6 | 6 | 9 | 10 |
| | 63 | 70 | 22 | 24 | 41 | 46 |

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System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disability issues | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure disorders NEC | 1 | 1 | | | 1 | 1 |
| Haemorrhages NEC | 2 | 2 | 2 | 2 | | |
| Peripheral embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 7 | 7 | | | 7 | 7 |
| Site specific vascular disorders NEC | 4 | 4 | | | 4 | 4 |
| Vascular hypotensive disorders | | 1 | | | | 1 |
| | 15 | 16 | 2 | 2 | 13 | 14 |

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Country Where Event Occurred

FRANCE

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemia deficiencies | 1 | 1 | | | 1 | 1 |
| Anaemias NEC | 2 | 2 | | | 2 | 2 |
| Eosinophilic disorders | 1 | 1 | | | 1 | 1 |
| Leukocytoses NEC | 6 | 7 | | | 6 | 7 |
| Leukopenias NEC | 5 | 6 | | 1 | 5 | 5 |
| Lymphatic system disorders NEC | 32 | 34 | 21 | 23 | 11 | 11 |
| Marrow depression and hypoplastic anaemias | 2 | 2 | | | 2 | 2 |
| Neutropenias | 3 | 3 | | | 3 | 3 |
| Thrombocytopenias | 5 | 6 | | | 5 | 6 |
| | 57 | 62 | 21 | 24 | 36 | 38 |

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System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 8 | 8 | | | 8 | 8 |
| Cardiac disorders NEC | 3 | 3 | | | 3 | 3 |
| Cardiac signs and symptoms NEC | 12 | 13 | 5 | 6 | 7 | 7 |
| Cardiomyopathies | 1 | 1 | | | 1 | 1 |
| Coronary artery disorders NEC | 2 | 2 | | | 2 | 2 |
| Heart failures NEC | 26 | 28 | | | 26 | 28 |
| Ischaemic coronary artery disorders | 25 | 25 | | | 25 | 25 |
| Left ventricular failures | 1 | 1 | | | 1 | 1 |
| Mitral valvular disorders | 1 | 1 | | | 1 | 1 |
| Myocardial disorders NEC | 3 | 3 | | | 3 | 3 |
| Noninfectious myocarditis | 1 | 1 | | | 1 | 1 |
| Noninfectious pericarditis | 6 | 6 | | | 6 | 6 |
| Pericardial disorders NEC | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 105 | 110 | 19 | 21 | 86 | 89 |
| Supraventricular arrhythmias | 31 | 34 | 1 | 1 | 30 | 33 |
| Ventricular arrhythmias and cardiac arrest | 16 | 19 | | | 16 | 19 |
| | 242 | 256 | 25 | 28 | 217 | 228 |

System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Inborn errors of amino acid metabolism | 1 | 1 | 1 | 1 |
| Tongue disorders congenital | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 7 | 7 | 5 | 5 | 2 | 2 |
| Hearing losses | 4 | 4 | | | 4 | 4 |
| Inner ear disorders NEC | 4 | 4 | | | 4 | 4 |
| Inner ear signs and symptoms | 38 | 38 | 12 | 12 | 26 | 26 |
| | 53 | 53 | 17 | 17 | 36 | 36 |

System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic thyroiditis | 1 | 1 | | | 1 | 1 |
| Thyroid disorders NEC | 1 | 1 | 1 | 1 | | |
| Thyroid hyperfunction disorders | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival and corneal bleeding and vascular disorders | 6 | 6 | | | 6 | 6 |
| Eyelid movement disorders | 3 | 3 | 1 | 1 | 2 | 2 |
| Lacrimation disorders | 3 | 3 | 1 | 1 | 2 | 2 |
| Lid bleeding and vascular disorders | 1 | 1 | 1 | 1 | | |
| Lid, lash and lacrimal infections, irritations and inflammations | 6 | 7 | 3 | 4 | 3 | 3 |
| Ocular disorders NEC | 7 | 8 | 2 | 3 | 5 | 5 |
| Ocular infections, inflammations and associated manifestations | 2 | 2 | 1 | 1 | 1 | 1 |
| Ocular nerve and muscle disorders | 1 | 1 | | | 1 | 1 |
| Ocular sensation disorders | 4 | 4 | | | 4 | 4 |
| Optic nerve bleeding and vascular disorders | 1 | 1 | | | 1 | 1 |
| Pupil disorders | 3 | 3 | | | 3 | 3 |
| Retinal bleeding and vascular disorders (excl retinopathy) | 1 | 1 | | | 1 | 1 |
| Retinal, choroid and vitreous infections and inflammations | 1 | 1 | | | 1 | 1 |
| Visual disorders NEC | 11 | 11 | 3 | 3 | 8 | 8 |
| Visual impairment and blindness (excl colour blindness) | 6 | 6 | 1 | 1 | 5 | 5 |
| | 56 | 58 | 13 | 15 | 43 | 43 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | 3 | 3 | | | 3 | 3 |
| Colitis (excl infective) | 1 | 1 | 1 | 1 | | |
| Dental pain and sensation disorders | 1 | 1 | | | 1 | 1 |
| Diarrhoea (excl infective) | 52 | 56 | 19 | 21 | 33 | 35 |
| Dyspeptic signs and symptoms | 3 | 3 | | | 3 | 3 |
| Faecal abnormalities NEC | 2 | 2 | 2 | 2 | | |
| Flatulence, bloating and distension | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastric and pyloric stenosis and obstruction | 2 | 2 | | | 2 | 2 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 40 | 42 | 18 | 19 | 22 | 23 |
| Gastrointestinal atonic and hypomotility disorders NEC | 2 | 3 | 2 | 3 | | |
| Gastrointestinal disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal dyskinetic disorders | 1 | 1 | | | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 11 | 13 | 2 | 2 | 9 | 11 |
| Gastrointestinal spastic and hypermotility disorders | 1 | 1 | 1 | 1 | | |
| Gastrointestinal stenosis and obstruction NEC | 2 | 2 | | | 2 | 2 |
| Gingival disorders, signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Nausea and vomiting symptoms | 151 | 162 | 55 | 62 | 96 | 100 |
| Non-site specific gastrointestinal haemorrhages | 6 | 6 | | | 6 | 6 |
| Oral dryness and saliva altered | 5 | 5 | 2 | 2 | 3 | 3 |
| Oral soft tissue haemorrhages | 1 | 1 | 1 | 1 | | |
| Oral soft tissue signs and symptoms | 21 | 23 | 6 | 8 | 15 | 15 |
| Oral soft tissue swelling and oedema | 10 | 11 | 2 | 2 | 8 | 9 |
| Peritoneal and retroperitoneal disorders | 1 | 1 | | | 1 | 1 |
| Stomatitis and ulceration | 3 | 4 | 1 | 2 | 2 | 2 |
| Tongue disorders | 1 | 3 | | 2 | 1 | 1 |
| Tongue signs and symptoms | 10 | 11 | 2 | 3 | 8 | 8 |
| | 335 | 362 | 116 | 133 | 219 | 229 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 360 | 377 | 155 | 167 | 205 | 210 |
| Body temperature altered | 22 | 22 | 6 | 6 | 16 | 16 |
| Death and sudden death | 61 | 76 | | | 61 | 76 |
| Febrile disorders | 153 | 162 | 55 | 63 | 98 | 99 |
| Feelings and sensations NEC | 100 | 104 | 43 | 47 | 57 | 57 |
| Gait disturbances | 13 | 13 | 5 | 5 | 8 | 8 |
| General signs and symptoms NEC | 81 | 82 | 19 | 19 | 62 | 63 |
| Inflamations | 8 | 8 | 2 | 2 | 6 | 6 |
| Injection site reactions | 11 | 14 | 3 | 6 | 8 | 8 |
| Mass conditions NEC | 1 | 1 | | | 1 | 1 |
| Mucosal findings abnormal | 1 | 1 | 1 | 1 | | |
| Oedema NEC | 26 | 27 | 3 | 3 | 23 | 24 |
| Pain and discomfort NEC | 119 | 121 | 51 | 52 | 68 | 69 |
| Therapeutic and nontherapeutic responses | 100 | 107 | 1 | 1 | 99 | 106 |
| Vaccination site reactions | 250 | 266 | 172 | 188 | 78 | 78 |
| | 1,306 | 1,381 | 516 | 560 | 790 | 821 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholecystitis and cholelithiasis | 1 | 1 | | | 1 | 1 |
| Cholestasis and jaundice | 3 | 3 | | | 3 | 3 |
| Hepatic enzymes and function abnormalities | 1 | 1 | 1 | 1 | | |
| Hepatocellular damage and hepatitis NEC | 5 | 5 | | | 5 | 5 |
| | 10 | 10 | 1 | 1 | 9 | 9 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 39 | 40 | 16 | 16 | 23 | 24 |
| Allergies to foods, food additives, drugs and other chemicals | 4 | 4 | 1 | 1 | 3 | 3 |
| Anaphylactic and anaphylactoid responses | 23 | 25 | | | 23 | 25 |
| | 66 | 69 | 17 | 17 | 49 | 52 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacterial infections NEC | 5 | 5 | | | 5 | 5 |
| Candida infections | 1 | 1 | | | 1 | 1 |
| Central nervous system and spinal infections | 2 | 2 | | | 2 | 2 |
| Coronavirus infections | 140 | 147 | 18 | 18 | 122 | 129 |
| Cytomegaloviral infections | 1 | 1 | | | 1 | 1 |
| Dental and oral soft tissue infections | 1 | 1 | 1 | 1 | | |
| Ear infections | | 1 | | 1 | | |
| Epstein-Barr viral infections | 2 | 2 | | | 2 | 2 |
| Escherichia infections | 1 | 1 | | | 1 | 1 |
| Eye and eyelid infections | 1 | 1 | | | 1 | 1 |
| Herpes viral infections | 19 | 20 | 3 | 4 | 16 | 16 |
| Infections NEC | 6 | 6 | 1 | 1 | 5 | 5 |
| Influenza viral infections | 6 | 6 | | | 6 | 6 |
| Klebsiella infections | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract and lung infections | 11 | 12 | | | 11 | 12 |
| Moraxella infections | 1 | 1 | | | 1 | 1 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 4 | 4 | | | 4 | 4 |
| Skin structures and soft tissue infections | 2 | 2 | | | 2 | 2 |
| Streptococcal infections | 3 | 3 | | | 3 | 3 |
| Upper respiratory tract infections | 8 | 8 | 5 | 5 | 3 | 3 |
| Urinary tract infections | 1 | 1 | | | 1 | 1 |
| Viral infections NEC | 4 | 4 | | | 4 | 4 |
| | 220 | 230 | 28 | 30 | 192 | 200 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac and vascular procedural complications | 1 | 1 | | | 1 | 1 |
| Cerebral injuries NEC | 1 | 1 | | | 1 | 1 |
| Chest and respiratory tract injuries NEC | 1 | 1 | | | 1 | 1 |
| Conditions caused by cold | 3 | 3 | 2 | 2 | 1 | 1 |
| Exposures associated with pregnancy, delivery and lactation | | 2 | | 2 | | |
| Eye injuries NEC | 1 | 1 | | | 1 | 1 |
| Medication errors, product use errors and issues NEC | 11 | 14 | 11 | 14 | | |
| Non-site specific injuries NEC | 20 | 21 | 4 | 4 | 16 | 17 |
| Occupational exposures | 1 | 2 | 1 | 2 | | |
| Off label uses | 10 | 11 | 10 | 11 | | |
| Overdoses NEC | 2 | 8 | 2 | 8 | | |
| Product administration errors and issues | 136 | 147 | 134 | 145 | 2 | 2 |
| Product preparation errors and issues | 3 | 22 | 3 | 22 | | |
| Product transcribing errors and communication issues | 1 | 1 | 1 | 1 | | |
| Site specific injuries NEC | 4 | 4 | | | 4 | 4 |
| Thoracic cage fractures and dislocations | 1 | 1 | | | 1 | 1 |
| Underdoses NEC | 2 | 16 | 2 | 16 | | |
| Vaccination related complications | 3 | 4 | 1 | 2 | 2 | 2 |
| | 201 | 260 | 171 | 229 | 30 | 31 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 42 | 43 | 4 | 4 | 38 | 39 |
| Carbohydrate tolerance analyses (incl diabetes) | 2 | 3 | 1 | 2 | 1 | 1 |
| Cardiac auscultatory investigations | 1 | 1 | | | 1 | 1 |
| Coagulation and bleeding analyses | 1 | 2 | 1 | 1 | | 1 |
| ECG investigations | 2 | 2 | | | 2 | 2 |
| Haematological analyses NEC | 1 | 1 | 1 | 1 | | |
| Heart rate and pulse investigations | 10 | 10 | 4 | 4 | 6 | 6 |
| Liver function analyses | 7 | 7 | 6 | 6 | 1 | 1 |
| Metabolism tests NEC | 2 | 3 | | 1 | 2 | 2 |
| Mineral and electrolyte analyses | 1 | 1 | 1 | 1 | | |
| Neurologic diagnostic procedures | 1 | 1 | | | 1 | 1 |
| Physical examination procedures and organ system status | 4 | 4 | 1 | 1 | 3 | 3 |
| Pituitary analyses anterior | 1 | 1 | 1 | 1 | | |
| Platelet analyses | 1 | 1 | 1 | 1 | | |
| Protein analyses NEC | 14 | 16 | 7 | 8 | 7 | 8 |
| Red blood cell analyses | 2 | 2 | 2 | 2 | | |
| Renal function analyses | 3 | 3 | | | 3 | 3 |
| Skeletal and cardiac muscle analyses | 2 | 2 | | | 2 | 2 |
| Tissue enzyme analyses NEC | 2 | 2 | 2 | 2 | | |
| Vascular tests NEC (incl blood pressure) | 22 | 23 | 4 | 4 | 18 | 19 |
| Virus identification and serology | 18 | 18 | 12 | 12 | 6 | 6 |
| White blood cell analyses | 7 | 7 | 3 | 3 | 4 | 4 |
| | 146 | 153 | 51 | 54 | 95 | 99 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 16 | 17 | 8 | 9 | 8 | 8 |
| Calcium metabolism disorders | 1 | 1 | | | 1 | 1 |
| Diabetes mellitus (incl subtypes) | 4 | 4 | | | 4 | 4 |
| Diabetic complications NEC | 5 | 5 | | | 5 | 5 |
| Disorders of purine metabolism | 1 | 1 | | | 1 | 1 |
| Fluid intake increased | 2 | 2 | 1 | 1 | 1 | 1 |
| General nutritional disorders NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Hyperglycaemic conditions NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Hypervitaminoses NEC | 1 | 1 | | | 1 | 1 |
| Hypoglycaemic conditions NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Lipid metabolism and deposit disorders NEC | 1 | 1 | 1 | 1 | | |
| Metabolic acidoses (excl diabetic acidoses) | 1 | 1 | | | 1 | 1 |
| Potassium imbalance | 5 | 5 | | | 5 | 5 |
| Sodium imbalance | 2 | 2 | 2 | 2 | | |
| Total fluid volume decreased | 6 | 6 | 1 | 1 | 5 | 5 |
| | 54 | 55 | 17 | 18 | 37 | 37 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 3 | 3 | | | 3 | 3 |
| Bone related signs and symptoms | 3 | 3 | 2 | 2 | 1 | 1 |
| Bursal disorders | 3 | 3 | 2 | 2 | 1 | 1 |
| Joint related disorders NEC | 1 | 1 | | | 1 | 1 |
| Joint related signs and symptoms | 48 | 50 | 23 | 25 | 25 | 25 |
| Lupus erythematosus (incl subtypes) | 1 | 1 | | | 1 | 1 |
| Muscle infections and inflammations | 1 | 1 | 1 | 1 | | |
| Muscle pains | 93 | 95 | 42 | 44 | 51 | 51 |
| Muscle related signs and symptoms NEC | 9 | 9 | 5 | 5 | 4 | 4 |
| Muscle tone abnormalities | 2 | 2 | 2 | 2 | | |
| Muscle weakness conditions | 3 | 3 | 2 | 2 | 1 | 1 |
| Musculoskeletal and connective tissue conditions NEC | 37 | 38 | 9 | 10 | 28 | 28 |
| Musculoskeletal and connective tissue pain and discomfort | 51 | 54 | 23 | 26 | 28 | 28 |
| Myopathies | 1 | 1 | | | 1 | 1 |
| Osteoarthropathies | 1 | 1 | 1 | 1 | | |
| Rheumatoid arthropathies | 1 | 1 | | | 1 | 1 |
| Spondyloarthropathies | 3 | 3 | | | 3 | 3 |
| Synovial disorders | 1 | 1 | | | 1 | 1 |
| Tendon disorders | 4 | 4 | 3 | 3 | 1 | 1 |
| | 266 | 274 | 115 | 123 | 151 | 151 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast and nipple neoplasms benign | 1 | 1 | 1 | 1 | | |
| Islet cell neoplasms and APUDoma NEC | 1 | 1 | | | 1 | 1 |
| Metastases to specified sites | 1 | 1 | | | 1 | 1 |
| Oncologic complications and emergencies | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal reflexes | 2 | 2 | 1 | 1 | 1 | 1 |
| Absence seizures | | 1 | | | | 1 |
| Autonomic nervous system disorders | 1 | 1 | | | 1 | 1 |
| Central nervous system haemorrhages and cerebrovascular accidents | 28 | 32 | | | 28 | 32 |
| Central nervous system vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Coma states | 4 | 4 | | | 4 | 4 |
| Coordination and balance disturbances | 12 | 12 | 3 | 3 | 9 | 9 |
| Cortical dysfunction NEC | 6 | 6 | 1 | 1 | 5 | 5 |
| Dementia (excl Alzheimer's type) | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 57 | 60 | 5 | 5 | 52 | 55 |
| Dyskinesias and movement disorders NEC | 6 | 6 | | | 6 | 6 |
| Encephalopathies NEC | 1 | 1 | | | 1 | 1 |
| Eye movement disorders | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 31 | 31 | | | 31 | 31 |
| Generalised tonic-clonic seizures | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 175 | 184 | 76 | 85 | 99 | 99 |
| Memory loss (excl dementia) | 2 | 2 | | | 2 | 2 |
| Mental impairment (excl dementia and memory loss) | 8 | 9 | 4 | 4 | 4 | 5 |
| Migraine headaches | 16 | 16 | 9 | 9 | 7 | 7 |
| Muscle tone abnormal | 1 | 2 | 1 | 1 | | 1 |
| Narcolepsy and hypersomnia | 3 | 3 | 1 | 1 | 2 | 2 |
| Nervous system disorders NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Neurological signs and symptoms NEC | 70 | 72 | 27 | 28 | 43 | 44 |
| Neurologic visual problems NEC | 2 | 2 | | | 2 | 2 |
| Neuromuscular disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Olfactory nerve disorders | 5 | 6 | 3 | 4 | 2 | 2 |
| Paraesthesias and dysaesthesias | 74 | 77 | 30 | 32 | 44 | 45 |
| Paralysis and paresis (excl cranial nerve) | 17 | 17 | | | 17 | 17 |
| Parkinson's disease and parkinsonism | 1 | 1 | | | 1 | 1 |
| Peripheral neuropathies NEC | 1 | 1 | | | 1 | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Seizures and seizure disorders NEC | 23 | 23 | | | 23 | 23 |
| Sensory abnormalities NEC | 30 | 31 | 11 | 12 | 19 | 19 |
| Speech and language abnormalities | 9 | 10 | 2 | 2 | 7 | 8 |
| Transient cerebrovascular events | 8 | 8 | | | 8 | 8 |
| Tremor (excl congenital) | 16 | 17 | 5 | 6 | 11 | 11 |
| | 620 | 648 | 181 | 196 | 439 | 452 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|-----|
| | | | Nonserious | |
| | | | I | C |
| Device physical property and chemical issues | | 1 | | 1 |
| Product distribution and storage issues | 115 | 116 | 115 | 116 |
| Product packaging issues | 1 | 1 | 1 | 1 |
| | 116 | 118 | 116 | 118 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal behaviour NEC | 4 | 4 | | | 4 | 4 |
| Anxiety disorders NEC | 1 | 1 | 1 | 1 | | |
| Anxiety symptoms | 18 | 20 | 7 | 7 | 11 | 13 |
| Behaviour and socialisation disturbances | 3 | 3 | | | 3 | 3 |
| Bipolar disorders | 1 | 1 | | | 1 | 1 |
| Cognitive and attention disorders and disturbances NEC | 1 | 1 | | | 1 | 1 |
| Confusion and disorientation | 13 | 14 | 4 | 4 | 9 | 10 |
| Deliria | 1 | 1 | | | 1 | 1 |
| Dementia NEC | 1 | 1 | | | 1 | 1 |
| Depressive disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 17 | 19 | 8 | 10 | 9 | 9 |
| Eating disorders NEC | 1 | 1 | | | 1 | 1 |
| Emotional and mood disturbances NEC | 1 | 1 | 1 | 1 | | |
| Fear symptoms and phobic disorders (incl social phobia) | 2 | 3 | 1 | 1 | 1 | 2 |
| Hallucinations (excl sleep-related) | 2 | 2 | | | 2 | 2 |
| Increased physical activity levels | 4 | 4 | 2 | 2 | 2 | 2 |
| Mood disorders NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Parasomnias | 2 | 2 | 2 | 2 | | |
| Sleep disorders NEC | 5 | 5 | 2 | 2 | 3 | 3 |
| Speech and language usage disturbances | 1 | 1 | | | 1 | 1 |
| Speech articulation and rhythm disturbances | 3 | 3 | | | 3 | 3 |
| Suicidal and self-injurious behaviour | 1 | 1 | | | 1 | 1 |
| Thinking disturbances | 1 | 1 | | | 1 | 1 |
| | 89 | 95 | 31 | 33 | 58 | 62 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| Glomerulonephritis and nephrotic syndrome | 1 | 1 | | | 1 | 1 |
| Renal failure and impairment | 14 | 15 | | | 14 | 15 |
| Urinary abnormalities | 1 | 1 | | | 1 | 1 |
| Urinary tract signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| | 19 | 20 | 1 | 1 | 18 | 19 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 | | |
| Erection and ejaculation conditions and disorders | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 87 | 90 | 14 | 14 | 73 | 76 |
| Bronchospasm and obstruction | 16 | 17 | 1 | 1 | 15 | 16 |
| Conditions associated with abnormal gas exchange | 9 | 9 | | | 9 | 9 |
| Coughing and associated symptoms | 26 | 29 | 12 | 13 | 14 | 16 |
| Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) | 3 | 3 | | | 3 | 3 |
| Laryngeal spasm, oedema and obstruction | 4 | 4 | | | 4 | 4 |
| Lower respiratory tract inflammatory and immunologic conditions | 13 | 13 | | | 13 | 13 |
| Lower respiratory tract signs and symptoms | 5 | 7 | | | 5 | 7 |
| Nasal congestion and inflammations | 2 | 3 | 1 | 2 | 1 | 1 |
| Nasal disorders NEC | 2 | 2 | 2 | 2 | | |
| Paranasal sinus disorders (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 |
| Parenchymal lung disorders NEC | 2 | 2 | | | 2 | 2 |
| Pharyngeal disorders (excl infections and neoplasms) | 6 | 6 | 2 | 2 | 4 | 4 |
| Pneumothorax and pleural effusions NEC | 2 | 2 | | | 2 | 2 |
| Pulmonary hypertensions | 1 | 1 | | | 1 | 1 |
| Pulmonary oedemas | 15 | 16 | | | 15 | 16 |
| Pulmonary thrombotic and embolic conditions | 14 | 14 | | | 14 | 14 |
| Respiratory failures (excl neonatal) | 7 | 8 | | | 7 | 8 |
| Respiratory signs and symptoms NEC | 3 | 3 | | | 3 | 3 |
| Respiratory tract disorders NEC | 10 | 10 | 1 | 1 | 9 | 9 |
| Upper respiratory tract signs and symptoms | 27 | 28 | 15 | 15 | 12 | 13 |
| | 255 | 268 | 48 | 50 | 207 | 218 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 10 | 11 | | | 10 | 11 |
| Apocrine and eccrine gland disorders | 24 | 25 | 6 | 7 | 18 | 18 |
| Bullous conditions | 2 | 2 | | | 2 | 2 |
| Dermal and epidermal conditions NEC | 11 | 13 | 6 | 8 | 5 | 5 |
| Dermatitis and eczema | 2 | 2 | 1 | 1 | 1 | 1 |
| Erythemas | 38 | 41 | 16 | 19 | 22 | 22 |
| Papulosquamous conditions | 1 | 1 | | | 1 | 1 |
| Photosensitivity and photodermatosis conditions | 1 | 1 | 1 | 1 | | |
| Pilar disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Pruritus NEC | 25 | 28 | 12 | 15 | 13 | 13 |
| Purpura and related conditions | 6 | 6 | 2 | 2 | 4 | 4 |
| Rashes, eruptions and exanthems NEC | 43 | 45 | 23 | 25 | 20 | 20 |
| Skin and subcutaneous conditions NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Skin vasculitides | 2 | 2 | | | 2 | 2 |
| Skin vasomotor conditions | 5 | 5 | 1 | 1 | 4 | 4 |
| Urticarias | 24 | 26 | 10 | 10 | 14 | 16 |
| | 198 | 212 | 80 | 91 | 118 | 121 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disability issues | 4 | 4 | 1 | 1 | 3 | 3 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 11 | 12 | | | 11 | 12 |
| Aortic aneurysms and dissections | | 2 | | | | 2 |
| Blood pressure disorders NEC | 1 | 1 | | | 1 | 1 |
| Circulatory collapse and shock | 6 | 6 | 1 | 1 | 5 | 5 |
| Haemorrhages NEC | 3 | 3 | | | 3 | 3 |
| Non-site specific embolism and thrombosis | 5 | 5 | | | 5 | 5 |
| Non-site specific necrosis and vascular insufficiency NEC | 1 | 1 | | | 1 | 1 |
| Non-site specific vascular disorders NEC | 2 | 2 | 2 | 2 | | |
| Peripheral embolism and thrombosis | 6 | 6 | 1 | 1 | 5 | 5 |
| Peripheral vascular disorders NEC | 31 | 32 | 12 | 13 | 19 | 19 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 3 | 3 | 2 | 2 | 1 | 1 |
| Site specific vascular disorders NEC | 9 | 9 | | | 9 | 9 |
| Vascular hypertensive disorders NEC | 89 | 91 | 15 | 17 | 74 | 74 |
| Vascular hypotensive disorders | 44 | 45 | 12 | 12 | 32 | 33 |
| Vasculitides NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 213 | 220 | 46 | 49 | 167 | 171 |

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Country Where Event Occurred

FRENCH POLYNESIA

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Bullous conditions | 1 | 1 | 1 | 1 |
| Dermal and epidermal conditions NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

GERMANY

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Anaemias NEC | 1 | 1 | | | | | 1 | 1 |
| Leukocytoses NEC | 2 | 2 | | | | | 2 | 2 |
| Leukopenias NEC | 1 | 2 | | | | | 1 | 2 |
| Lymphatic system disorders NEC | 28 | 45 | 1 | 1 | 28 | 45 | | |
| Neutropenias | 2 | 2 | | | | | 2 | 2 |
| Thrombocytopenias | 4 | 4 | | | | | 4 | 4 |
| | 38 | 56 | 1 | 1 | 28 | 45 | 10 | 11 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Cardiac conduction disorders | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Cardiac disorders NEC | 15 | 22 | | | 8 | 13 | 7 | 9 |
| Cardiac signs and symptoms NEC | 16 | 34 | 4 | 4 | 9 | 24 | 7 | 10 |
| Heart failures NEC | 14 | 24 | | | | | 14 | 24 |
| Ischaemic coronary artery disorders | 14 | 23 | | | | | 14 | 23 |
| Left ventricular failures | 1 | 1 | | | | | 1 | 1 |
| Myocardial disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Noninfectious myocarditis | 5 | 5 | | | | | 5 | 5 |
| Noninfectious pericarditis | 1 | 1 | | | | | 1 | 1 |
| Rate and rhythm disorders NEC | 47 | 75 | 7 | 7 | 10 | 18 | 37 | 57 |
| Right ventricular failures | 1 | 1 | | | | | 1 | 1 |
| Supraventricular arrhythmias | 11 | 14 | | | 4 | 4 | 7 | 10 |
| Ventricular arrhythmias and cardiac arrest | 7 | 10 | | | | | 7 | 10 |
| | 135 | 213 | 11 | 11 | 32 | 60 | 103 | 153 |

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System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Neurological disorders congenital NEC | | 3 | | 3 |
| | | 3 | | 3 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 3 | 6 | 3 | 6 | | |
| Hearing losses | 6 | 7 | | | 6 | 7 |
| Inner ear signs and symptoms | 6 | 10 | 5 | 9 | 1 | 1 |
| | 15 | 23 | 8 | 15 | 7 | 8 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival and corneal bleeding and vascular disorders | 2 | 2 | | | 2 | 2 |
| Lacrimation disorders | 5 | 7 | 3 | 5 | 2 | 2 |
| Lid, lash and lacrimal infections, irritations and inflammations | 3 | 3 | 2 | 2 | 1 | 1 |
| Ocular bleeding and vascular disorders NEC | 2 | 3 | | | 2 | 3 |
| Ocular disorders NEC | 9 | 12 | 8 | 10 | 1 | 2 |
| Ocular infections, inflammations and associated manifestations | 7 | 13 | 3 | 8 | 4 | 5 |
| Ocular sensation disorders | | 1 | | 1 | | |
| Retinal structural change, deposit and degeneration | 2 | 2 | | | 2 | 2 |
| Retinopathies NEC | 1 | 1 | | | 1 | 1 |
| Scleral infections, irritations and inflammations | | 1 | | 1 | | |
| Visual disorders NEC | 7 | 10 | 5 | 6 | 2 | 4 |
| Visual impairment and blindness (excl colour blindness) | 10 | 12 | 4 | 5 | 6 | 7 |
| Visual pathway disorders | 1 | 1 | | | 1 | 1 |
| | 49 | 68 | 25 | 38 | 24 | 30 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute and chronic pancreatitis | 1 | 1 | | | | | 1 | 1 |
| Diarrhoea (excl infective) | 29 | 50 | 11 | 11 | 21 | 41 | 8 | 9 |
| Dyspeptic signs and symptoms | | 1 | | | | 1 | | |
| Faecal abnormalities NEC | 2 | 7 | | | 2 | 7 | | |
| Flatulence, bloating and distension | 1 | 3 | 1 | 1 | 1 | 3 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 15 | 27 | 2 | 2 | 9 | 21 | 6 | 6 |
| Gastrointestinal atonic and hypomotility disorders NEC | | 1 | | | | 1 | | |
| Gastrointestinal disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal inflammatory disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 11 | 15 | | | 7 | 7 | 4 | 8 |
| Gastrointestinal vascular occlusion and infarction | 1 | 2 | | | | | 1 | 2 |
| Gingival disorders, signs and symptoms NEC | 1 | 1 | | | 1 | 1 | | |
| Nausea and vomiting symptoms | 91 | 146 | 43 | 43 | 62 | 108 | 29 | 38 |
| Non-mechanical ileus | 1 | 1 | | | | | 1 | 1 |
| Non-site specific gastrointestinal haemorrhages | 6 | 6 | | | | | 6 | 6 |
| Oral dryness and saliva altered | 4 | 5 | | | 2 | 3 | 2 | 2 |
| Oral soft tissue signs and symptoms | 8 | 14 | 1 | 1 | 6 | 10 | 2 | 4 |
| Oral soft tissue swelling and oedema | 6 | 9 | | | | 1 | 6 | 8 |
| Stomatitis and ulceration | 1 | 2 | | | | 1 | 1 | 1 |
| Tongue disorders | 1 | 2 | | | 1 | 2 | | |
| Tongue signs and symptoms | 9 | 13 | | | 2 | 4 | 7 | 9 |
| | 190 | 308 | 58 | 58 | 114 | 211 | 76 | 97 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|-----|-------------|------|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Adverse effect absent | 2 | 3 | | | 2 | 3 | | |
| Application and instillation site reactions | 1 | 1 | | | | | 1 | 1 |
| Asthenic conditions | 165 | 343 | 103 | 105 | 142 | 305 | 23 | 38 |
| Death and sudden death | 61 | 100 | | | | | 61 | 100 |
| Febrile disorders | 93 | 149 | 25 | 26 | 69 | 114 | 24 | 35 |
| Feelings and sensations NEC | 97 | 154 | 27 | 27 | 75 | 126 | 22 | 28 |
| Gait disturbances | 6 | 8 | | | 1 | 3 | 5 | 5 |
| General signs and symptoms NEC | 64 | 127 | 4 | 4 | 33 | 72 | 31 | 55 |
| Inflamations | 1 | 1 | | | | | 1 | 1 |
| Injection site reactions | 1 | 4 | | | 1 | 3 | | 1 |
| Interactions | | 1 | | | | 1 | | |
| Mass conditions NEC | 1 | 1 | | | 1 | 1 | | |
| Mucosal findings abnormal | 1 | 1 | | | | | 1 | 1 |
| Necrosis NEC | 1 | 1 | | | | | 1 | 1 |
| Oedema NEC | 2 | 4 | | | 1 | 1 | 1 | 3 |
| Pain and discomfort NEC | 24 | 46 | 3 | 3 | 19 | 38 | 5 | 8 |
| Therapeutic and nontherapeutic responses | 150 | 255 | | | 5 | 5 | 145 | 250 |
| Vaccination site reactions | 190 | 438 | 68 | 68 | 179 | 424 | 11 | 14 |
| | 860 | 1,637 | 230 | 233 | 528 | 1096 | 332 | 541 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholecystitis and cholelithiasis | | 1 | | 1 | | |
| Cholestasis and jaundice | 1 | 2 | | 1 | 1 | 1 |
| Hepatobiliary signs and symptoms | 1 | 1 | 1 | 1 | | |
| | 2 | 4 | 1 | 3 | 1 | 1 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Allergic conditions NEC | 35 | 52 | 4 | 4 | 12 | 19 | 23 | 33 |
| Allergies to foods, food additives, drugs and other chemicals | 3 | 5 | | | 1 | 2 | 2 | 3 |
| Anaphylactic and anaphylactoid responses | 53 | 68 | 1 | 1 | | | 53 | 68 |
| | 91 | 125 | 5 | 5 | 13 | 21 | 78 | 104 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|--|--|
| | | | Serious | | Nonserious | | Serious | | | |
| | | | I | C | I | C | I | C | | |
| Abdominal and gastrointestinal infections | | | 1 | 1 | | | | | | |
| Bacterial infections NEC | 3 | 4 | | | | | 3 | 4 | | |
| Cardiac infections | 1 | 1 | | | | | 1 | 1 | | |
| Central nervous system and spinal infections | 2 | 2 | | | | | 2 | 2 | | |
| Coronavirus infections | 180 | 270 | 1 | 1 | 26 | 27 | 154 | 243 | | |
| Dental and oral soft tissue infections | 1 | 1 | | | | | 1 | 1 | | |
| Ear infections | | 1 | | | | 1 | | | | |
| Escherichia infections | 1 | 1 | | | | | 1 | 1 | | |
| Eye and eyelid infections | 1 | 3 | | | 1 | 2 | | 1 | | |
| Herpes viral infections | 21 | 25 | | | 9 | 13 | 12 | 12 | | |
| Infections NEC | 5 | 11 | 1 | 1 | 2 | 2 | 3 | 9 | | |
| Lower respiratory tract and lung infections | 18 | 25 | | | 1 | 1 | 17 | 24 | | |
| Muscle and soft tissue infections | 1 | 1 | | | | | 1 | 1 | | |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 4 | 7 | | | | | 4 | 7 | | |
| Skin structures and soft tissue infections | 3 | 3 | 1 | 1 | 1 | 1 | 2 | 2 | | |
| Staphylococcal infections | | 1 | | | | | | 1 | | |
| Streptococcal infections | 1 | 1 | | | | | 1 | 1 | | |
| Upper respiratory tract infections | 15 | 24 | 1 | 1 | 11 | 20 | 4 | 4 | | |
| Urinary tract infections | 1 | 1 | | | | | 1 | 1 | | |
| | 258 | 382 | 5 | 5 | 51 | 67 | 207 | 315 | | |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 13 | 28 | | | 12 | 27 | 1 | 1 |
| Fractures and dislocations NEC | 1 | 1 | | | | | 1 | 1 |
| Limb fractures and dislocations | 1 | 2 | | | | | 1 | 2 |
| Medication errors, product use errors and issues NEC | 10 | 20 | | | 10 | 20 | | |
| Muscle, tendon and ligament injuries | | | 1 | 1 | | | | |
| Non-site specific injuries NEC | 6 | 10 | | | 2 | 2 | 4 | 8 |
| Occupational exposures | | 1 | | | | 1 | | |
| Off label uses | 11 | 18 | | | 11 | 18 | | |
| Poisoning and toxicity | 1 | 1 | | | | | 1 | 1 |
| Product administration errors and issues | 41 | 68 | | | 40 | 63 | 1 | 5 |
| Product preparation errors and issues | 8 | 11 | | | 8 | 11 | | |
| Product storage errors and issues in the product use system | 1 | 1 | | | 1 | 1 | | |
| Site specific injuries NEC | | 1 | | | | | | 1 |
| Skin injuries NEC | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Underdoses NEC | 9 | 18 | | | 9 | 18 | | |
| Vaccination related complications | 2 | 2 | 1 | 1 | | | 2 | 2 |
| | 107 | 186 | 2 | 2 | 94 | 163 | 13 | 23 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Blood gas and acid base analyses | 4 | 8 | | | | | 4 | 8 |
| Carbohydrate tolerance analyses (incl diabetes) | | 1 | | | | 1 | | |
| Chemistry analyses NEC | 1 | 1 | | | | | 1 | 1 |
| Cholesterol analyses | 2 | 2 | | | 2 | 2 | | |
| Digestive enzymes | 1 | 1 | | | | | 1 | 1 |
| Haematological analyses NEC | 1 | 1 | | | 1 | 1 | | |
| Heart rate and pulse investigations | 7 | 9 | | | 3 | 4 | 4 | 5 |
| Liver function analyses | 5 | 5 | | | | | 5 | 5 |
| Mineral and electrolyte analyses | | 2 | | | | 2 | | |
| Physical examination procedures and organ system status | 27 | 39 | | | 18 | 27 | 9 | 12 |
| Platelet analyses | 1 | 1 | | | | | 1 | 1 |
| Protein analyses NEC | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Red blood cell analyses | | 3 | | | | 3 | | |
| Renal function analyses | 1 | 2 | | | 1 | 2 | | |
| Respiratory tract and thoracic imaging procedures | 1 | 1 | | | | | 1 | 1 |
| Skeletal and cardiac muscle analyses | | 2 | | | | 2 | | |
| Tissue enzyme analyses NEC | 2 | 2 | | | | | 2 | 2 |
| Urinalysis NEC | | 2 | | | | 1 | | 1 |
| Vascular tests NEC (incl blood pressure) | 14 | 20 | 3 | 3 | 5 | 8 | 9 | 12 |
| Virus identification and serology | 54 | 92 | | | 41 | 53 | 13 | 39 |
| White blood cell analyses | 2 | 2 | | | | | 2 | 2 |
| | 126 | 199 | 3 | 3 | 72 | 107 | 54 | 92 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 7 | 13 | 2 | 3 | 5 | 10 |
| Calcium metabolism disorders | 2 | 3 | | | 2 | 3 |
| Diabetes mellitus (incl subtypes) | | 2 | | | | 2 |
| Disorders of purine metabolism | 1 | 1 | 1 | 1 | | |
| Hypoglycaemic conditions NEC | 1 | 1 | 1 | 1 | | |
| Mixed acid-base disorders | 1 | 1 | | | 1 | 1 |
| Potassium imbalance | 1 | 1 | | | 1 | 1 |
| Sodium imbalance | 2 | 2 | | | 2 | 2 |
| Total fluid volume decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| | 17 | 26 | 5 | 6 | 12 | 20 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Arthropathies NEC | 3 | 3 | | | | | 3 | 3 |
| Bone related signs and symptoms | 11 | 12 | | | 9 | 10 | 2 | 2 |
| Bursal disorders | | | 1 | 1 | | | | |
| Joint related disorders NEC | 1 | 1 | | | 1 | 1 | | |
| Joint related signs and symptoms | 27 | 46 | 22 | 22 | 24 | 42 | 3 | 4 |
| Muscle pains | 55 | 110 | 34 | 35 | 47 | 102 | 8 | 8 |
| Muscle related signs and symptoms NEC | 7 | 10 | 1 | 1 | 3 | 6 | 4 | 4 |
| Muscle weakness conditions | 6 | 12 | | | 4 | 10 | 2 | 2 |
| Musculoskeletal and connective tissue conditions NEC | 6 | 12 | | | 5 | 9 | 1 | 3 |
| Musculoskeletal and connective tissue pain and discomfort | 103 | 187 | | | 98 | 180 | 5 | 7 |
| Rheumatoid arthropathies | 1 | 1 | | | | | 1 | 1 |
| Spondyloarthropathies | 1 | 1 | | | | | 1 | 1 |
| Tendon disorders | 1 | 1 | | | 1 | 1 | | |
| | 222 | 396 | 58 | 59 | 192 | 361 | 30 | 35 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acute polyneuropathies | 2 | 2 | | | | | 2 | 2 |
| Alzheimer's disease (incl subtypes) | | 1 | | | | | | 1 |
| Autonomic nervous system disorders | 1 | 2 | | | | | 1 | 2 |
| Central nervous system haemorrhages and cerebrovascular accidents | 18 | 23 | | | | | 18 | 23 |
| Central nervous system vascular disorders NEC | 3 | 3 | | | | | 3 | 3 |
| Coordination and balance disturbances | 9 | 10 | | | | 1 | 9 | 9 |
| Cortical dysfunction NEC | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Cranial nerve disorders NEC | 1 | 2 | | | 1 | 2 | | |
| Dementia (excl Alzheimer's type) | 1 | 2 | | | | | 1 | 2 |
| Disturbances in consciousness NEC | 44 | 56 | 2 | 2 | 5 | 9 | 39 | 47 |
| Dyskinesias and movement disorders NEC | 4 | 9 | | | 2 | 5 | 2 | 4 |
| Eye movement disorders | 1 | 1 | | | | | 1 | 1 |
| Facial cranial nerve disorders | 13 | 15 | | | 1 | 1 | 12 | 14 |
| Generalised tonic-clonic seizures | 2 | 2 | | | | | 2 | 2 |
| Headaches NEC | 149 | 270 | 55 | 56 | 130 | 244 | 19 | 26 |
| Increased intracranial pressure disorders | 1 | 1 | | | | | 1 | 1 |
| Memory loss (excl dementia) | 5 | 5 | | | 2 | 2 | 3 | 3 |
| Mental impairment (excl dementia and memory loss) | 13 | 18 | | | 8 | 12 | 5 | 6 |
| Migraine headaches | 1 | 2 | | | | 1 | 1 | 1 |
| Motor neurone diseases | 1 | 1 | | | | | 1 | 1 |
| Multiple sclerosis acute and progressive | 1 | 1 | | | | | 1 | 1 |
| Muscle tone abnormal | 5 | 7 | | | 2 | 3 | 3 | 4 |
| Narcolepsy and hypersomnia | 2 | 4 | | | 1 | 2 | 1 | 2 |
| Nervous system disorders NEC | 3 | 3 | | | | | 3 | 3 |
| Neurological signs and symptoms NEC | 89 | 150 | 41 | 41 | 48 | 96 | 41 | 54 |
| Neuromuscular disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Olfactory nerve disorders | 2 | 4 | | | 2 | 4 | | |
| Optic nerve disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Paraesthesias and dysaesthesias | 43 | 66 | 5 | 5 | 29 | 48 | 14 | 18 |
| Paralysis and paresis (excl cranial nerve) | 8 | 10 | | | | 1 | 8 | 9 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|--------------------------|-----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Peripheral neuropathies NEC | 1 | 2 | | | | | 1 | 2 |
| Seizures and seizure disorders NEC | 33 | 42 | | | | | 33 | 42 |
| Sensory abnormalities NEC | 11 | 22 | | | 9 | 19 | 2 | 3 |
| Sleep disturbances NEC | 3 | 5 | | | 2 | 3 | 1 | 2 |
| Speech and language abnormalities | 4 | 6 | | | 1 | 1 | 3 | 5 |
| Structural brain disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Transient cerebrovascular events | 1 | 2 | | | | | 1 | 2 |
| Tremor (excl congenital) | 12 | 19 | | | 4 | 8 | 8 | 11 |
| | 494 | 775 | 103 | 104 | 249 | 464 | 245 | 311 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortions not specified as induced or spontaneous | 1 | 1 | 1 | 1 |
| Abortions spontaneous | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Product distribution and storage issues | 25 | 25 | 24 | 24 | 1 | 1 |
| Product physical issues | | 1 | | 1 | | |
| Product quality issues NEC | 1 | 1 | 1 | 1 | | |
| | 26 | 27 | 25 | 26 | 1 | 1 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 8 | 12 | 3 | 7 | 5 | 5 |
| Behaviour and socialisation disturbances | 7 | 8 | 1 | 1 | 6 | 7 |
| Communications disorders | 1 | 1 | 1 | 1 | | |
| Confusion and disorientation | 11 | 13 | 5 | 7 | 6 | 6 |
| Deliria | 2 | 2 | | | 2 | 2 |
| Depressive disorders | 1 | 1 | 1 | 1 | | |
| Disturbances in initiating and maintaining sleep | 6 | 8 | 6 | 8 | | |
| Eating disorders NEC | 1 | 1 | 1 | 1 | | |
| Hallucinations (excl sleep-related) | 2 | 2 | | | 2 | 2 |
| Increased physical activity levels | 5 | 7 | 3 | 5 | 2 | 2 |
| Mental disorders NEC | 1 | 2 | 1 | 1 | | 1 |
| Mood disorders NEC | 2 | 4 | 1 | 1 | 1 | 3 |
| Sleep disorders NEC | 5 | 7 | 5 | 7 | | |
| Somatic symptom disorders | 1 | 1 | | | 1 | 1 |
| Stereotypies and automatisms | 1 | 1 | | | 1 | 1 |
| | 54 | 70 | 28 | 40 | 26 | 30 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | | 3 | | 3 | | |
| Glomerulonephritis and nephrotic syndrome | 2 | 2 | | | 2 | 2 |
| Renal failure and impairment | 10 | 18 | | | 10 | 18 |
| Urinary abnormalities | 1 | 2 | | 1 | 1 | 1 |
| Urinary tract signs and symptoms NEC | | 1 | | 1 | | |
| | 13 | 26 | | 5 | 13 | 21 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|
| | | | Serious | | Nonserious | |
| | | | I | C | I | C |
| Breast signs and symptoms | | | 1 | 1 | | |
| Menstruation and uterine bleeding NEC | 5 | 5 | | | 5 | 5 |
| Menstruation with increased bleeding | 1 | 1 | | | 1 | 1 |
| Reproductive tract signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 1 | 1 | 7 | 7 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Breathing abnormalities | 93 | 126 | 2 | 2 | 21 | 32 | 72 | 94 |
| Bronchial conditions NEC | | 1 | | | | 1 | | |
| Bronchospasm and obstruction | 16 | 19 | | | 5 | 7 | 11 | 12 |
| Conditions associated with abnormal gas exchange | 1 | 1 | | | 1 | 1 | | |
| Coughing and associated symptoms | 20 | 31 | 1 | 1 | 12 | 22 | 8 | 9 |
| Laryngeal spasm, oedema and obstruction | 5 | 8 | | | | | 5 | 8 |
| Lower respiratory tract inflammatory and immunologic conditions | | 3 | | | | | | 3 |
| Lower respiratory tract signs and symptoms | 2 | 4 | | | 1 | 1 | 1 | 3 |
| Nasal congestion and inflammations | 2 | 5 | | | 2 | 5 | | |
| Nasal disorders NEC | 1 | 4 | 1 | 1 | | 3 | 1 | 1 |
| Paranasal sinus disorders (excl infections and neoplasms) | 2 | 2 | | | 2 | 2 | | |
| Parenchymal lung disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 7 | 12 | 1 | 1 | 4 | 6 | 3 | 6 |
| Pleural infections and inflammations | 1 | 1 | | | | | 1 | 1 |
| Pulmonary oedemas | 4 | 4 | | | | | 4 | 4 |
| Pulmonary thrombotic and embolic conditions | 4 | 7 | | | | | 4 | 7 |
| Respiratory failures (excl neonatal) | 11 | 14 | | | | | 11 | 14 |
| Respiratory signs and symptoms NEC | 1 | 2 | | | 1 | 2 | | |
| Respiratory tract disorders NEC | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Upper respiratory tract signs and symptoms | 37 | 69 | 2 | 2 | 32 | 60 | 5 | 9 |
| | 210 | 316 | 7 | 7 | 82 | 143 | 128 | 173 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Acnes | | 1 | | | | 1 | | | |
| Angioedemas | 10 | 12 | | | | | 10 | 12 | |
| Apocrine and eccrine gland disorders | 20 | 29 | 1 | 1 | 15 | 23 | 5 | 6 | |
| Bullous conditions | 1 | 2 | | | | 1 | 1 | 1 | |
| Dermal and epidermal conditions NEC | 6 | 8 | | | 4 | 6 | 2 | 2 | |
| Dermatitis and eczema | 11 | 15 | | | 10 | 14 | 1 | 1 | |
| Erythemas | 23 | 34 | 2 | 2 | 17 | 27 | 6 | 7 | |
| Photosensitivity and photodermatosis conditions | | 1 | | | | 1 | | | |
| Pruritus NEC | 20 | 32 | 2 | 2 | 12 | 20 | 8 | 12 | |
| Psoriatic conditions | 1 | 2 | | | | 1 | 1 | 1 | |
| Purpura and related conditions | 3 | 3 | | | 1 | 1 | 2 | 2 | |
| Rashes, eruptions and exanthems NEC | 30 | 54 | 4 | 4 | 15 | 30 | 15 | 24 | |
| Rosaceas | | 1 | | | | | | | 1 |
| Skin vasculitides | 1 | 1 | | | | | 1 | 1 | |
| Skin vasomotor conditions | | 1 | | | | 1 | | | |
| Urticarias | 13 | 18 | 1 | 1 | 6 | 9 | 7 | 9 | |
| | 139 | 214 | 10 | 10 | 80 | 135 | 59 | 79 | |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disability issues | 1 | 2 | 1 | 1 | | 1 |
| | 1 | 2 | 1 | 1 | | 1 |

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System Organ Class

Vascular disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| | | Non Interventional Study | | Spontaneous | | | | |
|--|-----|--------------------------|---|-------------|----|---------|----|-----|
| | | Serious | | Nonserious | | Serious | | |
| | | I | C | I | C | I | C | |
| Accelerated and malignant hypertension | 9 | 9 | | | | | 9 | 9 |
| Aortic aneurysms and dissections | 1 | 1 | | | | | 1 | 1 |
| Blood pressure disorders NEC | | 1 | | | 1 | | | |
| Circulatory collapse and shock | 18 | 22 | 1 | 1 | | | 18 | 22 |
| Haemorrhages NEC | 6 | 7 | | | 2 | 3 | 4 | 4 |
| Non-site specific embolism and thrombosis | 3 | 3 | | | | | 3 | 3 |
| Non-site specific necrosis and vascular insufficiency NEC | 3 | 3 | | | | | 3 | 3 |
| Peripheral embolism and thrombosis | 6 | 7 | | | | 1 | 6 | 6 |
| Peripheral vascular disorders NEC | 34 | 48 | 1 | 1 | 15 | 20 | 19 | 28 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | | | 1 | 1 | | |
| Site specific vascular disorders NEC | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Vascular hypertensive disorders NEC | 21 | 35 | 3 | 3 | 6 | 11 | 15 | 24 |
| Vascular hypotensive disorders | 13 | 21 | | | 1 | 3 | 12 | 18 |
| | 118 | 161 | 5 | 5 | 26 | 41 | 92 | 120 |

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Country Where Event Occurred

GIBRALTAR

System Organ Class

General disorders and administration site conditions

High Level Term

Death and sudden death

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

Spontaneous

Serious

I

C

1

1

1

1

1

1

1

1

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Country Where Event Occurred

GREECE

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytoses NEC | | 1 | | | | 1 |
| Leukopenias NEC | 1 | 1 | 1 | 1 | | |
| Lymphatic system disorders NEC | 27 | 29 | 10 | 12 | 17 | 17 |
| | 28 | 31 | 11 | 13 | 17 | 18 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 17 | 19 | 11 | 13 | 6 | 6 |
| Cardiac valve disorders NEC | | 1 | | | | 1 |
| Ischaemic coronary artery disorders | | 2 | | | | 2 |
| Rate and rhythm disorders NEC | 38 | 48 | 16 | 22 | 22 | 26 |
| Supraventricular arrhythmias | | 1 | | | | 1 |
| Ventricular arrhythmias and cardiac arrest | | 3 | | | | 3 |
| | 55 | 74 | 27 | 35 | 28 | 39 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 2 | 2 | 2 | 2 | | |
| Hearing losses | 2 | 3 | | | 2 | 3 |
| Inner ear signs and symptoms | 10 | 12 | 7 | 9 | 3 | 3 |
| | 14 | 17 | 9 | 11 | 5 | 6 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid movement disorders | 2 | 3 | 1 | 1 | 1 | 2 |
| Lid, lash and lacrimal infections, irritations and inflammations | 2 | 2 | 1 | 1 | 1 | 1 |
| Ocular disorders NEC | 2 | 4 | 1 | 2 | 1 | 2 |
| Ocular infections, inflammations and associated manifestations | 2 | 4 | | 2 | 2 | 2 |
| Visual disorders NEC | 2 | 2 | 2 | 2 | | |
| | 10 | 15 | 5 | 8 | 5 | 7 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | 1 | 1 | | | 1 | 1 |
| Diarrhoea (excl infective) | 15 | 18 | 8 | 10 | 7 | 8 |
| Dyspeptic signs and symptoms | 5 | 5 | 3 | 3 | 2 | 2 |
| Flatulence, bloating and distension | 1 | 2 | | | 1 | 2 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 12 | 14 | 8 | 10 | 4 | 4 |
| Gastrointestinal disorders NEC | 7 | 9 | 7 | 9 | | |
| Gastrointestinal signs and symptoms NEC | 8 | 12 | 4 | 5 | 4 | 7 |
| Gastrointestinal spastic and hypermotility disorders | | 2 | | | | 2 |
| Nausea and vomiting symptoms | 32 | 42 | 18 | 26 | 14 | 16 |
| Oral dryness and saliva altered | 4 | 6 | 2 | 4 | 2 | 2 |
| Oral soft tissue disorders NEC | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 15 | 23 | 6 | 11 | 9 | 12 |
| Oral soft tissue swelling and oedema | 6 | 6 | 3 | 3 | 3 | 3 |
| Tongue disorders | | 1 | | 1 | | |
| Tongue signs and symptoms | 3 | 3 | | | 3 | 3 |
| | 110 | 145 | 59 | 82 | 51 | 63 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse effect absent | 5 | 7 | 5 | 7 | | |
| Asthenic conditions | 78 | 93 | 36 | 49 | 42 | 44 |
| Body temperature altered | 1 | 1 | | | 1 | 1 |
| Death and sudden death | 4 | 6 | | | 4 | 6 |
| Febrile disorders | 78 | 90 | 37 | 47 | 41 | 43 |
| Feelings and sensations NEC | 51 | 58 | 18 | 23 | 33 | 35 |
| Gait disturbances | 1 | 3 | | 2 | 1 | 1 |
| General signs and symptoms NEC | 6 | 8 | 1 | 2 | 5 | 6 |
| Inflamations | 2 | 2 | | | 2 | 2 |
| Interactions | | 1 | | | | 1 |
| Mucosal findings abnormal | | 1 | | | | 1 |
| Oedema NEC | 10 | 10 | 4 | 4 | 6 | 6 |
| Pain and discomfort NEC | 35 | 40 | 15 | 18 | 20 | 22 |
| Therapeutic and nontherapeutic responses | 15 | 17 | | 1 | 15 | 16 |
| Vaccination site reactions | 67 | 87 | 54 | 74 | 13 | 13 |
| | 353 | 424 | 170 | 227 | 183 | 197 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 19 | 28 | 7 | 13 | 12 | 15 |
| Allergies to foods, food additives, drugs and other chemicals | 3 | 4 | 1 | 1 | 2 | 3 |
| Anaphylactic and anaphylactoid responses | 10 | 16 | | | 10 | 16 |
| | 32 | 48 | 8 | 14 | 24 | 34 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal infections | 1 | 1 | | | 1 | 1 |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 20 | 21 | 3 | 3 | 17 | 18 |
| Eye and eyelid infections | 1 | 1 | 1 | 1 | | |
| Herpes viral infections | 4 | 5 | 2 | 3 | 2 | 2 |
| Infections NEC | | 1 | | | | 1 |
| Lower respiratory tract and lung infections | | 1 | | | | 1 |
| Upper respiratory tract infections | 1 | 1 | 1 | 1 | | |
| Viral infections NEC | 2 | 2 | 2 | 2 | | |
| | 30 | 34 | 9 | 10 | 21 | 24 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | | 1 | | 1 | | |
| Medication errors, product use errors and issues NEC | 6 | 6 | 6 | 6 | | |
| Non-site specific injuries NEC | 1 | 3 | | 1 | 1 | 2 |
| Off label uses | 3 | 4 | 3 | 4 | | |
| Product administration errors and issues | 4 | 8 | 4 | 8 | | |
| Vaccination related complications | 1 | 1 | | | 1 | 1 |
| | 15 | 23 | 13 | 20 | 2 | 3 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 3 | 3 | 1 | 1 | 2 | 2 |
| Carbohydrate tolerance analyses (incl diabetes) | 1 | 1 | 1 | 1 | | |
| Coagulation and bleeding analyses | 2 | 2 | 1 | 1 | 1 | 1 |
| Heart rate and pulse investigations | 18 | 18 | 14 | 14 | 4 | 4 |
| Immunology analyses NEC | 1 | 2 | 1 | 2 | | |
| Liver function analyses | 3 | 3 | 2 | 2 | 1 | 1 |
| Physical examination procedures and organ system status | | 1 | | 1 | | |
| Protein analyses NEC | 2 | 2 | 2 | 2 | | |
| Vascular tests NEC (incl blood pressure) | 28 | 33 | 16 | 20 | 12 | 13 |
| Virus identification and serology | 2 | 2 | 2 | 2 | | |
| | 60 | 67 | 40 | 46 | 20 | 21 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 2 | 2 | 2 | 2 | | |
| Diabetes mellitus (incl subtypes) | 1 | 1 | | | 1 | 1 |
| Fluid intake increased | 1 | 1 | 1 | 1 | | |
| General nutritional disorders NEC | 2 | 2 | | | 2 | 2 |
| Hyperglycaemic conditions NEC | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 3 | 3 | 4 | 4 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Bone related signs and symptoms | 5 | 5 | 2 | 2 | 3 | 3 |
| Bursal disorders | 1 | 1 | 1 | 1 | | |
| Joint related disorders NEC | 1 | 1 | 1 | 1 | | |
| Joint related signs and symptoms | 43 | 45 | 15 | 17 | 28 | 28 |
| Muscle pains | 66 | 69 | 35 | 37 | 31 | 32 |
| Muscle related signs and symptoms NEC | 5 | 6 | 1 | 2 | 4 | 4 |
| Muscle tone abnormalities | 1 | 1 | 1 | 1 | | |
| Muscle weakness conditions | 1 | 2 | | 1 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 18 | 25 | 15 | 22 | 3 | 3 |
| Rheumatoid arthropathies | 1 | 2 | | | 1 | 2 |
| | 144 | 159 | 72 | 85 | 72 | 74 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute polyneuropathies | 2 | 2 | | | 2 | 2 |
| Autonomic nervous system disorders | 3 | 3 | | | 3 | 3 |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 1 | | | 1 | 1 |
| Coordination and balance disturbances | 2 | 2 | 1 | 1 | 1 | 1 |
| Disturbances in consciousness NEC | 25 | 28 | 9 | 11 | 16 | 17 |
| Dyskinesias and movement disorders NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Facial cranial nerve disorders | 2 | 2 | | | 2 | 2 |
| Headaches NEC | 63 | 75 | 36 | 47 | 27 | 28 |
| Migraine headaches | 2 | 3 | 1 | 2 | 1 | 1 |
| Neurological signs and symptoms NEC | 52 | 65 | 33 | 41 | 19 | 24 |
| Olfactory nerve disorders | 1 | 1 | 1 | 1 | | |
| Paraesthesias and dysaesthesias | 51 | 59 | 35 | 42 | 16 | 17 |
| Paralysis and paresis (excl cranial nerve) | 3 | 3 | | | 3 | 3 |
| Peripheral neuropathies NEC | 1 | 1 | | | 1 | 1 |
| Seizures and seizure disorders NEC | | 1 | | | | 1 |
| Sensory abnormalities NEC | 12 | 17 | 3 | 6 | 9 | 11 |
| Sleep disturbances NEC | | 1 | | 1 | | |
| Speech and language abnormalities | 2 | 2 | | | 2 | 2 |
| Tremor (excl congenital) | 9 | 11 | 6 | 6 | 3 | 5 |
| Trigeminal disorders | 1 | 1 | | | 1 | 1 |
| | 235 | 281 | 127 | 160 | 108 | 121 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product physical issues | 1 | 4 | 1 | 4 |
| | 1 | 4 | 1 | 4 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 4 | 5 | 2 | 3 | 2 | 2 |
| Behaviour and socialisation disturbances | 1 | 1 | | | 1 | 1 |
| Confusion and disorientation | 6 | 6 | 1 | 1 | 5 | 5 |
| Disturbances in initiating and maintaining sleep | 2 | 2 | 2 | 2 | | |
| Emotional and mood disturbances NEC | 1 | 2 | 1 | 1 | | 1 |
| Obsessive-compulsive disorders and symptoms | 1 | 1 | | | 1 | 1 |
| Panic attacks and disorders | 1 | 1 | | | 1 | 1 |
| | 16 | 18 | 6 | 7 | 10 | 11 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 1 | 1 | 1 | 1 | | |
| Urinary abnormalities | 1 | 1 | | | 1 | 1 |
| Urinary tract signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 2 | 2 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 20 | 27 | 7 | 10 | 13 | 17 |
| Bronchospasm and obstruction | 10 | 12 | 1 | 1 | 9 | 11 |
| Coughing and associated symptoms | 16 | 19 | 7 | 7 | 9 | 12 |
| Laryngeal spasm, oedema and obstruction | 7 | 8 | | | 7 | 8 |
| Nasal congestion and inflammations | | 2 | | 2 | | |
| Nasal disorders NEC | | 1 | | 1 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 |
| Pulmonary oedemas | 1 | 2 | | | 1 | 2 |
| Pulmonary thrombotic and embolic conditions | 2 | 3 | | | 2 | 3 |
| Respiratory failures (excl neonatal) | | 1 | | | | 1 |
| Upper respiratory tract signs and symptoms | 24 | 33 | 8 | 14 | 16 | 19 |
| | 81 | 109 | 23 | 35 | 58 | 74 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 10 | 12 | | | 10 | 12 |
| Apocrine and eccrine gland disorders | 13 | 16 | 5 | 7 | 8 | 9 |
| Bullous conditions | 3 | 4 | 3 | 4 | | |
| Dermal and epidermal conditions NEC | 2 | 3 | | 1 | 2 | 2 |
| Dermatitis and eczema | 1 | 1 | | | 1 | 1 |
| Erythemas | 42 | 44 | 30 | 31 | 12 | 13 |
| Pruritus NEC | 41 | 43 | 25 | 26 | 16 | 17 |
| Rashes, eruptions and exanthems NEC | 54 | 64 | 25 | 33 | 29 | 31 |
| Skin vasomotor conditions | 1 | 1 | 1 | 1 | | |
| Urticarias | 5 | 5 | 3 | 3 | 2 | 2 |
| | 172 | 193 | 92 | 106 | 80 | 87 |

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System Organ Class

Surgical and medical procedures

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Nervous system therapeutic procedures NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 6 | 8 | | | 6 | 8 |
| Blood pressure disorders NEC | 1 | 2 | 1 | 2 | | |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Lymphoedemas | 1 | 1 | | | 1 | 1 |
| Non-site specific vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Peripheral vascular disorders NEC | 18 | 22 | 12 | 14 | 6 | 8 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | | | 1 | 1 |
| Site specific vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Vascular hypertensive disorders NEC | 18 | 24 | 10 | 14 | 8 | 10 |
| Vascular hypotensive disorders | 12 | 14 | 3 | 5 | 9 | 9 |
| | 60 | 75 | 28 | 37 | 32 | 38 |

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Country Where Event Occurred
HOLY SEE (VATICAN CITY STATE)

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ocular disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenic conditions | 1 | 1 | 1 | 1 |
| Injection site reactions | 1 | 1 | 1 | 1 |
| Oedema NEC | 2 | 2 | 2 | 2 |
| Vaccination site reactions | 2 | 2 | 2 | 2 |
| | 6 | 6 | 6 | 6 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Musculoskeletal and connective tissue pain and discomfort | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

HUNGARY

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 23 | 30 | 19 | 25 | 4 | 5 |
| | 23 | 30 | 19 | 25 | 4 | 5 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 2 | 3 | 1 | 2 | 1 | 1 |
| Ischaemic coronary artery disorders | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 8 | 8 | 4 | 4 | 4 | 4 |
| Supraventricular arrhythmias | 1 | 1 | | | 1 | 1 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 13 | 14 | 5 | 6 | 8 | 8 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear disorders NEC | 2 | 6 | 2 | 6 |
| Inner ear signs and symptoms | 1 | 2 | 1 | 2 |
| | 3 | 8 | 3 | 8 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lacrimation disorders | 1 | 2 | 1 | 2 | | |
| Ocular bleeding and vascular disorders NEC | 2 | 2 | | | 2 | 2 |
| Ocular disorders NEC | 1 | 1 | | | 1 | 1 |
| Visual disorders NEC | | 1 | | 1 | | |
| | 4 | 6 | 1 | 3 | 3 | 3 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 4 | 4 | 4 | 4 | | |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 3 | 3 | 3 | 3 | | |
| Gastrointestinal signs and symptoms NEC | 6 | 6 | 2 | 2 | 4 | 4 |
| Nausea and vomiting symptoms | 19 | 29 | 18 | 26 | 1 | 3 |
| Oral dryness and saliva altered | | 1 | | | | 1 |
| Oral soft tissue signs and symptoms | 2 | 4 | 2 | 4 | | |
| Oral soft tissue swelling and oedema | 1 | 1 | | | 1 | 1 |
| Tongue signs and symptoms | 1 | 1 | 1 | 1 | | |
| | 37 | 50 | 31 | 41 | 6 | 9 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse effect absent | | 1 | | 1 | | |
| Asthenic conditions | 49 | 73 | 45 | 66 | 4 | 7 |
| Death and sudden death | 2 | 2 | | | 2 | 2 |
| Febrile disorders | 32 | 45 | 31 | 42 | 1 | 3 |
| Feelings and sensations NEC | 23 | 39 | 21 | 33 | 2 | 6 |
| Gait disturbances | | 2 | | 2 | | |
| General signs and symptoms NEC | 5 | 9 | 4 | 8 | 1 | 1 |
| Injection site reactions | 1 | 1 | 1 | 1 | | |
| Oedema NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Pain and discomfort NEC | 6 | 12 | 6 | 12 | | |
| Therapeutic and nontherapeutic responses | 5 | 8 | 1 | 1 | 4 | 7 |
| Vaccination site reactions | 22 | 57 | 21 | 56 | 1 | 1 |
| | 147 | 252 | 131 | 223 | 16 | 29 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 4 | 5 | 4 | 5 | | |
| Allergies to foods, food additives, drugs and other chemicals | 2 | 3 | 2 | 2 | | 1 |
| Anaphylactic and anaphylactoid responses | 2 | 3 | | | 2 | 3 |
| | 8 | 11 | 6 | 7 | 2 | 4 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 6 | 8 | 2 | 2 | 4 | 6 |
| Dental and oral soft tissue infections | 1 | 1 | 1 | 1 | | |
| Herpes viral infections | 4 | 8 | 4 | 8 | | |
| Lower respiratory tract and lung infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 1 | 2 | 1 | 2 | | |
| | 13 | 20 | 8 | 13 | 5 | 7 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone and joint injuries NEC | 1 | 1 | | | 1 | 1 |
| Exposures associated with pregnancy, delivery and lactation | 4 | 5 | 4 | 5 | | |
| Medication errors, product use errors and issues NEC | 1 | 1 | 1 | 1 | | |
| Muscle, tendon and ligament injuries | 2 | 2 | 2 | 2 | | |
| Non-site specific injuries NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Off label uses | 1 | 3 | 1 | 3 | | |
| Product administration errors and issues | | 1 | | 1 | | |
| Skull fractures, facial bone fractures and dislocations | 1 | 1 | | | 1 | 1 |
| | 12 | 16 | 9 | 13 | 3 | 3 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| High Level Term | | | | | | | |
| Blood gas and acid base analyses | | 1 | | 1 | | | |
| Carbohydrate tolerance analyses (incl diabetes) | | 1 | | 1 | | | |
| Heart rate and pulse investigations | 2 | 4 | 2 | 4 | | | |
| Physical examination procedures and organ system status | | 2 | | 2 | | | |
| Vascular tests NEC (incl blood pressure) | 6 | 9 | 3 | 5 | 3 | 4 | |
| Virus identification and serology | 7 | 8 | 6 | 6 | 1 | 2 | |
| | 15 | 25 | 11 | 19 | 4 | 6 | |

System Organ Class

| Metabolism and nutrition disorders | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| High Level Term | | | | | | | |
| Appetite disorders | 2 | 2 | 2 | 2 | | | |
| General nutritional disorders NEC | 1 | 1 | | | 1 | 1 | |
| Hypoglycaemic conditions NEC | | 1 | | 1 | | | |
| Metabolic acidoses (excl diabetic acidoses) | 1 | 1 | | | 1 | 1 | |
| | 4 | 5 | 2 | 3 | 2 | 2 | |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 1 | | | 1 | 1 |
| Bursal disorders | 1 | 1 | 1 | 1 | | |
| Joint related signs and symptoms | 5 | 7 | 5 | 6 | | 1 |
| Muscle pains | 15 | 23 | 15 | 22 | | 1 |
| Muscle related signs and symptoms NEC | | 1 | | 1 | | |
| Musculoskeletal and connective tissue conditions NEC | 2 | 4 | 1 | 3 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 17 | 32 | 17 | 32 | | |
| | 41 | 69 | 39 | 65 | 2 | 4 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Neoplasms unspecified malignancy and site unspecified NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 1 | | | 1 | 1 |
| Cervical spinal cord and nerve root disorders | 1 | 1 | 1 | 1 | | |
| Disturbances in consciousness NEC | 8 | 10 | 5 | 7 | 3 | 3 |
| Dyskinesias and movement disorders NEC | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 5 | 5 | 1 | 1 | 4 | 4 |
| Headaches NEC | 24 | 43 | 23 | 39 | 1 | 4 |
| Migraine headaches | 2 | 2 | 2 | 2 | | |
| Neurological signs and symptoms NEC | 13 | 21 | 10 | 17 | 3 | 4 |
| Olfactory nerve disorders | 2 | 3 | 2 | 3 | | |
| Paraesthesias and dysaesthesias | 7 | 17 | 6 | 15 | 1 | 2 |
| Paralysis and paresis (excl cranial nerve) | 1 | 1 | | | 1 | 1 |
| Sensory abnormalities NEC | 6 | 9 | 6 | 9 | | |
| Sleep disturbances NEC | 1 | 1 | 1 | 1 | | |
| Tremor (excl congenital) | 2 | 4 | 2 | 3 | | 1 |
| | 74 | 119 | 59 | 98 | 15 | 21 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Anxiety symptoms | 3 | 4 | 3 | 4 |
| Confusion and disorientation | | 1 | | 1 |
| Depressive disorders | | 1 | | 1 |
| Disturbances in initiating and maintaining sleep | 2 | 2 | 2 | 2 |
| Emotional and mood disturbances NEC | 2 | 2 | 2 | 2 |
| Mood alterations with depressive symptoms | 1 | 1 | 1 | 1 |
| Panic attacks and disorders | | 1 | | 1 |
| | 8 | 12 | 8 | 12 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Bladder and urethral symptoms | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 |
| Vulvovaginal signs and symptoms | | 1 | | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 7 | 8 | 4 | 4 | 3 | 4 |
| Bronchospasm and obstruction | 1 | 1 | 1 | 1 | | |
| Conditions associated with abnormal gas exchange | 2 | 2 | | | 2 | 2 |
| Laryngeal spasm, oedema and obstruction | 1 | 2 | | | 1 | 2 |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 6 | 9 | 6 | 9 | | |
| | 18 | 23 | 12 | 15 | 6 | 8 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 4 | 6 | 4 | 6 | | |
| Bullous conditions | | 1 | | 1 | | |
| Dermal and epidermal conditions NEC | 6 | 8 | 5 | 7 | 1 | 1 |
| Dermatitis and eczema | 1 | 2 | 1 | 2 | | |
| Erythemas | 6 | 8 | 6 | 8 | | |
| Pruritus NEC | 4 | 8 | 3 | 7 | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 13 | 18 | 12 | 16 | 1 | 2 |
| Urticarias | 2 | 4 | 1 | 3 | 1 | 1 |
| | 36 | 55 | 32 | 50 | 4 | 5 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 1 | 1 | | | 1 | 1 |
| Blood pressure disorders NEC | 1 | 1 | | | 1 | 1 |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Haemorrhages NEC | | 1 | | | | 1 |
| Lymphoedemas | | 1 | | 1 | | |
| Non-site specific vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Peripheral vascular disorders NEC | 4 | 4 | 3 | 3 | 1 | 1 |
| Site specific vascular disorders NEC | | 1 | | 1 | | |
| Vascular hypertensive disorders NEC | 1 | 1 | 1 | 1 | | |
| Vascular hypotensive disorders | 3 | 3 | 1 | 1 | 2 | 2 |
| Vasculitides NEC | 1 | 1 | 1 | 1 | | |
| | 13 | 16 | 7 | 9 | 6 | 7 |

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Country Where Event Occurred

ICELAND

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Heart failures NEC | | 2 | | | | 2 |
| Ischaemic coronary artery disorders | 1 | 2 | | | 1 | 2 |
| Rate and rhythm disorders NEC | 1 | 3 | | 1 | 1 | 2 |
| Supraventricular arrhythmias | 1 | 1 | | | 1 | 1 |
| | 3 | 8 | | 1 | 3 | 7 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear disorders NEC | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ocular disorders NEC | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Gastrointestinal and abdominal pains (excl oral and throat) | 1 | 1 | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 1 | 1 | 1 | 1 |
| Nausea and vomiting symptoms | 1 | 7 | 1 | 7 |
| Oral dryness and saliva altered | | 1 | | 1 |
| | 3 | 10 | 3 | 10 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 20 | 38 | 18 | 34 | 2 | 4 |
| Death and sudden death | | 3 | | | | 3 |
| Febrile disorders | 10 | 25 | 8 | 21 | 2 | 4 |
| Feelings and sensations NEC | 6 | 11 | 6 | 11 | | |
| General signs and symptoms NEC | 1 | 3 | 1 | 2 | | 1 |
| Pain and discomfort NEC | 5 | 8 | 4 | 7 | 1 | 1 |
| Vaccination site reactions | 14 | 24 | 14 | 24 | | |
| | 56 | 112 | 51 | 99 | 5 | 13 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lower respiratory tract and lung infections | 2 | 4 | | | 2 | 4 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | 1 | | | | 1 |
| Upper respiratory tract infections | | 5 | | 5 | | |
| | 2 | 10 | | 5 | 2 | 5 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 2 | 2 | | | 2 | 2 |
| Heart rate and pulse investigations | 1 | 2 | 1 | 2 | | |
| Liver function analyses | 2 | 2 | 1 | 1 | 1 | 1 |
| Physical examination procedures and organ system status | 1 | 1 | | | 1 | 1 |
| Vascular tests NEC (incl blood pressure) | 1 | 2 | | 1 | 1 | 1 |
| | 7 | 9 | 2 | 4 | 5 | 5 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 2 | 2 | 2 | 2 | | |
| Total fluid volume increased | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Bone related signs and symptoms | | 2 | | 2 |
| Joint related signs and symptoms | 5 | 6 | 5 | 6 |
| Muscle pains | 9 | 12 | 9 | 12 |
| Muscle related signs and symptoms NEC | 2 | 2 | 2 | 2 |
| Musculoskeletal and connective tissue pain and discomfort | 4 | 6 | 4 | 6 |
| | 20 | 28 | 20 | 28 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 1 | | | 1 | 1 |
| Cortical dysfunction NEC | 1 | 1 | 1 | 1 | | |
| Disturbances in consciousness NEC | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 9 | 22 | 9 | 22 | | |
| Migraine headaches | | 1 | | 1 | | |
| Neurological signs and symptoms NEC | 4 | 9 | 4 | 9 | | |
| Paraesthesias and dysaesthesias | 1 | 5 | 1 | 5 | | |
| Sensory abnormalities NEC | 1 | 2 | 1 | 2 | | |
| Transient cerebrovascular events | 1 | 1 | | | 1 | 1 |
| Tremor (excl congenital) | | 1 | | 1 | | |
| | 19 | 44 | 16 | 41 | 3 | 3 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast infections and inflammations | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 2 | 4 | 1 | 2 | 1 | 2 |
| Bronchospasm and obstruction | 2 | 2 | | | 2 | 2 |
| Conditions associated with abnormal gas exchange | 3 | 3 | | | 3 | 3 |
| Coughing and associated symptoms | 2 | 5 | 2 | 4 | | 1 |
| Lower respiratory tract signs and symptoms | 1 | 1 | 1 | 1 | | |
| Parenchymal lung disorders NEC | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | | 1 | | 1 | | |
| Pulmonary oedemas | 1 | 1 | | | 1 | 1 |
| Respiratory failures (excl neonatal) | 1 | 1 | | | 1 | 1 |
| Respiratory signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 3 | 9 | 3 | 9 | | |
| | 17 | 29 | 8 | 18 | 9 | 11 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 2 | 3 | 1 | 2 | 1 | 1 |
| Dermal and epidermal conditions NEC | 3 | 3 | 3 | 3 | | |
| Erythemas | 2 | 3 | 2 | 3 | | |
| Pruritus NEC | 3 | 4 | 3 | 4 | | |
| Rashes, eruptions and exanthems NEC | 1 | 1 | 1 | 1 | | |
| | 11 | 14 | 10 | 13 | 1 | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aortic aneurysms and dissections | | 1 | | | | 1 |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Peripheral embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | | 1 | | 1 | | |
| Site specific vascular disorders NEC | | 1 | | 1 | | |
| Vascular hypertensive disorders NEC | 1 | 1 | 1 | 1 | | |
| | 3 | 6 | 1 | 3 | 2 | 3 |

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Country Where Event Occurred

INDIA

System Organ Class

Product issues

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| | |
|-------------|---|
| Spontaneous | |
| Nonserious | |
| I | C |
| | 1 |
| | 1 |

Counterfeit, falsified and substandard products

1

1

1

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Country Where Event Occurred

IRELAND

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 11 | 12 | | 1 | 11 | 11 |
| Neutropenias | 1 | 1 | | | 1 | 1 |
| | 12 | 13 | | 1 | 12 | 12 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac disorders NEC | 1 | 1 | | | 1 | 1 |
| Cardiac signs and symptoms NEC | 11 | 11 | 1 | 1 | 10 | 10 |
| Heart failures NEC | 1 | 1 | | | 1 | 1 |
| Ischaemic coronary artery disorders | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 17 | 17 | | | 17 | 17 |
| Supraventricular arrhythmias | 1 | 1 | | | 1 | 1 |
| | 32 | 32 | 1 | 1 | 31 | 31 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 3 | 3 | | | 3 | 3 |
| Hearing losses | | 1 | | | | 1 |
| Inner ear signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| | 5 | 6 | 1 | 1 | 4 | 5 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Choroid and vitreous structural change, deposit and degeneration | 2 | 2 | | | 2 | 2 |
| Eyelid movement disorders | 1 | 1 | | | 1 | 1 |
| Lacrimation disorders | 3 | 3 | | | 3 | 3 |
| Lid, lash and lacrimal infections, irritations and inflammations | 3 | 3 | 1 | 1 | 2 | 2 |
| Ocular disorders NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Ocular infections, inflammations and associated manifestations | 2 | 2 | | | 2 | 2 |
| Ocular nerve and muscle disorders | 1 | 1 | | | 1 | 1 |
| Visual disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual impairment and blindness (excl colour blindness) | 1 | 3 | | | 1 | 3 |
| | 20 | 22 | 3 | 3 | 17 | 19 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | 1 | 1 | | | 1 | 1 |
| Diarrhoea (excl infective) | 8 | 8 | 2 | 2 | 6 | 6 |
| Faecal abnormalities NEC | 1 | 1 | | | 1 | 1 |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 5 | 5 | 1 | 1 | 4 | 4 |
| Gastrointestinal disorders NEC | 1 | 1 | | | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Nausea and vomiting symptoms | 58 | 59 | 7 | 7 | 51 | 52 |
| Non-site specific gastrointestinal haemorrhages | 4 | 4 | | | 4 | 4 |
| Oral dryness and saliva altered | 1 | 1 | | | 1 | 1 |
| Oral soft tissue disorders NEC | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 11 | 11 | | | 11 | 11 |
| Oral soft tissue swelling and oedema | 5 | 5 | | | 5 | 5 |
| Tongue disorders | 1 | 1 | | | 1 | 1 |
| Tongue signs and symptoms | 6 | 6 | 1 | 1 | 5 | 5 |
| | 105 | 106 | 12 | 12 | 93 | 94 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse effect absent | 1 | 5 | 1 | 5 | | |
| Asthenic conditions | 90 | 94 | 10 | 13 | 80 | 81 |
| Death and sudden death | 3 | 5 | | | 3 | 5 |
| Febrile disorders | 29 | 31 | 2 | 3 | 27 | 28 |
| Feelings and sensations NEC | 53 | 53 | 6 | 6 | 47 | 47 |
| Gait disturbances | 2 | 2 | | | 2 | 2 |
| General signs and symptoms NEC | 20 | 20 | 3 | 3 | 17 | 17 |
| Inflammatons | 1 | 1 | | | 1 | 1 |
| Injection site reactions | | 1 | | | | 1 |
| Pain and discomfort NEC | 43 | 44 | 5 | 5 | 38 | 39 |
| Therapeutic and nontherapeutic responses | 5 | 5 | | | 5 | 5 |
| Vaccination site reactions | 21 | 21 | 2 | 2 | 19 | 19 |
| | 268 | 282 | 29 | 37 | 239 | 245 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Allergic conditions NEC | 3 | 3 | 3 | 3 |
| Allergies to foods, food additives, drugs and other chemicals | 2 | 2 | 2 | 2 |
| Anaphylactic and anaphylactoid responses | 6 | 6 | 6 | 6 |
| | 11 | 11 | 11 | 11 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast infections | 1 | 1 | | | 1 | 1 |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 7 | 7 | 1 | 1 | 6 | 6 |
| Herpes viral infections | 2 | 2 | | | 2 | 2 |
| Infections NEC | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract and lung infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 2 | 2 | | | 2 | 2 |
| | 15 | 15 | 1 | 1 | 14 | 14 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 5 | 5 | 4 | 4 | 1 | 1 |
| Medication errors, product use errors and issues NEC | 2 | 2 | 2 | 2 | | |
| Nerve injuries NEC | 1 | 1 | | | 1 | 1 |
| Non-site specific injuries NEC | 1 | 1 | | | 1 | 1 |
| Off label uses | 3 | 3 | 3 | 3 | | |
| Product administration errors and issues | 1 | 6 | 1 | 6 | | |
| Product preparation errors and issues | 1 | 6 | 1 | 6 | | |
| Site specific injuries NEC | 1 | 1 | | | 1 | 1 |
| Skin injuries NEC | 1 | 1 | 1 | 1 | | |
| | 16 | 26 | 12 | 22 | 4 | 4 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 5 | 5 | | | 5 | 5 |
| Heart rate and pulse investigations | 4 | 5 | | | 4 | 5 |
| Investigations NEC | 1 | 1 | | | 1 | 1 |
| Liver function analyses | 1 | 1 | | | 1 | 1 |
| Physical examination procedures and organ system status | 3 | 3 | | | 3 | 3 |
| Platelet analyses | 1 | 1 | | | 1 | 1 |
| Protein analyses NEC | 2 | 2 | | | 2 | 2 |
| Red blood cell analyses | 1 | 1 | | | 1 | 1 |
| Vascular tests NEC (incl blood pressure) | 5 | 5 | 1 | 1 | 4 | 4 |
| Virus identification and serology | 1 | 1 | | | 1 | 1 |
| | 24 | 25 | 1 | 1 | 23 | 24 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Appetite disorders | 3 | 3 | 3 | 3 |
| Hypoglycaemic conditions NEC | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| Joint related disorders NEC | | 1 | | | | 1 |
| Joint related signs and symptoms | 22 | 22 | 3 | 3 | 19 | 19 |
| Muscle pains | 17 | 17 | 2 | 2 | 15 | 15 |
| Muscle related signs and symptoms NEC | 7 | 7 | 1 | 1 | 6 | 6 |
| Muscle weakness conditions | 3 | 3 | | | 3 | 3 |
| Musculoskeletal and connective tissue conditions NEC | 2 | 2 | | | 2 | 2 |
| Musculoskeletal and connective tissue pain and discomfort | 35 | 35 | 4 | 4 | 31 | 31 |
| | 88 | 89 | 11 | 11 | 77 | 78 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coordination and balance disturbances | 2 | 2 | 1 | 1 | 1 | 1 |
| Disturbances in consciousness NEC | 19 | 22 | 1 | 1 | 18 | 21 |
| Dyskinesias and movement disorders NEC | 2 | 2 | | | 2 | 2 |
| Eye movement disorders | 1 | 2 | | | 1 | 2 |
| Facial cranial nerve disorders | 9 | 9 | | | 9 | 9 |
| Headaches NEC | 58 | 61 | 7 | 9 | 51 | 52 |
| Mental impairment (excl dementia and memory loss) | 3 | 3 | 1 | 1 | 2 | 2 |
| Migraine headaches | 1 | 1 | | | 1 | 1 |
| Muscle tone abnormal | 1 | 1 | | | 1 | 1 |
| Myelitis (incl infective) | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 38 | 39 | 5 | 5 | 33 | 34 |
| Olfactory nerve disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Paraesthesias and dysaesthesias | 46 | 46 | 6 | 6 | 40 | 40 |
| Peripheral neuropathies NEC | 1 | 1 | | | 1 | 1 |
| Sensory abnormalities NEC | 8 | 8 | 1 | 1 | 7 | 7 |
| Sleep disturbances NEC | 1 | 1 | 1 | 1 | | |
| Speech and language abnormalities | 3 | 3 | | | 3 | 3 |
| Tremor (excl congenital) | 5 | 5 | 1 | 1 | 4 | 4 |
| Trigeminal disorders | 2 | 2 | | | 2 | 2 |
| | 203 | 211 | 25 | 27 | 178 | 184 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product quality issues NEC | | 5 | | 5 |
| | | 5 | | 5 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 5 | 5 | 2 | 2 | 3 | 3 |
| Confusion and disorientation | 5 | 5 | | | 5 | 5 |
| Disturbances in initiating and maintaining sleep | 8 | 8 | 1 | 1 | 7 | 7 |
| Emotional and mood disturbances NEC | 2 | 2 | | | 2 | 2 |
| Panic attacks and disorders | 2 | 2 | | | 2 | 2 |
| | 22 | 22 | 3 | 3 | 19 | 19 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Menstruation and uterine bleeding NEC | 2 | 2 | 2 | 2 |
| Vulvovaginal disorders NEC | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 17 | 18 | 2 | 2 | 15 | 16 |
| Bronchospasm and obstruction | 7 | 7 | | | 7 | 7 |
| Coughing and associated symptoms | 6 | 6 | | | 6 | 6 |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 1 | 1 | | | 1 | 1 |
| Nasal congestion and inflammations | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 4 | 4 | | | 4 | 4 |
| Upper respiratory tract signs and symptoms | 13 | 13 | 3 | 3 | 10 | 10 |
| | 50 | 51 | 5 | 5 | 45 | 46 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 1 | 1 | | | 1 | 1 |
| Apocrine and eccrine gland disorders | 17 | 18 | 2 | 2 | 15 | 16 |
| Dermal and epidermal conditions NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Dermatitis and eczema | 1 | 1 | | | 1 | 1 |
| Erythemas | 5 | 5 | 2 | 2 | 3 | 3 |
| Pruritus NEC | 13 | 13 | 2 | 2 | 11 | 11 |
| Rashes, eruptions and exanthems NEC | 19 | 19 | 3 | 3 | 16 | 16 |
| Urticarias | 12 | 12 | 2 | 2 | 10 | 10 |
| | 70 | 71 | 12 | 12 | 58 | 59 |

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System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disability issues | 9 | 9 | 9 | 9 |
| | 9 | 9 | 9 | 9 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Non-site specific embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 5 | 6 | | 1 | 5 | 5 |
| Site specific vascular disorders NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Vascular hypertensive disorders NEC | 11 | 11 | | | 11 | 11 |
| Vascular hypotensive disorders | 4 | 4 | | | 4 | 4 |
| | 25 | 26 | 1 | 2 | 24 | 24 |

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Country Where Event Occurred

ISRAEL

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemias haemolytic immune | 1 | 1 | | | 1 | 1 |
| Anaemias haemolytic NEC | | 1 | | | | 1 |
| Leukocytoses NEC | 1 | 3 | | 1 | 1 | 2 |
| Leukopenias NEC | | 1 | | | | 1 |
| Lymphatic system disorders NEC | 2 | 7 | 2 | 7 | | |
| Thrombocytopenias | 1 | 1 | | | 1 | 1 |
| | 5 | 14 | 2 | 8 | 3 | 6 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac disorders NEC | | 2 | | | | 2 |
| Cardiac signs and symptoms NEC | 1 | 9 | 1 | 9 | | |
| Heart failures NEC | 1 | 2 | | | 1 | 2 |
| Ischaemic coronary artery disorders | 2 | 6 | | | 2 | 6 |
| Noninfectious myocarditis | 3 | 3 | | | 3 | 3 |
| Noninfectious pericarditis | 2 | 4 | | | 2 | 4 |
| Rate and rhythm disorders NEC | 5 | 11 | 2 | 5 | 3 | 6 |
| Supraventricular arrhythmias | 2 | 5 | | 1 | 2 | 4 |
| Ventricular arrhythmias and cardiac arrest | 1 | 7 | | | 1 | 7 |
| | 17 | 49 | 3 | 15 | 14 | 34 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 3 | 8 | 3 | 8 | | |
| Inner ear signs and symptoms | | 2 | | 1 | | 1 |
| | 3 | 10 | 3 | 9 | | 1 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Colour blindness (incl acquired) | 1 | 1 | 1 | 1 | | |
| Iris and uveal tract infections, irritations and inflammations | 1 | 1 | | | 1 | 1 |
| Lacrimation disorders | | 2 | | 1 | | 1 |
| Ocular bleeding and vascular disorders NEC | | 1 | | | | 1 |
| Ocular disorders NEC | 4 | 7 | 2 | 3 | 2 | 4 |
| Ocular infections, inflammations and associated manifestations | | 2 | | 1 | | 1 |
| Ocular sensation disorders | 1 | 1 | 1 | 1 | | |
| Visual disorders NEC | 2 | 6 | 2 | 6 | | |
| | 9 | 21 | 6 | 13 | 3 | 8 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | | 1 | | | | 1 |
| Dental pain and sensation disorders | | 3 | | 3 | | |
| Diarrhoea (excl infective) | 3 | 10 | 3 | 9 | | 1 |
| Dyspeptic signs and symptoms | 1 | 6 | 1 | 6 | | |
| Gastric and oesophageal haemorrhages | 1 | 1 | | | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 2 | 6 | 2 | 6 | | |
| Gastrointestinal necrosis and gangrene (excl gangrenous hernia) | 1 | 1 | | | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | | 5 | | 4 | | 1 |
| Gingival disorders, signs and symptoms NEC | | 1 | | 1 | | |
| Nausea and vomiting symptoms | 13 | 47 | 12 | 41 | 1 | 6 |
| Oesophagitis (excl infective) | | 1 | | 1 | | |
| Oral dryness and saliva altered | | 1 | | 1 | | |
| Oral soft tissue disorders NEC | | 1 | | 1 | | |
| Oral soft tissue signs and symptoms | 4 | 28 | 3 | 25 | 1 | 3 |
| Oral soft tissue swelling and oedema | | 2 | | 1 | | 1 |
| Stomatitis and ulceration | 1 | 1 | 1 | 1 | | |
| Tongue signs and symptoms | | 5 | | 1 | | 4 |
| | 26 | 120 | 22 | 101 | 4 | 19 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Adverse effect absent | 2 | 2 | | | 2 | 2 | | |
| Application and instillation site reactions | | 1 | | | | 1 | | |
| Asthenic conditions | 52 | 163 | | | 48 | 152 | 4 | 11 |
| Death and sudden death | 2 | 8 | | | | | 2 | 8 |
| Febrile disorders | 27 | 65 | | | 23 | 58 | 4 | 7 |
| Feelings and sensations NEC | 29 | 78 | | | 29 | 74 | | 4 |
| Gait disturbances | 1 | 3 | | | | | 1 | 3 |
| General signs and symptoms NEC | 11 | 28 | | | 9 | 24 | 2 | 4 |
| Inflamations | 1 | 2 | | | | | 1 | 2 |
| Injection site reactions | 1 | 6 | | | 1 | 6 | | |
| Oedema NEC | 1 | 1 | | | | | 1 | 1 |
| Pain and discomfort NEC | 13 | 30 | | | 11 | 27 | 2 | 3 |
| Therapeutic and nontherapeutic responses | 15 | 33 | | 1 | 1 | 4 | 14 | 29 |
| Vaccination site reactions | 18 | 97 | | | 18 | 97 | | |
| | 173 | 517 | | 1 | 142 | 445 | 31 | 72 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholestasis and jaundice | | 1 | | 1 | | |
| Hepatocellular damage and hepatitis NEC | 1 | 2 | | | 1 | 2 |
| | 1 | 3 | | 1 | 1 | 2 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 2 | 6 | | 1 | 2 | 5 |
| Allergies to foods, food additives, drugs and other chemicals | 1 | 5 | 1 | 2 | | 3 |
| Anaphylactic and anaphylactoid responses | 2 | 6 | | | 2 | 6 |
| | 5 | 17 | 1 | 3 | 4 | 14 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Bacterial infections NEC | 1 | 2 | | | | 1 | 1 | 1 |
| Cardiac infections | 1 | 1 | | | | | 1 | 1 |
| Coronavirus infections | 17 | 25 | | 1 | 2 | 2 | 15 | 23 |
| Dental and oral soft tissue infections | | 1 | | | | 1 | | |
| Ear infections | | 1 | | | | 1 | | |
| Eye and eyelid infections | 1 | 2 | | | | 1 | 1 | 1 |
| Herpes viral infections | 11 | 15 | | | 10 | 13 | 1 | 2 |
| Infections NEC | | 1 | | | | 1 | | |
| Influenza viral infections | 1 | 3 | | | 1 | 3 | | |
| Lower respiratory tract and lung infections | 3 | 3 | | | | | 3 | 3 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | 1 | | | | | | 1 |
| Upper respiratory tract infections | 3 | 5 | | | 3 | 5 | | |
| Urinary tract infections | 1 | 1 | | | 1 | 1 | | |
| Viral infections NEC | | 1 | | | | 1 | | |
| | 39 | 62 | | 1 | 17 | 30 | 22 | 32 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Abdominal and gastrointestinal injuries NEC | | 1 | | | | 1 | | | |
| Bone and joint injuries NEC | 1 | 1 | | | | | 1 | 1 | |
| Exposures associated with pregnancy, delivery and lactation | 5 | 10 | | | 5 | 10 | | | |
| Exposures to agents or circumstances NEC | | | | 1 | | | | | |
| Intentional product use issues | | 1 | | | | 1 | | | |
| Limb fractures and dislocations | | 1 | | | | | | | 1 |
| Medication errors, product use errors and issues NEC | 2 | 6 | | | 2 | 6 | | | |
| Non-site specific injuries NEC | 1 | 4 | | | | 1 | 1 | 3 | |
| Off label uses | 4 | 6 | | | 4 | 6 | | | |
| Overdoses NEC | | 4 | | | | 4 | | | |
| Pelvic fractures and dislocations | | 1 | | | | | | | 1 |
| Product administration errors and issues | 3 | 38 | | | 3 | 38 | | | |
| Product preparation errors and issues | | 5 | | | | 5 | | | |
| Site specific injuries NEC | | 1 | | | | | | | 1 |
| Skin injuries NEC | | 1 | | | | | | | 1 |
| Thoracic cage fractures and dislocations | | 1 | | | | | | | 1 |
| Underdoses NEC | | 3 | | | | 3 | | | |
| Vaccination related complications | 1 | 1 | | | | | 1 | 1 | |
| | 17 | 85 | | 1 | 14 | 75 | 3 | 10 | |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| High Level Term | | | | | | | |
| Blood gas and acid base analyses | | 2 | | 1 | | 1 | |
| Carbohydrate tolerance analyses (incl diabetes) | | 3 | | 1 | | 2 | |
| Chemistry analyses NEC | | 1 | | | | 1 | |
| Coagulation and bleeding analyses | | 1 | | | | 1 | |
| Heart rate and pulse investigations | 2 | 11 | 1 | 9 | 1 | 2 | |
| Immunology analyses NEC | | 1 | | 1 | | | |
| Mineral and electrolyte analyses | | 2 | | 1 | | 1 | |
| Physical examination procedures and organ system status | 2 | 6 | 2 | 4 | | 2 | |
| Platelet analyses | | 1 | | 1 | | | |
| Protein analyses NEC | | 1 | | 1 | | | |
| Red blood cell analyses | | 6 | | 5 | | 1 | |
| Renal function analyses | | 1 | | | | 1 | |
| Vascular tests NEC (incl blood pressure) | 2 | 13 | 2 | 8 | | 5 | |
| Virus identification and serology | 4 | 11 | 4 | 4 | | 7 | |
| White blood cell analyses | | 2 | | 1 | | 1 | |
| | 10 | 62 | 9 | 37 | 1 | 25 | |

System Organ Class

| Metabolism and nutrition disorders | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| High Level Term | | | | | | |
| Appetite disorders | 2 | 7 | 1 | 5 | 1 | 2 |
| Food malabsorption and intolerance syndromes (excl sugar intolerance) | 1 | 1 | 1 | 1 | | |
| | 3 | 8 | 2 | 6 | 1 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | | 1 | | 1 | | |
| Bone related signs and symptoms | 2 | 6 | 2 | 6 | | |
| Joint related signs and symptoms | 17 | 29 | 13 | 23 | 4 | 6 |
| Muscle pains | 16 | 48 | 15 | 45 | 1 | 3 |
| Muscle related signs and symptoms NEC | | 1 | | 1 | | |
| Muscle tone abnormalities | 1 | 2 | 1 | 1 | | 1 |
| Muscle weakness conditions | 3 | 4 | 2 | 3 | 1 | 1 |
| Musculoskeletal and connective tissue conditions NEC | 3 | 4 | 2 | 2 | 1 | 2 |
| Musculoskeletal and connective tissue deformities of skull, face and buccal cavity | | 1 | | 1 | | |
| Musculoskeletal and connective tissue pain and discomfort | 22 | 64 | 21 | 63 | 1 | 1 |
| Spondyloarthropathies | 1 | 1 | | | 1 | 1 |
| | 65 | 161 | 56 | 146 | 9 | 15 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 6 | | | 1 | 6 |
| Chronic polyneuropathies | 1 | 1 | | | 1 | 1 |
| Coordination and balance disturbances | 1 | 3 | 1 | 2 | | 1 |
| Disturbances in consciousness NEC | 4 | 16 | 1 | 2 | 3 | 14 |
| Dyskinesias and movement disorders NEC | 4 | 7 | 3 | 4 | 1 | 3 |
| Facial cranial nerve disorders | 8 | 20 | | | 8 | 20 |
| Headaches NEC | 32 | 79 | 30 | 73 | 2 | 6 |
| Migraine headaches | 1 | 2 | 1 | 2 | | |
| Multiple sclerosis acute and progressive | | 4 | | | | 4 |
| Neurological signs and symptoms NEC | 10 | 42 | 8 | 34 | 2 | 8 |
| Neuromuscular disorders NEC | 2 | 4 | 2 | 4 | | |
| Neuromuscular junction dysfunction | 1 | 1 | | | 1 | 1 |
| Olfactory nerve disorders | 2 | 6 | 2 | 6 | | |
| Paraesthesias and dysaesthesias | 8 | 56 | 5 | 50 | 3 | 6 |
| Paralysis and paresis (excl cranial nerve) | 3 | 5 | | | 3 | 5 |
| Parkinson's disease and parkinsonism | | 1 | | 1 | | |
| Peripheral neuropathies NEC | | 3 | | 3 | | |
| Seizures and seizure disorders NEC | 10 | 10 | | | 10 | 10 |
| Sensory abnormalities NEC | 3 | 18 | 2 | 17 | 1 | 1 |
| Sleep disturbances NEC | | 1 | | 1 | | |
| Speech and language abnormalities | 3 | 5 | 1 | 3 | 2 | 2 |
| Structural brain disorders NEC | 1 | 1 | | | 1 | 1 |
| Tremor (excl congenital) | 1 | 5 | 1 | 5 | | |
| | 96 | 296 | 57 | 207 | 39 | 89 |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortions spontaneous | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Product packaging issues | | 12 | | 12 |
| Product physical issues | 1 | 16 | 1 | 16 |
| Product quality issues NEC | | 1 | | 1 |
| | 1 | 29 | 1 | 29 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 2 | 4 | 2 | 4 | | |
| Behaviour and socialisation disturbances | | 1 | | 1 | | |
| Confusion and disorientation | 1 | 2 | | 1 | 1 | 1 |
| Depressive disorders | 1 | 2 | | 1 | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 3 | 6 | 3 | 6 | | |
| Emotional and mood disturbances NEC | 1 | 2 | 1 | 2 | | |
| Hallucinations (excl sleep-related) | 1 | 1 | | | 1 | 1 |
| Increased physical activity levels | 1 | 1 | | | 1 | 1 |
| Mental disorders NEC | 1 | 1 | 1 | 1 | | |
| Mood alterations with depressive symptoms | 2 | 3 | 1 | 2 | 1 | 1 |
| Sexual desire disorders | 1 | 1 | 1 | 1 | | |
| Sleep disorders NEC | 1 | 2 | 1 | 2 | | |
| Suicidal and self-injurious behaviour | 1 | 1 | | | 1 | 1 |
| Thinking disturbances | 1 | 1 | 1 | 1 | | |
| Tic disorders | | 1 | | 1 | | |
| | 17 | 29 | 11 | 23 | 6 | 6 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast infections and inflammations | 1 | 1 | 1 | 1 |
| Menstruation and uterine bleeding NEC | 2 | 2 | 2 | 2 |
| Menstruation with increased bleeding | 1 | 1 | 1 | 1 |
| Reproductive tract signs and symptoms NEC | | 1 | | 1 |
| Vulvovaginal disorders NEC | 2 | 2 | 2 | 2 |
| | 6 | 7 | 6 | 7 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 12 | 31 | 6 | 14 | 6 | 17 |
| Bronchospasm and obstruction | 1 | 3 | | 1 | 1 | 2 |
| Coughing and associated symptoms | 2 | 8 | 2 | 8 | | |
| Lower respiratory tract signs and symptoms | | 1 | | | | 1 |
| Parenchymal lung disorders NEC | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 4 | | 3 | 1 | 1 |
| Pneumothorax and pleural effusions NEC | | 1 | | | | 1 |
| Pulmonary oedemas | 1 | 1 | | | 1 | 1 |
| Respiratory signs and symptoms NEC | | 1 | | 1 | | |
| Respiratory tract disorders NEC | 1 | 2 | | 1 | 1 | 1 |
| Tracheal disorders (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 1 | 21 | 1 | 17 | | 4 |
| | 21 | 75 | 9 | 45 | 12 | 30 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Alopecias | | 1 | | 1 | | |
| Angioedemas | 1 | 1 | | | 1 | 1 |
| Apocrine and eccrine gland disorders | 2 | 7 | 2 | 7 | | |
| Dermal and epidermal conditions NEC | | 3 | | 3 | | |
| Erythemas | 2 | 9 | 1 | 8 | 1 | 1 |
| Pruritus NEC | | 3 | | 2 | | 1 |
| Rashes, eruptions and exanthems NEC | 1 | 13 | 1 | 10 | | 3 |
| Urticarias | 2 | 8 | 2 | 5 | | 3 |
| | 8 | 45 | 6 | 36 | 2 | 9 |

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System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disability issues | 1 | 1 | 1 | 1 |
| Social issues NEC | | 1 | | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Circulatory collapse and shock | | 1 | | | | 1 |
| Non-site specific embolism and thrombosis | | 3 | | | | 3 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | 1 | 1 | | |
| Vascular hypertensive disorders NEC | 1 | 6 | 1 | 2 | | 4 |
| Vascular hypotensive disorders | | 2 | | 1 | | 1 |
| | 2 | 13 | 2 | 4 | | 9 |

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Country Where Event Occurred

ITALY

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemias NEC | 2 | 2 | 2 | 2 | | |
| Coagulopathies | 1 | 1 | | | 1 | 1 |
| Leukocytoses NEC | 1 | 1 | 1 | 1 | | |
| Leukopenias NEC | 1 | 1 | | | 1 | 1 |
| Lymphatic system disorders NEC | 163 | 205 | 52 | 91 | 111 | 114 |
| Thrombocytopenias | 2 | 2 | | | 2 | 2 |
| | 170 | 212 | 55 | 94 | 115 | 118 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Cardiac conduction disorders | | 1 | | | | | | | 1 |
| Cardiac signs and symptoms NEC | 11 | 14 | | | 5 | 8 | 6 | 6 | |
| Coronary artery disorders NEC | 1 | 1 | | | | | 1 | 1 | |
| Heart failures NEC | 1 | 2 | | | | | 1 | 2 | |
| Ischaemic coronary artery disorders | 3 | 10 | | | | | 3 | 10 | |
| Noninfectious myocarditis | 2 | 2 | | | | | 2 | 2 | |
| Noninfectious pericarditis | 4 | 4 | | | | | 4 | 4 | |
| Pericardial disorders NEC | 1 | 1 | | | | | 1 | 1 | |
| Rate and rhythm disorders NEC | 122 | 154 | 4 | 4 | 25 | 48 | 97 | 106 | |
| Supraventricular arrhythmias | 12 | 15 | | | 3 | 5 | 9 | 10 | |
| Ventricular arrhythmias and cardiac arrest | 7 | 7 | | | 1 | 1 | 6 | 6 | |
| | 164 | 211 | 4 | 4 | 34 | 62 | 130 | 149 | |

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System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Tongue disorders congenital | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ear disorders NEC | 19 | 21 | | | 11 | 13 | 8 | 8 |
| Hearing losses | 6 | 7 | | | | | 6 | 7 |
| Inner ear signs and symptoms | 76 | 100 | 1 | 1 | 28 | 50 | 48 | 50 |
| | 101 | 128 | 1 | 1 | 39 | 63 | 62 | 65 |

System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic thyroiditis | 1 | 1 | | | 1 | 1 |
| Thyroid disorders NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Thyroid hyperfunction disorders | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 1 | 1 | 4 | 4 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Choroid and vitreous structural change, deposit and degeneration | 3 | 3 | | | | | 3 | 3 |
| Conjunctival and corneal bleeding and vascular disorders | 3 | 4 | | | | | 3 | 4 |
| Conjunctival infections, irritations and inflammations | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Eyelid movement disorders | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Iris and ciliary body structural change, deposit and degeneration | 1 | 1 | | | | | 1 | 1 |
| Iris and uveal tract infections, irritations and inflammations | 2 | 2 | | | | | 2 | 2 |
| Lacrimation disorders | 3 | 5 | | | 2 | 4 | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 9 | 11 | 1 | 1 | 2 | 3 | 7 | 8 |
| Lid, lash and lacrimal structural disorders | 1 | 1 | | | | | 1 | 1 |
| Ocular bleeding and vascular disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Ocular disorders NEC | 22 | 27 | | | 9 | 13 | 13 | 14 |
| Ocular infections, inflammations and associated manifestations | 15 | 22 | 1 | 1 | 7 | 12 | 8 | 10 |
| Ocular nerve and muscle disorders | 1 | 1 | | | | | 1 | 1 |
| Ocular sensation disorders | 8 | 10 | | | 6 | 8 | 2 | 2 |
| Optic disc abnormalities NEC | 1 | 1 | | | | | 1 | 1 |
| Orbital structural change, deposit and degeneration | 1 | 1 | | | | | 1 | 1 |
| Pupil disorders | 1 | 1 | | | 1 | 1 | | |
| Refractive and accommodative disorders | 1 | 1 | | | | | 1 | 1 |
| Retinal bleeding and vascular disorders (excl retinopathy) | 1 | 1 | | | | | 1 | 1 |
| Retinal structural change, deposit and degeneration | 4 | 4 | | | | | 4 | 4 |
| Scleral infections, irritations and inflammations | 1 | 1 | | | | | 1 | 1 |
| Scleral structural change, deposit and degeneration | 1 | 1 | | | | | 1 | 1 |
| Visual colour distortions | 1 | 1 | | | | | 1 | 1 |
| Visual disorders NEC | 22 | 27 | | | 5 | 10 | 17 | 17 |

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System Organ Class

Eye disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|----|---------|----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 2 | 3 | 8 | 8 |
| | | | | 1 | 1 |
| 2 | 2 | 36 | 56 | 86 | 91 |

Visual impairment and blindness (excl colour blindness)

10 11

Visual pathway disorders

1 1

122 147

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|--|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Abdominal findings abnormal | | 1 | | | | 1 | | | |
| Anal and rectal disorders NEC | 1 | 1 | | | | | 1 | 1 | |
| Dental pain and sensation disorders | 1 | 1 | | | 1 | 1 | | | |
| Diarrhoea (excl infective) | 89 | 117 | | | 33 | 61 | 56 | 56 | |
| Dyspeptic signs and symptoms | 7 | 8 | | | 5 | 6 | 2 | 2 | |
| Faecal abnormalities NEC | 2 | 2 | | | 1 | 1 | 1 | 1 | |
| Flatulence, bloating and distension | 5 | 7 | | | 1 | 3 | 4 | 4 | |
| Gastritis (excl infective) | | 1 | | | | 1 | | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 79 | 101 | | | 36 | 57 | 43 | 44 | |
| Gastrointestinal atonic and hypomotility disorders NEC | 1 | 2 | | | | 1 | 1 | 1 | |
| Gastrointestinal disorders NEC | 4 | 6 | | | 3 | 5 | 1 | 1 | |
| Gastrointestinal inflammatory disorders NEC | 1 | 1 | | | | | 1 | 1 | |
| Gastrointestinal signs and symptoms NEC | 31 | 43 | 2 | 2 | 10 | 18 | 21 | 25 | |
| Gastrointestinal spastic and hypermotility disorders | 2 | 2 | | | | | 2 | 2 | |
| Gastrointestinal stenosis and obstruction NEC | 1 | 1 | | | | | 1 | 1 | |
| Gingival disorders, signs and symptoms NEC | 1 | 2 | | | | 1 | 1 | 1 | |
| Nausea and vomiting symptoms | 319 | 388 | 2 | 2 | 105 | 169 | 214 | 219 | |
| Non-site specific gastrointestinal haemorrhages | 2 | 2 | | | | | 2 | 2 | |
| Oral dryness and saliva altered | 18 | 31 | 1 | 1 | 4 | 15 | 14 | 16 | |
| Oral soft tissue signs and symptoms | 91 | 125 | 2 | 2 | 28 | 56 | 63 | 69 | |
| Oral soft tissue swelling and oedema | 34 | 51 | | | 6 | 18 | 28 | 33 | |
| Salivary gland enlargements | | 1 | | | | 1 | | | |
| Stomatitis and ulceration | 6 | 6 | | | 3 | 3 | 3 | 3 | |
| Tongue disorders | 4 | 5 | | | | 1 | 4 | 4 | |
| Tongue signs and symptoms | 27 | 39 | | | 5 | 12 | 22 | 27 | |
| | 726 | 944 | 7 | 7 | 241 | 431 | 485 | 513 | |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Administration site reactions NEC | 1 | 2 | | | | | 1 | 2 |
| Adverse effect absent | 1 | 1 | | | 1 | 1 | | |
| Application and instillation site reactions | 1 | 1 | | | 1 | 1 | | |
| Asthenic conditions | 471 | 567 | 3 | 4 | 193 | 282 | 278 | 285 |
| Body temperature altered | 20 | 22 | | | 4 | 5 | 16 | 17 |
| Death and sudden death | 5 | 8 | | | | | 5 | 8 |
| Febrile disorders | 712 | 833 | 5 | 6 | 215 | 328 | 497 | 505 |
| Feelings and sensations NEC | 318 | 390 | 3 | 5 | 136 | 201 | 182 | 189 |
| Gait disturbances | 11 | 11 | | | 4 | 4 | 7 | 7 |
| General signs and symptoms NEC | 56 | 77 | 1 | 1 | 18 | 35 | 38 | 42 |
| Inflammations | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Injection site reactions | 11 | 14 | | | 4 | 7 | 7 | 7 |
| Mucosal findings abnormal | 4 | 5 | | | | 1 | 4 | 4 |
| Oedema NEC | 21 | 26 | | | 7 | 11 | 14 | 15 |
| Pain and discomfort NEC | 145 | 177 | 2 | 2 | 56 | 84 | 89 | 93 |
| Therapeutic and nontherapeutic responses | 56 | 65 | | | 2 | 2 | 54 | 63 |
| Vaccination site reactions | 375 | 621 | 3 | 3 | 193 | 430 | 182 | 191 |
| | 2,210 | 2,823 | 17 | 21 | 835 | 1393 | 1375 | 1430 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hepatic enzymes and function abnormalities | 2 | 2 | 2 | 2 |
| Hepatocellular damage and hepatitis NEC | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|---|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Allergic conditions NEC | 27 | 30 | 1 | 1 | 3 | 4 | 24 | 26 |
| Allergies to foods, food additives, drugs and other chemicals | 10 | 11 | | | | | 10 | 11 |
| Anaphylactic and anaphylactoid responses | 21 | 43 | | | | | 21 | 43 |
| Atopic disorders | 1 | 1 | | | | | 1 | 1 |
| | 59 | 85 | 1 | 1 | 3 | 4 | 56 | 81 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal and gastrointestinal infections | 99 | 99 | 1 | 1 | | | 99 | 99 |
| Bacterial infections NEC | 2 | 2 | | | | | 2 | 2 |
| Bone and joint infections | 1 | 1 | | | | | 1 | 1 |
| Breast infections | 3 | 4 | | | | | 3 | 4 |
| Candida infections | 1 | 1 | | | 1 | 1 | | |
| Central nervous system and spinal infections | 1 | 1 | | | | | 1 | 1 |
| Coronavirus infections | 62 | 73 | | | 5 | 8 | 57 | 65 |
| Coxiella infections | 6 | 6 | | | | | 6 | 6 |
| Dental and oral soft tissue infections | 2 | 2 | | | 2 | 2 | | |
| Ear infections | 4 | 4 | | | 1 | 1 | 3 | 3 |
| Eye and eyelid infections | 6 | 6 | | | 2 | 2 | 4 | 4 |
| Herpes viral infections | 18 | 22 | | | 4 | 7 | 14 | 15 |
| Infections NEC | 1 | 1 | | | | | 1 | 1 |
| Influenza viral infections | 6 | 6 | | | 5 | 5 | 1 | 1 |
| Listeria infections | 1 | 1 | | | | | 1 | 1 |
| Lower respiratory tract and lung infections | 2 | 2 | | | | | 2 | 2 |
| Muscle and soft tissue infections | 1 | 1 | | | | | 1 | 1 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 3 | 3 | | | | | 3 | 3 |
| Upper respiratory tract infections | 11 | 16 | | | 5 | 9 | 6 | 7 |
| Urinary tract infections | 2 | 2 | | | 2 | 2 | | |
| Vascular infections | 3 | 4 | | | | | 3 | 4 |
| | 235 | 257 | 1 | 1 | 27 | 37 | 208 | 220 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Atmospheric pressure injuries | 1 | 1 | | | 1 | 1 | | |
| Chest and respiratory tract injuries NEC | 1 | 1 | | | | | 1 | 1 |
| Exposures associated with pregnancy, delivery and lactation | 6 | 8 | | | 5 | 7 | 1 | 1 |
| Exposures to agents or circumstances NEC | 1 | 1 | | | 1 | 1 | | |
| Medication errors, product use errors and issues NEC | 12 | 17 | | | 10 | 15 | 2 | 2 |
| Non-site specific injuries NEC | 4 | 5 | | | | | 4 | 5 |
| Off label uses | 16 | 19 | | | 15 | 18 | 1 | 1 |
| Overdoses NEC | 29 | 32 | | | 29 | 32 | | |
| Product administration errors and issues | 15 | 25 | 1 | 1 | 15 | 25 | | |
| Product confusion errors and issues | | 1 | | | | 1 | | |
| Product preparation errors and issues | 6 | 7 | | | 6 | 7 | | |
| Site specific injuries NEC | 1 | 1 | | | | | 1 | 1 |
| Skin injuries NEC | 1 | 1 | | | 1 | 1 | | |
| Skull fractures, facial bone fractures and dislocations | 1 | 1 | | | | | 1 | 1 |
| Spinal cord injuries NEC | 1 | 1 | | | | | 1 | 1 |
| Stoma complications | 1 | 1 | | | | | 1 | 1 |
| Thermal burns | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Underdoses NEC | 5 | 10 | | | 5 | 10 | | |
| Vaccination related complications | 17 | 19 | 1 | 1 | 4 | 6 | 13 | 13 |
| | 120 | 153 | 2 | 2 | 93 | 125 | 27 | 28 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Blood gas and acid base analyses | 26 | 28 | | | 3 | 4 | 23 | 24 |
| Carbohydrate tolerance analyses (incl diabetes) | 1 | 2 | | | | 1 | 1 | 1 |
| Coagulation and bleeding analyses | 2 | 2 | | | 2 | 2 | | |
| Digestive enzymes | 1 | 1 | | | | | 1 | 1 |
| ECG investigations | 1 | 1 | | | | | 1 | 1 |
| Haem metabolism analyses | 1 | 1 | | | | | 1 | 1 |
| Heart rate and pulse investigations | 14 | 15 | | | 3 | 4 | 11 | 11 |
| Investigations NEC | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Liver function analyses | 5 | 5 | | | 2 | 2 | 3 | 3 |
| Mineral and electrolyte analyses | 1 | 1 | | | 1 | 1 | | |
| Neurologic diagnostic procedures | | 1 | | | | | | 1 |
| Physical examination procedures and organ system status | 8 | 16 | | | 3 | 9 | 5 | 7 |
| Protein analyses NEC | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Red blood cell analyses | 3 | 3 | | | 2 | 2 | 1 | 1 |
| Respiratory and pulmonary function diagnostic procedures | | 1 | | | | 1 | | |
| Skeletal and cardiac muscle analyses | 2 | 2 | | | | | 2 | 2 |
| Thyroid analyses | 1 | 1 | | | | | 1 | 1 |
| Tissue enzyme analyses NEC | 1 | 1 | | | | | 1 | 1 |
| Urinary tract function analyses NEC | 1 | 1 | | | | | 1 | 1 |
| Vascular tests NEC (incl blood pressure) | 36 | 45 | 1 | 1 | 11 | 17 | 25 | 28 |
| Virus identification and serology | 7 | 13 | | | 3 | 8 | 4 | 5 |
| White blood cell analyses | 10 | 10 | | | 2 | 2 | 8 | 8 |
| | 125 | 154 | 1 | 1 | 34 | 55 | 91 | 99 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 13 | 15 | 6 | 8 | 7 | 7 |
| General nutritional disorders NEC | 1 | 1 | | | 1 | 1 |
| Hyperglycaemic conditions NEC | 1 | 1 | | | 1 | 1 |
| Hypoglycaemic conditions NEC | | 1 | | 1 | | |
| Total fluid volume decreased | 2 | 3 | | | 2 | 3 |
| Total fluid volume increased | 1 | 1 | 1 | 1 | | |
| | 18 | 22 | 7 | 10 | 11 | 12 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Bone related signs and symptoms | 46 | 55 | | | 26 | 35 | 20 | 20 |
| Connective tissue disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Joint related disorders NEC | 2 | 2 | | | | | 2 | 2 |
| Joint related signs and symptoms | 245 | 290 | 2 | 2 | 106 | 149 | 139 | 141 |
| Muscle infections and inflammations | | | 1 | 1 | | | | |
| Muscle pains | 275 | 326 | 3 | 3 | 125 | 174 | 150 | 152 |
| Muscle related signs and symptoms NEC | 15 | 17 | | | 7 | 9 | 8 | 8 |
| Muscle tone abnormalities | 9 | 13 | | | 4 | 6 | 5 | 7 |
| Muscle weakness conditions | 16 | 19 | | | 6 | 9 | 10 | 10 |
| Musculoskeletal and connective tissue conditions NEC | 19 | 22 | 1 | 1 | 5 | 8 | 14 | 14 |
| Musculoskeletal and connective tissue pain and discomfort | 214 | 276 | 3 | 3 | 86 | 144 | 128 | 132 |
| Rheumatoid arthropathies | 1 | 1 | | | | | 1 | 1 |
| | 843 | 1,022 | 10 | 10 | 365 | 534 | 478 | 488 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Nervous system neoplasms unspecified malignancy NEC | 1 | 1 | 1 | 1 |
| Soft tissue neoplasms benign NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal reflexes | 2 | 2 | | | | | 2 | 2 |
| Central nervous system aneurysms and dissections | 1 | 1 | | | | | 1 | 1 |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 3 | | | | | 1 | 3 |
| Cerebrovascular venous and sinus thrombosis | 1 | 1 | | | | | 1 | 1 |
| Cervical spinal cord and nerve root disorders | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Chronic polyneuropathies | 1 | 1 | | | | | 1 | 1 |
| Coma states | 2 | 2 | | | | | 2 | 2 |
| Coordination and balance disturbances | 9 | 11 | | | | 2 | 9 | 9 |
| Cortical dysfunction NEC | 5 | 5 | | | 2 | 2 | 3 | 3 |
| Cranial nerve disorders NEC | 2 | 4 | | | 1 | 1 | 1 | 3 |
| Disturbances in consciousness NEC | 187 | 212 | 1 | 1 | 19 | 37 | 168 | 175 |
| Dyskinesias and movement disorders NEC | 10 | 10 | | | 2 | 2 | 8 | 8 |
| Encephalopathies NEC | 1 | 1 | | | | | 1 | 1 |
| Eye movement disorders | 2 | 2 | | | | | 2 | 2 |
| Facial cranial nerve disorders | 42 | 46 | | | 2 | 2 | 40 | 44 |
| Generalised tonic-clonic seizures | 1 | 1 | | | | | 1 | 1 |
| Headaches NEC | 454 | 588 | 5 | 6 | 202 | 333 | 252 | 255 |
| Hypoglossal nerve disorders | 1 | 1 | | | | | 1 | 1 |
| Lumbar spinal cord and nerve root disorders | 1 | 2 | | | | 1 | 1 | 1 |
| Memory loss (excl dementia) | 6 | 6 | | | 2 | 2 | 4 | 4 |
| Mental impairment (excl dementia and memory loss) | 7 | 7 | | | 1 | 1 | 6 | 6 |
| Migraine headaches | 27 | 37 | | | 10 | 20 | 17 | 17 |
| Multiple sclerosis acute and progressive | 2 | 3 | | | | 1 | 2 | 2 |
| Muscle tone abnormal | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Narcolepsy and hypersomnia | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Nervous system disorders NEC | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Neurological signs and symptoms NEC | 155 | 188 | | | 57 | 88 | 98 | 100 |
| Neurologic visual problems NEC | 1 | 1 | | | | | 1 | 1 |
| Neuromuscular disorders NEC | 2 | 3 | | | 1 | 1 | 1 | 2 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Neuromuscular junction dysfunction | 1 | 1 | | | | | 1 | 1 |
| Olfactory nerve disorders | 8 | 10 | | | 4 | 6 | 4 | 4 |
| Optic nerve disorders NEC | 4 | 4 | | | | | 4 | 4 |
| Paraesthesias and dysaesthesias | 206 | 259 | 2 | 2 | 52 | 101 | 154 | 158 |
| Paralysis and paresis (excl cranial nerve) | 23 | 25 | | | | 1 | 23 | 24 |
| Parkinson's disease and parkinsonism | | 1 | | | | | | 1 |
| Peripheral neuropathies NEC | 9 | 10 | 1 | 1 | 1 | 2 | 8 | 8 |
| Seizures and seizure disorders NEC | 17 | 18 | | | | | 17 | 18 |
| Sensory abnormalities NEC | 45 | 65 | | | 14 | 32 | 31 | 33 |
| Speech and language abnormalities | 2 | 3 | | | 1 | 2 | 1 | 1 |
| Spinal cord and nerve root disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Tremor (excl congenital) | 42 | 54 | 1 | 1 | 9 | 20 | 33 | 34 |
| Trigeminal disorders | 6 | 6 | | | 2 | 2 | 4 | 4 |
| | 1,298 | 1,606 | 10 | 11 | 387 | 664 | 911 | 942 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortions not specified as induced or spontaneous | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 16 | 22 | 6 | 12 | 10 | 10 |
| Confusion and disorientation | 30 | 38 | 9 | 16 | 21 | 22 |
| Deliria | 1 | 1 | | | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 24 | 28 | 13 | 17 | 11 | 11 |
| Emotional and mood disturbances NEC | 4 | 5 | 2 | 3 | 2 | 2 |
| Hallucinations (excl sleep-related) | 6 | 6 | | | 6 | 6 |
| Increased physical activity levels | 3 | 4 | | | 3 | 4 |
| Mental disorders NEC | 1 | 1 | | | 1 | 1 |
| Mood disorders NEC | 1 | 1 | | | 1 | 1 |
| Panic attacks and disorders | 3 | 3 | 2 | 2 | 1 | 1 |
| Parasomnias | 1 | 1 | 1 | 1 | | |
| Sleep disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 92 | 112 | 34 | 52 | 58 | 60 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 4 | 5 | 1 | 1 | 3 | 4 |
| Bladder infections and inflammations | 4 | 4 | | | 4 | 4 |
| Myoneurogenic bladder disorders | 1 | 1 | | | 1 | 1 |
| Renal failure and impairment | 3 | 5 | | | 3 | 5 |
| Renal failure complications | 1 | 1 | | | 1 | 1 |
| Urinary abnormalities | 4 | 4 | 2 | 2 | 2 | 2 |
| Urinary tract signs and symptoms NEC | 2 | 4 | 1 | 3 | 1 | 1 |
| | 19 | 24 | 4 | 6 | 15 | 18 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast signs and symptoms | 2 | 5 | 1 | 1 | 1 | 4 |
| Menstruation and uterine bleeding NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Vulvovaginal disorders NEC | 1 | 1 | | | 1 | 1 |
| Vulvovaginal signs and symptoms | 1 | 1 | 1 | 1 | | |
| | 7 | 10 | 3 | 3 | 4 | 7 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Breathing abnormalities | 143 | 164 | 3 | 4 | 16 | 26 | 127 | 138 |
| Bronchospasm and obstruction | 33 | 35 | 1 | 1 | 3 | 3 | 30 | 32 |
| Conditions associated with abnormal gas exchange | 3 | 4 | | | | | 3 | 4 |
| Coughing and associated symptoms | 59 | 68 | 1 | 1 | 12 | 20 | 47 | 48 |
| Diaphragmatic disorders | 1 | 1 | | | | | 1 | 1 |
| Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) | 3 | 3 | | | | | 3 | 3 |
| Laryngeal spasm, oedema and obstruction | 44 | 54 | | | 1 | 1 | 43 | 53 |
| Lower respiratory tract inflammatory and immunologic conditions | 2 | 2 | | | | | 2 | 2 |
| Lower respiratory tract signs and symptoms | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Nasal congestion and inflammations | 4 | 7 | | | 3 | 6 | 1 | 1 |
| Nasal disorders NEC | 8 | 10 | | | 4 | 6 | 4 | 4 |
| Parenchymal lung disorders NEC | 2 | 2 | | | | | 2 | 2 |
| Pharyngeal disorders (excl infections and neoplasms) | 24 | 31 | | | 4 | 9 | 20 | 22 |
| Pleural infections and inflammations | 1 | 1 | | | | | 1 | 1 |
| Pulmonary thrombotic and embolic conditions | 1 | 2 | | | | | 1 | 2 |
| Respiratory failures (excl neonatal) | 5 | 6 | | | | | 5 | 6 |
| Respiratory signs and symptoms NEC | 2 | 3 | | | | | 2 | 3 |
| Respiratory tract disorders NEC | 3 | 4 | | | | 1 | 3 | 3 |
| Tracheal disorders (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 109 | 140 | 2 | 2 | 27 | 52 | 82 | 88 |
| | 451 | 541 | 7 | 8 | 72 | 126 | 379 | 415 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Angioedemas | 30 | 32 | | | | | 30 | 32 |
| Apocrine and eccrine gland disorders | 51 | 67 | | | 15 | 29 | 36 | 38 |
| Bullous conditions | 10 | 10 | | | 2 | 2 | 8 | 8 |
| Dermal and epidermal conditions NEC | 20 | 22 | | | 2 | 4 | 18 | 18 |
| Dermatitis and eczema | 4 | 6 | | | 2 | 2 | 2 | 4 |
| Dermatitis ascribed to specific agent | 1 | 1 | | | | | 1 | 1 |
| Erythemas | 73 | 105 | | | 14 | 40 | 59 | 65 |
| Exfoliative conditions | 2 | 3 | | | | | 2 | 3 |
| Lipodystrophies | 1 | 1 | | | | | 1 | 1 |
| Panniculitides | 1 | 1 | | | | | 1 | 1 |
| Papulosquamous conditions | | 1 | | | | 1 | | |
| Photosensitivity and photodermatitis conditions | 1 | 1 | | | | | 1 | 1 |
| Pruritus NEC | 69 | 97 | 1 | 1 | 15 | 39 | 54 | 58 |
| Psoriatic conditions | 1 | 1 | | | | | 1 | 1 |
| Purpura and related conditions | 4 | 4 | | | 3 | 3 | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 95 | 125 | 2 | 2 | 22 | 49 | 73 | 76 |
| Rosaceas | 1 | 1 | | | 1 | 1 | | |
| Scaly conditions | 1 | 1 | | | 1 | 1 | | |
| Skin haemorrhages | 1 | 1 | | | | | 1 | 1 |
| Urticarias | 75 | 111 | 2 | 2 | 13 | 45 | 62 | 66 |
| | 441 | 591 | 5 | 5 | 90 | 216 | 351 | 375 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disability issues | 4 | 4 | 2 | 2 | 2 | 2 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Accelerated and malignant hypertension | 45 | 52 | | | | | 45 | 52 |
| Blood pressure disorders NEC | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Circulatory collapse and shock | 1 | 2 | | | | | 1 | 2 |
| Haemorrhages NEC | | 1 | | | | 1 | | |
| Lymphoedemas | 4 | 5 | | | 2 | 3 | 2 | 2 |
| Non-site specific necrosis and vascular insufficiency NEC | 1 | 2 | | | 1 | 1 | | 1 |
| Non-site specific vascular disorders NEC | 4 | 4 | | | | | 4 | 4 |
| Peripheral embolism and thrombosis | 4 | 5 | | | | | 4 | 5 |
| Peripheral vascular disorders NEC | 38 | 56 | | | 8 | 26 | 30 | 30 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 7 | 13 | 1 | 1 | 2 | 8 | 5 | 5 |
| Site specific vascular disorders NEC | 7 | 10 | | | 1 | 4 | 6 | 6 |
| Vascular hypertensive disorders NEC | 40 | 47 | | | 5 | 7 | 35 | 40 |
| Vascular hypotensive disorders | 47 | 58 | 1 | 1 | 10 | 18 | 37 | 40 |
| Vasculitides NEC | 1 | 1 | | | | | 1 | 1 |
| | 201 | 258 | 2 | 2 | 30 | 69 | 171 | 189 |

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Country Where Event Occurred

JAPAN

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 1 | 1 | 1 | | |
| Oral soft tissue haemorrhages | 1 | 1 | 1 | 1 | | |
| Oral soft tissue signs and symptoms | 2 | 2 | | | 2 | 2 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 2 | 2 | 2 | 2 | | |
| Death and sudden death | 1 | 1 | | | 1 | 1 |
| Febrile disorders | 1 | 1 | 1 | 1 | | |
| Feelings and sensations NEC | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | 2 | 2 | 2 | 2 | | |
| Injection site reactions | 1 | 1 | 1 | 1 | | |
| Pain and discomfort NEC | 1 | 1 | 1 | 1 | | |
| | 9 | 9 | 8 | 8 | 1 | 1 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Anaphylactic and anaphylactoid responses | 2 | 2 | | | 2 | 2 |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Joint related signs and symptoms | 1 | 1 | 1 | 1 |
| Muscle pains | 1 | 1 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Facial cranial nerve disorders | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 1 | 1 | 1 | 1 | | |
| Increased intracranial pressure disorders | 1 | 1 | | | 1 | 1 |
| Seizures and seizure disorders NEC | 1 | 1 | | | 1 | 1 |
| Sensory abnormalities NEC | 1 | 1 | | | 1 | 1 |
| | 5 | 5 | 1 | 1 | 4 | 4 |

System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Abortions not specified as induced or spontaneous | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Affect alterations NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Breathing abnormalities | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Dermatitis and eczema | 1 | 1 | 1 | 1 |
| Erythemas | 1 | 1 | 1 | 1 |
| Pruritus NEC | 1 | 1 | 1 | 1 |
| Urticarias | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Surgical and medical procedures

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Therapeutic procedures NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Haemorrhages NEC | 1 | 1 | 1 | 1 |
| Site specific vascular disorders NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

JORDAN

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenic conditions | 2 | 2 | 2 | 2 |
| Vaccination site reactions | 2 | 2 | 2 | 2 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle pains | 1 | 1 | 1 | 1 |
| Muscle related signs and symptoms NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Headaches NEC | 1 | 1 | 1 | 1 |
| Sensory abnormalities NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

KUWAIT

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | | 1 | | 1 | | |
| Febrile disorders | | 1 | | 1 | | |
| General signs and symptoms NEC | 1 | 2 | 1 | 2 | | |
| Pain and discomfort NEC | 1 | 2 | 1 | 2 | | |
| Therapeutic and nontherapeutic responses | 1 | 1 | | | 1 | 1 |
| Vaccination site reactions | | 2 | | 2 | | |
| | 3 | 9 | 2 | 8 | 1 | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Coronavirus infections | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle pains | | 1 | | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 1 | 2 | 1 | 2 |
| | 1 | 3 | 1 | 3 |

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Country Where Event Occurred

LATVIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 13 | 15 | 9 | 10 | 4 | 5 |
| | 13 | 15 | 9 | 10 | 4 | 5 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Cardiac signs and symptoms NEC | 3 | 3 | 3 | 3 |
| Rate and rhythm disorders NEC | 6 | 6 | 6 | 6 |
| Supraventricular arrhythmias | 1 | 1 | 1 | 1 |
| | 10 | 10 | 10 | 10 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 2 | 2 | | | 2 | 2 |
| Hearing losses | 1 | 1 | 1 | 1 | | |
| Inner ear signs and symptoms | 3 | 3 | 3 | 3 | | |
| | 6 | 6 | 4 | 4 | 2 | 2 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival and corneal bleeding and vascular disorders | 1 | 1 | | | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 1 | 1 | 1 | | |
| Ocular disorders NEC | 8 | 9 | 8 | 9 | | |
| Ocular sensation disorders | 3 | 3 | 2 | 2 | 1 | 1 |
| Visual disorders NEC | 1 | 1 | | | 1 | 1 |
| | 14 | 15 | 11 | 12 | 3 | 3 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 4 | 5 | 4 | 5 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 6 | 6 | 4 | 4 | 2 | 2 |
| Nausea and vomiting symptoms | 19 | 21 | 17 | 19 | 2 | 2 |
| Oral dryness and saliva altered | 1 | 2 | 1 | 1 | | 1 |
| Oral soft tissue signs and symptoms | 1 | 1 | | | 1 | 1 |
| Oral soft tissue swelling and oedema | | 1 | | 1 | | |
| | 31 | 36 | 26 | 30 | 5 | 6 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 50 | 58 | 40 | 47 | 10 | 11 |
| Febrile disorders | 45 | 49 | 40 | 43 | 5 | 6 |
| Feelings and sensations NEC | 32 | 34 | 31 | 33 | 1 | 1 |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | 1 | 4 | | 3 | 1 | 1 |
| Pain and discomfort NEC | 3 | 4 | 2 | 3 | 1 | 1 |
| Therapeutic and nontherapeutic responses | 1 | 3 | | | 1 | 3 |
| Vaccination site reactions | 68 | 79 | 53 | 63 | 15 | 16 |
| | 201 | 232 | 167 | 193 | 34 | 39 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Immune and associated conditions NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | | 4 | | 2 | | 2 |
| Upper respiratory tract infections | 1 | 1 | 1 | 1 | | |
| | 1 | 5 | 1 | 3 | | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Exposures associated with pregnancy, delivery and lactation | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Physical examination procedures and organ system status | 33 | 39 | 33 | 38 | | 1 |
| Protein analyses NEC | 1 | 1 | 1 | 1 | | |
| Vascular tests NEC (incl blood pressure) | 1 | 4 | | 2 | 1 | 2 |
| Virus identification and serology | 1 | 2 | | | 1 | 2 |
| | 36 | 46 | 34 | 41 | 2 | 5 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Appetite disorders | 5 | 5 | 5 | 5 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 2 | 2 | 2 | 2 | | |
| Joint related signs and symptoms | 29 | 34 | 25 | 29 | 4 | 5 |
| Muscle pains | 32 | 36 | 28 | 32 | 4 | 4 |
| Muscle related signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Muscle weakness conditions | 4 | 4 | 2 | 2 | 2 | 2 |
| Musculoskeletal and connective tissue conditions NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 8 | 12 | 7 | 10 | 1 | 2 |
| | 78 | 91 | 66 | 77 | 12 | 14 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coordination and balance disturbances | 1 | 1 | 1 | 1 | | |
| Disturbances in consciousness NEC | 9 | 10 | 6 | 6 | 3 | 4 |
| Facial cranial nerve disorders | 2 | 2 | | | 2 | 2 |
| Headaches NEC | 41 | 46 | 36 | 39 | 5 | 7 |
| Mental impairment (excl dementia and memory loss) | 7 | 7 | 3 | 3 | 4 | 4 |
| Migraine headaches | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 15 | 16 | 11 | 12 | 4 | 4 |
| Neurologic visual problems NEC | 1 | 1 | | | 1 | 1 |
| Paraesthesias and dysaesthesias | 9 | 11 | 3 | 3 | 6 | 8 |
| Peripheral neuropathies NEC | 1 | 1 | | | 1 | 1 |
| Sensory abnormalities NEC | 2 | 4 | 1 | 1 | 1 | 3 |
| | 89 | 100 | 61 | 65 | 28 | 35 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | | 1 | | | | 1 |
| Depressive disorders | 1 | 1 | 1 | 1 | | |
| Disturbances in initiating and maintaining sleep | 2 | 2 | 1 | 1 | 1 | 1 |
| Mood alterations with depressive symptoms | 1 | 1 | 1 | 1 | | |
| Sleep disorders NEC | 2 | 2 | 2 | 2 | | |
| Thinking disturbances | 1 | 1 | 1 | 1 | | |
| | 7 | 8 | 6 | 6 | 1 | 2 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 2 | 3 | | 1 | 2 | 2 |
| Bronchospasm and obstruction | | 1 | | 1 | | |
| Coughing and associated symptoms | 4 | 5 | 4 | 5 | | |
| Nasal congestion and inflammations | 1 | 1 | 1 | 1 | | |
| Nasal disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 11 | 12 | 10 | 11 | 1 | 1 |
| | 21 | 25 | 17 | 21 | 4 | 4 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 6 | 8 | 5 | 6 | 1 | 2 |
| Dermal and epidermal conditions NEC | 2 | 2 | | | 2 | 2 |
| Erythemas | 1 | 2 | 1 | 1 | | 1 |
| Pruritus NEC | 1 | 2 | | | 1 | 2 |
| Rashes, eruptions and exanthems NEC | 5 | 5 | 4 | 4 | 1 | 1 |
| | 15 | 19 | 10 | 11 | 5 | 8 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 2 | 2 | | | 2 | 2 |
| Peripheral vascular disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | | 2 | | 1 | | 1 |
| Vascular hypertensive disorders NEC | 1 | 1 | 1 | 1 | | |
| | 5 | 7 | 2 | 3 | 3 | 4 |

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Country Where Event Occurred

LEBANON

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Allergic conditions NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Angioedemas | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

LITHUANIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ischaemic coronary artery disorders | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | | 1 | | 1 | | |
| | 1 | 2 | | 1 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 3 | | 2 | 1 | 1 |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 1 | 1 | 1 | 1 | | |
| Nausea and vomiting symptoms | 5 | 6 | 1 | 2 | 4 | 4 |
| Oral soft tissue signs and symptoms | 1 | 1 | | | 1 | 1 |
| Oral soft tissue swelling and oedema | 1 | 1 | 1 | 1 | | |
| | 10 | 13 | 4 | 7 | 6 | 6 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 2 | 3 | | 1 | 2 | 2 |
| Death and sudden death | 1 | 1 | | | 1 | 1 |
| Febrile disorders | 2 | 8 | 2 | 8 | | |
| Feelings and sensations NEC | 2 | 5 | 1 | 4 | 1 | 1 |
| General signs and symptoms NEC | 4 | 5 | 1 | 2 | 3 | 3 |
| Pain and discomfort NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Vaccination site reactions | 11 | 15 | 7 | 11 | 4 | 4 |
| | 26 | 41 | 13 | 28 | 13 | 13 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactic and anaphylactoid responses | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 1 | 1 | 1 | 1 | | |
| Medication errors, product use errors and issues NEC | 1 | 1 | 1 | 1 | | |
| Off label uses | 1 | 1 | 1 | 1 | | |
| Overdoses NEC | | 1 | | 1 | | |
| Product administration errors and issues | 1 | 1 | | | 1 | 1 |
| Product preparation errors and issues | 1 | 1 | | | 1 | 1 |
| Underdoses NEC | | 1 | | 1 | | |
| Vaccination related complications | | 1 | | 1 | | |
| | 5 | 8 | 3 | 6 | 2 | 2 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Heart rate and pulse investigations | 3 | 3 | 1 | 1 | 2 | 2 |
| Physical examination procedures and organ system status | 1 | 1 | 1 | 1 | | |
| Vascular tests NEC (incl blood pressure) | 5 | 6 | | 1 | 5 | 5 |
| | 9 | 10 | 2 | 3 | 7 | 7 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint related signs and symptoms | 2 | 4 | 2 | 4 | | |
| Muscle infections and inflammations | 2 | 2 | 1 | 1 | 1 | 1 |
| Muscle pains | 1 | 6 | 1 | 6 | | |
| Muscle related signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Muscle weakness conditions | 1 | 1 | 1 | 1 | | |
| Musculoskeletal and connective tissue pain and discomfort | 2 | 6 | 2 | 6 | | |
| Tendon disorders | 1 | 1 | 1 | 1 | | |
| | 10 | 21 | 9 | 20 | 1 | 1 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in consciousness NEC | 2 | 2 | | | 2 | 2 |
| Headaches NEC | 5 | 9 | 2 | 6 | 3 | 3 |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 1 | 3 | | 2 | 1 | 1 |
| Paraesthesias and dysaesthesias | 6 | 7 | 4 | 5 | 2 | 2 |
| Seizures and seizure disorders NEC | 2 | 2 | | | 2 | 2 |
| Sensory abnormalities NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Tremor (excl congenital) | 3 | 4 | 1 | 2 | 2 | 2 |
| | 22 | 30 | 8 | 16 | 14 | 14 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Anxiety symptoms | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 3 | 3 | 1 | 1 | 2 | 2 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | | 1 | | 1 | | |
| Dermal and epidermal conditions NEC | | 1 | | 1 | | |
| Erythemas | 1 | 1 | | | 1 | 1 |
| Pruritus NEC | 1 | 1 | 1 | 1 | | |
| Skin and subcutaneous conditions NEC | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | 1 | 3 | 2 | 2 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure disorders NEC | 1 | 1 | 1 | 1 | | |
| Vascular hypertensive disorders NEC | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

LUXEMBOURG

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Diarrhoea (excl infective) | 2 | 2 | 2 | 2 |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 |
| Nausea and vomiting symptoms | 2 | 2 | 2 | 2 |
| Oral dryness and saliva altered | 1 | 1 | 1 | 1 |
| Tongue disorders | 1 | 1 | 1 | 1 |
| | 7 | 7 | 7 | 7 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 6 | 6 | | | 6 | 6 |
| Body temperature altered | 1 | 1 | | | 1 | 1 |
| Febrile disorders | 3 | 3 | | | 3 | 3 |
| Feelings and sensations NEC | 4 | 4 | | | 4 | 4 |
| General signs and symptoms NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Oedema NEC | 1 | 1 | | | 1 | 1 |
| Pain and discomfort NEC | 1 | 1 | | | 1 | 1 |
| Therapeutic and nontherapeutic responses | 1 | 1 | | | 1 | 1 |
| Vaccination site reactions | 3 | 3 | | | 3 | 3 |
| | 22 | 22 | 1 | 1 | 21 | 21 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Allergic conditions NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 1 | 1 | | | 1 | 1 |
| Herpes viral infections | | 2 | | 2 | | |
| Influenza viral infections | 1 | 1 | 1 | 1 | | |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | 1 | 3 | 2 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conditions caused by cold | 1 | 1 | 1 | 1 | | |
| Vaccination related complications | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Heart rate and pulse investigations | 2 | 2 | 2 | 2 |
| Virus identification and serology | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Appetite disorders | 1 | 1 | 1 | 1 |
| General nutritional disorders NEC | 1 | 1 | 1 | 1 |
| Sodium imbalance | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint related signs and symptoms | 1 | 1 | | | 1 | 1 |
| Muscle pains | 4 | 4 | | | 4 | 4 |
| Musculoskeletal and connective tissue conditions NEC | 1 | 1 | | | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 3 | 3 | 1 | 1 | 2 | 2 |
| | 9 | 9 | 1 | 1 | 8 | 8 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Disturbances in consciousness NEC | 3 | 3 | 3 | 3 |
| Headaches NEC | 5 | 5 | 5 | 5 |
| Migraine headaches | 1 | 1 | 1 | 1 |
| Neurological signs and symptoms NEC | 2 | 2 | 2 | 2 |
| Paraesthesias and dysaesthesias | 1 | 1 | 1 | 1 |
| Seizures and seizure disorders NEC | 1 | 1 | 1 | 1 |
| Sensory abnormalities NEC | 1 | 1 | 1 | 1 |
| Tremor (excl congenital) | 1 | 1 | 1 | 1 |
| | 15 | 15 | 15 | 15 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Renal failure and impairment | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Breathing abnormalities | 2 | 2 | 2 | 2 |
| Lower respiratory tract signs and symptoms | 1 | 1 | 1 | 1 |
| Respiratory tract disorders NEC | 1 | 1 | 1 | 1 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Apocrine and eccrine gland disorders | 1 | 1 | 1 | 1 |
| Dermal and epidermal conditions NEC | 1 | 1 | 1 | 1 |
| Pruritus NEC | 1 | 1 | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 1 | 1 | 1 | 1 |
| Skin haemorrhages | 1 | 1 | 1 | 1 |
| | 5 | 5 | 5 | 5 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Site specific vascular disorders NEC | 1 | 1 | 1 | 1 |
| Vascular hypotensive disorders | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

MALTA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 1 | 2 | | 1 | 1 | 1 |
| Rate and rhythm disorders NEC | 1 | 2 | | | 1 | 2 |
| Supraventricular arrhythmias | 1 | 1 | | | 1 | 1 |
| | 3 | 5 | | 1 | 3 | 4 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 2 | 3 | 1 | 2 | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 2 | 2 | 2 | 2 | | |
| Gastrointestinal spastic and hypermotility disorders | 1 | 1 | 1 | 1 | | |
| Nausea and vomiting symptoms | 4 | 7 | 2 | 5 | 2 | 2 |
| | 9 | 13 | 6 | 10 | 3 | 3 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Administration site reactions NEC | 1 | 1 | 1 | 1 | | |
| Asthenic conditions | 11 | 14 | 9 | 12 | 2 | 2 |
| Febrile disorders | 7 | 8 | 5 | 6 | 2 | 2 |
| Feelings and sensations NEC | 2 | 3 | 2 | 3 | | |
| Gait disturbances | 2 | 2 | 2 | 2 | | |
| General signs and symptoms NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Injection site reactions | | 1 | | 1 | | |
| Pain and discomfort NEC | 4 | 5 | 4 | 5 | | |
| Therapeutic and nontherapeutic responses | | 1 | | | | 1 |
| Vaccination site reactions | 7 | 9 | 6 | 8 | 1 | 1 |
| | 36 | 46 | 30 | 39 | 6 | 7 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Allergic conditions NEC | | 1 | | 1 |
| Anaphylactic and anaphylactoid responses | 3 | 4 | 3 | 4 |
| | 3 | 5 | 3 | 5 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Coronavirus infections | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Medication errors, product use errors and issues NEC | | 1 | | 1 |
| Off label uses | | 1 | | 1 |
| Overdoses NEC | 1 | 1 | 1 | 1 |
| Product administration errors and issues | | 1 | | 1 |
| | 1 | 4 | 1 | 4 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Appetite disorders | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint related signs and symptoms | 2 | 2 | 2 | 2 | | |
| Muscle pains | 3 | 5 | 2 | 4 | 1 | 1 |
| Musculoskeletal and connective tissue conditions NEC | 2 | 2 | 2 | 2 | | |
| Musculoskeletal and connective tissue pain and discomfort | 10 | 10 | 7 | 7 | 3 | 3 |
| | 17 | 19 | 13 | 15 | 4 | 4 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in consciousness NEC | 5 | 9 | 3 | 7 | 2 | 2 |
| Facial cranial nerve disorders | 2 | 3 | | | 2 | 3 |
| Generalised tonic-clonic seizures | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 1 | 2 | 1 | 2 | | |
| Paraesthesias and dysaesthesias | 5 | 8 | 4 | 7 | 1 | 1 |
| Sensory abnormalities NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 16 | 25 | 9 | 17 | 7 | 8 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 |
| Fear symptoms and phobic disorders (incl social phobia) | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 4 | 5 | | | 4 | 5 |
| Bronchospasm and obstruction | 3 | 5 | | | 3 | 5 |
| Coughing and associated symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| Upper respiratory tract signs and symptoms | 3 | 3 | 1 | 1 | 2 | 2 |
| | 12 | 15 | 2 | 2 | 10 | 13 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 2 | 2 | 2 | 2 | | |
| Erythemas | 1 | 2 | | 1 | 1 | 1 |
| Pruritus NEC | 1 | 1 | | | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 3 | 5 | | 1 | 3 | 4 |
| Urticarias | 1 | 1 | | | 1 | 1 |
| | 8 | 11 | 2 | 4 | 6 | 7 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 1 | 2 | 1 | 2 | | |
| Vascular hypertensive disorders NEC | 1 | 2 | | | 1 | 2 |
| | 3 | 5 | 1 | 2 | 2 | 3 |

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Country Where Event Occurred

MEXICO

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukopenias NEC | | 1 | | | | 1 |
| Lymphatic system disorders NEC | 32 | 35 | 28 | 31 | 4 | 4 |
| Thrombocytopenias | 1 | 1 | 1 | 1 | | |
| | 33 | 37 | 29 | 32 | 4 | 5 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 4 | 5 | 4 | 5 | | |
| Ischaemic coronary artery disorders | | 1 | | | | 1 |
| Rate and rhythm disorders NEC | 191 | 202 | 152 | 162 | 39 | 40 |
| Supraventricular arrhythmias | 3 | 3 | 1 | 1 | 2 | 2 |
| | 198 | 211 | 157 | 168 | 41 | 43 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 7 | 8 | 7 | 8 | | |
| External ear disorders NEC | 1 | 1 | 1 | 1 | | |
| External ear infections and inflammations | 1 | 1 | 1 | 1 | | |
| Hearing losses | 2 | 2 | | | 2 | 2 |
| Inner ear signs and symptoms | 13 | 14 | 10 | 11 | 3 | 3 |
| Tympanic membrane disorders (excl infections) | 1 | 1 | 1 | 1 | | |
| | 25 | 27 | 20 | 22 | 5 | 5 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival infections, irritations and inflammations | 1 | 1 | 1 | 1 | | |
| Lacrimation disorders | 3 | 3 | 3 | 3 | | |
| Lid, lash and lacrimal infections, irritations and inflammations | 4 | 4 | 4 | 4 | | |
| Ocular disorders NEC | 10 | 13 | 10 | 12 | | 1 |
| Ocular infections, inflammations and associated manifestations | 6 | 7 | 6 | 7 | | |
| Ocular nerve and muscle disorders | 1 | 1 | | | 1 | 1 |
| Ocular sensation disorders | 2 | 2 | 2 | 2 | | |
| Visual disorders NEC | 14 | 14 | 12 | 12 | 2 | 2 |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | | | 1 | 1 |
| | 42 | 46 | 38 | 41 | 4 | 5 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Colitis (excl infective) | 1 | 1 | 1 | 1 | | |
| Dental pain and sensation disorders | 1 | 1 | 1 | 1 | | |
| Diarrhoea (excl infective) | 66 | 72 | 56 | 61 | 10 | 11 |
| Dyspeptic signs and symptoms | | 1 | | 1 | | |
| Faecal abnormalities NEC | 1 | 1 | | | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 60 | 66 | 53 | 59 | 7 | 7 |
| Gastrointestinal disorders NEC | | 1 | | | | 1 |
| Gastrointestinal dyskinetic disorders | 1 | 2 | 1 | 2 | | |
| Gastrointestinal signs and symptoms NEC | 6 | 6 | 5 | 5 | 1 | 1 |
| Gastrointestinal stenosis and obstruction NEC | 2 | 2 | | | 2 | 2 |
| Nausea and vomiting symptoms | 241 | 262 | 208 | 225 | 33 | 37 |
| Non-site specific gastrointestinal haemorrhages | 3 | 3 | | | 3 | 3 |
| Oral dryness and saliva altered | 8 | 8 | 4 | 4 | 4 | 4 |
| Oral soft tissue haemorrhages | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 37 | 39 | 30 | 31 | 7 | 8 |
| Oral soft tissue swelling and oedema | 2 | 3 | 2 | 3 | | |
| Salivary gland enlargements | | 1 | | 1 | | |
| Tongue signs and symptoms | 3 | 3 | 2 | 2 | 1 | 1 |
| | 433 | 473 | 363 | 396 | 70 | 77 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 496 | 525 | 438 | 465 | 58 | 60 |
| Body temperature altered | 6 | 6 | 3 | 3 | 3 | 3 |
| Febrile disorders | 163 | 194 | 143 | 173 | 20 | 21 |
| Feelings and sensations NEC | 216 | 234 | 182 | 200 | 34 | 34 |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | 97 | 100 | 86 | 89 | 11 | 11 |
| Inflamations | 45 | 47 | 38 | 39 | 7 | 8 |
| Injection site reactions | 1 | 1 | 1 | 1 | | |
| Mass conditions NEC | 51 | 52 | 45 | 46 | 6 | 6 |
| Oedema NEC | 84 | 92 | 68 | 76 | 16 | 16 |
| Pain and discomfort NEC | 309 | 332 | 274 | 296 | 35 | 36 |
| Therapeutic and nontherapeutic responses | 11 | 21 | 1 | 1 | 10 | 20 |
| Vaccination site reactions | 177 | 233 | 165 | 220 | 12 | 13 |
| | 1,657 | 1,838 | 1445 | 1610 | 212 | 228 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholestasis and jaundice | 3 | 3 | | | 3 | 3 |
| Hepatobiliary signs and symptoms | 1 | 1 | 1 | 1 | | |
| | 4 | 4 | 1 | 1 | 3 | 3 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 22 | 25 | 16 | 19 | 6 | 6 |
| Allergies to foods, food additives, drugs and other chemicals | 5 | 8 | 3 | 6 | 2 | 2 |
| Anaphylactic and anaphylactoid responses | 27 | 29 | | | 27 | 29 |
| Immune and associated conditions NEC | 3 | 3 | 3 | 3 | | |
| | 57 | 65 | 22 | 28 | 35 | 37 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacterial infections NEC | 11 | 11 | 1 | 1 | 10 | 10 |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 18 | 28 | 6 | 7 | 12 | 21 |
| Dental and oral soft tissue infections | | 1 | | 1 | | |
| Ear infections | 4 | 4 | 4 | 4 | | |
| Eye and eyelid infections | 3 | 3 | 3 | 3 | | |
| Influenza viral infections | 2 | 2 | 2 | 2 | | |
| Lower respiratory tract and lung infections | 9 | 12 | | | 9 | 12 |
| Tuberculous infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 5 | 5 | 3 | 3 | 2 | 2 |
| Urinary tract infections | 2 | 2 | 1 | 1 | 1 | 1 |
| Vascular infections | 1 | 1 | | | 1 | 1 |
| Viral infections NEC | 1 | 1 | | | 1 | 1 |
| | 58 | 72 | 20 | 22 | 38 | 50 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chest and respiratory tract injuries NEC | 2 | 2 | 2 | 2 | | |
| Exposures associated with pregnancy, delivery and lactation | 5 | 6 | 5 | 6 | | |
| Eye injuries NEC | 10 | 10 | 7 | 7 | 3 | 3 |
| Medication errors, product use errors and issues NEC | 4 | 6 | 4 | 6 | | |
| Occupational exposures | 1 | 1 | 1 | 1 | | |
| Off label uses | 4 | 6 | 4 | 6 | | |
| Peripheral nerve injuries | | 1 | | | | 1 |
| Product administration errors and issues | 4 | 5 | 4 | 5 | | |
| | 30 | 37 | 27 | 33 | 3 | 4 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 25 | 26 | 14 | 14 | 11 | 12 |
| Carbohydrate tolerance analyses (incl diabetes) | 1 | 2 | 1 | 1 | | 1 |
| Coagulation and bleeding analyses | | 1 | | | | 1 |
| Heart rate and pulse investigations | 6 | 6 | 5 | 5 | 1 | 1 |
| Liver function analyses | 2 | 2 | | | 2 | 2 |
| Physical examination procedures and organ system status | 45 | 49 | 37 | 41 | 8 | 8 |
| Vascular tests NEC (incl blood pressure) | 17 | 18 | 10 | 10 | 7 | 8 |
| Virus identification and serology | 5 | 6 | 4 | 4 | 1 | 2 |
| White blood cell analyses | | 1 | | | | 1 |
| | 101 | 111 | 71 | 75 | 30 | 36 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 32 | 34 | 26 | 28 | 6 | 6 |
| Electrolyte imbalance NEC | 1 | 1 | | | 1 | 1 |
| Sodium imbalance | | 1 | | | | 1 |
| Total fluid volume decreased | 1 | 2 | | | 1 | 2 |
| | 34 | 38 | 26 | 28 | 8 | 10 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | | 1 | | | | 1 |
| Bone related signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| Joint related signs and symptoms | 202 | 237 | 181 | 215 | 21 | 22 |
| Lupus erythematosus (incl subtypes) | 1 | 1 | | | 1 | 1 |
| Muscle pains | 233 | 266 | 208 | 240 | 25 | 26 |
| Muscle related signs and symptoms NEC | 1 | 4 | 1 | 3 | | 1 |
| Muscle tone abnormalities | 1 | 1 | 1 | 1 | | |
| Muscle weakness conditions | 9 | 10 | 5 | 6 | 4 | 4 |
| Musculoskeletal and connective tissue conditions NEC | 4 | 8 | 4 | 8 | | |
| Musculoskeletal and connective tissue pain and discomfort | 30 | 36 | 27 | 33 | 3 | 3 |
| Soft tissue disorders NEC | 1 | 1 | 1 | 1 | | |
| | 484 | 567 | 429 | 508 | 55 | 59 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute polyneuropathies | 2 | 2 | | | 2 | 2 |
| Coordination and balance disturbances | 3 | 3 | | | 3 | 3 |
| Demyelinating disorders NEC | 1 | 3 | | | 1 | 3 |
| Disturbances in consciousness NEC | 41 | 45 | 7 | 8 | 34 | 37 |
| Dyskinesias and movement disorders NEC | 1 | 2 | 1 | 2 | | |
| Encephalitis NEC | | 1 | | | | 1 |
| Facial cranial nerve disorders | 4 | 4 | | | 4 | 4 |
| Generalised tonic-clonic seizures | 3 | 3 | | | 3 | 3 |
| Headaches NEC | 366 | 421 | 320 | 372 | 46 | 49 |
| Increased intracranial pressure disorders | 1 | 1 | | | 1 | 1 |
| Lumbar spinal cord and nerve root disorders | | 1 | | | | 1 |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | 1 | 1 | | |
| Mononeuropathies | 1 | 3 | | | 1 | 3 |
| Myelitis (incl infective) | | 1 | | | | 1 |
| Narcolepsy and hypersomnia | 1 | 1 | 1 | 1 | | |
| Nervous system disorders NEC | | 1 | | | | 1 |
| Neurological signs and symptoms NEC | 242 | 261 | 204 | 222 | 38 | 39 |
| Neuromuscular disorders NEC | 2 | 4 | 1 | 2 | 1 | 2 |
| Olfactory nerve disorders | 10 | 11 | 8 | 9 | 2 | 2 |
| Paraesthesias and dysaesthesias | 60 | 74 | 42 | 50 | 18 | 24 |
| Paralysis and paresis (excl cranial nerve) | 13 | 14 | | | 13 | 14 |
| Peripheral neuropathies NEC | 1 | 5 | | | 1 | 5 |
| Seizures and seizure disorders NEC | 21 | 28 | 3 | 3 | 18 | 25 |
| Sensory abnormalities NEC | 16 | 21 | 11 | 15 | 5 | 6 |
| Speech and language abnormalities | 2 | 2 | 2 | 2 | | |
| Spinal cord and nerve root disorders NEC | | 2 | | | | 2 |
| Tremor (excl congenital) | 7 | 7 | 7 | 7 | | |
| | 799 | 922 | 608 | 694 | 191 | 228 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Affect alterations NEC | 1 | 1 | 1 | 1 | | |
| Anxiety symptoms | 18 | 18 | 13 | 13 | 5 | 5 |
| Confusion and disorientation | 4 | 4 | 3 | 3 | 1 | 1 |
| Emotional and mood disturbances NEC | 20 | 20 | 17 | 17 | 3 | 3 |
| Mood alterations with depressive symptoms | 1 | 1 | 1 | 1 | | |
| Parasomnias | 1 | 1 | | | 1 | 1 |
| | 45 | 45 | 35 | 35 | 10 | 10 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Urinary abnormalities | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast signs and symptoms | 1 | 1 | 1 | 1 |
| Menstruation and uterine bleeding NEC | 1 | 1 | 1 | 1 |
| Reproductive tract signs and symptoms NEC | | 1 | | 1 |
| | 2 | 3 | 2 | 3 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 598 | 608 | 217 | 222 | 381 | 386 |
| Bronchial conditions NEC | 1 | 1 | 1 | 1 | | |
| Bronchospasm and obstruction | 30 | 31 | 13 | 14 | 17 | 17 |
| Coughing and associated symptoms | 124 | 133 | 106 | 115 | 18 | 18 |
| Laryngeal spasm, oedema and obstruction | 5 | 6 | | 1 | 5 | 5 |
| Lower respiratory tract signs and symptoms | 1 | 1 | 1 | 1 | | |
| Nasal congestion and inflammations | 6 | 7 | 6 | 7 | | |
| Nasal disorders NEC | 2 | 2 | 2 | 2 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 7 | 7 | 1 | 1 | 6 | 6 |
| Respiratory failures (excl neonatal) | 1 | 1 | | | 1 | 1 |
| Respiratory signs and symptoms NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Respiratory tract disorders NEC | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 248 | 260 | 217 | 229 | 31 | 31 |
| | 1,027 | 1,061 | 567 | 596 | 460 | 465 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | | 2 | | | | 2 |
| Apocrine and eccrine gland disorders | 13 | 14 | 10 | 11 | 3 | 3 |
| Bullous conditions | 2 | 2 | | | 2 | 2 |
| Dermal and epidermal conditions NEC | 145 | 145 | 129 | 129 | 16 | 16 |
| Dermatitis and eczema | 1 | 1 | 1 | 1 | | |
| Erythemas | 54 | 56 | 48 | 50 | 6 | 6 |
| Pruritus NEC | 59 | 64 | 49 | 53 | 10 | 11 |
| Purpura and related conditions | 4 | 4 | 1 | 1 | 3 | 3 |
| Rashes, eruptions and exanthems NEC | 63 | 78 | 45 | 57 | 18 | 21 |
| Skin haemorrhages | 1 | 1 | 1 | 1 | | |
| Urticarias | 3 | 4 | 3 | 4 | | |
| | 345 | 371 | 287 | 307 | 58 | 64 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disability issues | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 17 | 19 | | | 17 | 19 |
| Circulatory collapse and shock | 4 | 4 | | | 4 | 4 |
| Haemorrhages NEC | 3 | 3 | | | 3 | 3 |
| Peripheral vascular disorders NEC | 6 | 8 | 6 | 8 | | |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 3 | 3 | 3 | 3 | | |
| Site specific vascular disorders NEC | 2 | 2 | 2 | 2 | | |
| Vascular hypertensive disorders NEC | 35 | 37 | 20 | 21 | 15 | 16 |
| Vascular hypotensive disorders | 5 | 5 | 2 | 2 | 3 | 3 |
| | 75 | 81 | 33 | 36 | 42 | 45 |

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Country Where Event Occurred

NETHERLANDS

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | 8 | 8 | 8 | 8 |
| | 8 | 8 | 8 | 8 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 1 | 1 | 1 | 1 | | |
| Cardiac disorders NEC | 1 | 1 | | | 1 | 1 |
| Cardiac signs and symptoms NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Heart failures NEC | 8 | 8 | | | 8 | 8 |
| Ischaemic coronary artery disorders | 3 | 3 | | | 3 | 3 |
| Rate and rhythm disorders NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Supraventricular arrhythmias | 5 | 5 | 1 | 1 | 4 | 4 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 25 | 26 | 4 | 4 | 21 | 22 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 1 | 1 | 1 | 1 | | |
| Hearing losses | 5 | 5 | | | 5 | 5 |
| Hyperacusia | 1 | 1 | 1 | 1 | | |
| Inner ear signs and symptoms | 3 | 3 | 2 | 2 | 1 | 1 |
| | 10 | 10 | 4 | 4 | 6 | 6 |

System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hypothalamic and pituitary disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival infections, irritations and inflammations | 1 | 1 | | | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 1 | | | 1 | 1 |
| Ocular infections, inflammations and associated manifestations | 1 | 1 | | | 1 | 1 |
| Ocular nerve and muscle disorders | 1 | 1 | | | 1 | 1 |
| Pupil disorders | 1 | 1 | 1 | 1 | | |
| Refractive and accommodative disorders | 1 | 1 | 1 | 1 | | |
| Visual disorders NEC | 4 | 4 | 4 | 4 | | |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | | | 1 | 1 |
| | 11 | 11 | 6 | 6 | 5 | 5 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 1 | 2 | 1 | 2 | | |
| Faecal abnormalities NEC | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 1 | 2 | 1 | 2 | | |
| Gastrointestinal signs and symptoms NEC | 4 | 5 | 1 | 1 | 3 | 4 |
| Nausea and vomiting symptoms | 44 | 47 | 33 | 36 | 11 | 11 |
| Non-site specific gastrointestinal haemorrhages | 3 | 3 | | | 3 | 3 |
| Oral soft tissue signs and symptoms | 3 | 4 | 1 | 2 | 2 | 2 |
| Oral soft tissue swelling and oedema | 2 | 2 | | | 2 | 2 |
| Tongue disorders | 2 | 2 | | | 2 | 2 |
| Tongue signs and symptoms | 4 | 5 | | | 4 | 5 |
| | 65 | 73 | 38 | 44 | 27 | 29 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 92 | 95 | 61 | 63 | 31 | 32 |
| Death and sudden death | 13 | 13 | | | 13 | 13 |
| Febrile disorders | 33 | 33 | 7 | 7 | 26 | 26 |
| Feelings and sensations NEC | 35 | 37 | 30 | 31 | 5 | 6 |
| General signs and symptoms NEC | 7 | 9 | 1 | 3 | 6 | 6 |
| Injection site reactions | 10 | 10 | 10 | 10 | | |
| Pain and discomfort NEC | 3 | 5 | 3 | 4 | | 1 |
| Therapeutic and nontherapeutic responses | 1 | 1 | | | 1 | 1 |
| Vaccination site reactions | 70 | 77 | 68 | 75 | 2 | 2 |
| | 264 | 280 | 180 | 193 | 84 | 87 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hepatic failure and associated disorders | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Allergic conditions NEC | 5 | 5 | 5 | 5 |
| Allergies to foods, food additives, drugs and other chemicals | | 1 | | 1 |
| Anaphylactic and anaphylactoid responses | 10 | 12 | 10 | 12 |
| | 15 | 18 | 15 | 18 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Coronavirus infections | 3 | 3 | 3 | 3 |
| Dental and oral soft tissue infections | 2 | 2 | 2 | 2 |
| Herpes viral infections | 1 | 1 | 1 | 1 |
| Lower respiratory tract and lung infections | 2 | 2 | 2 | 2 |
| Upper respiratory tract infections | 2 | 2 | 2 | 2 |
| Urinary tract infections | 2 | 2 | 2 | 2 |
| Vascular infections | 1 | 1 | 1 | 1 |
| Viral infections NEC | 1 | 1 | 1 | 1 |
| | 14 | 14 | 14 | 14 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | | 1 | | 1 | | |
| Exposures to agents or circumstances NEC | 1 | 1 | 1 | 1 | | |
| Medication errors, product use errors and issues NEC | 1 | 2 | 1 | 2 | | |
| Non-site specific injuries NEC | 2 | 2 | | | 2 | 2 |
| Occupational exposures | 1 | 1 | 1 | 1 | | |
| Off label uses | 1 | 1 | 1 | 1 | | |
| Product administration errors and issues | | 1 | | 1 | | |
| Product confusion errors and issues | | 1 | | 1 | | |
| Product preparation errors and issues | | 1 | | 1 | | |
| | 6 | 11 | 4 | 9 | 2 | 2 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 7 | 7 | | | 7 | 7 |
| ECG investigations | 1 | 1 | | | 1 | 1 |
| Heart rate and pulse investigations | 2 | 2 | 1 | 1 | 1 | 1 |
| Physical examination procedures and organ system status | 8 | 8 | 5 | 5 | 3 | 3 |
| Vascular tests NEC (incl blood pressure) | 3 | 3 | 2 | 2 | 1 | 1 |
| | 21 | 21 | 8 | 8 | 13 | 13 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 2 | 2 | 2 | 2 | | |
| General nutritional disorders NEC | 1 | 1 | 1 | 1 | | |
| Hypoglycaemic conditions NEC | 1 | 1 | | | 1 | 1 |
| Sodium imbalance | 1 | 1 | 1 | 1 | | |
| Total fluid volume decreased | 1 | 1 | | | 1 | 1 |
| Total fluid volume increased | 1 | 1 | 1 | 1 | | |
| | 7 | 7 | 5 | 5 | 2 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint related signs and symptoms | 14 | 14 | 14 | 14 | | |
| Muscle pains | 33 | 36 | 30 | 33 | 3 | 3 |
| Muscle related signs and symptoms NEC | 2 | 2 | | | 2 | 2 |
| Muscle tone abnormalities | 1 | 1 | 1 | 1 | | |
| Muscle weakness conditions | 2 | 2 | 2 | 2 | | |
| Musculoskeletal and connective tissue conditions NEC | 1 | 1 | 1 | 1 | | |
| Musculoskeletal and connective tissue pain and discomfort | 4 | 4 | 4 | 4 | | |
| | 57 | 60 | 52 | 55 | 5 | 5 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 12 | 12 | | | 12 | 12 |
| Coordination and balance disturbances | 2 | 2 | 2 | 2 | | |
| Cortical dysfunction NEC | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 24 | 24 | 3 | 3 | 21 | 21 |
| Facial cranial nerve disorders | 2 | 2 | | | 2 | 2 |
| Generalised tonic-clonic seizures | 2 | 2 | | | 2 | 2 |
| Headaches NEC | 41 | 45 | 37 | 41 | 4 | 4 |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | 1 | 1 | | |
| Migraine headaches | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 15 | 18 | 10 | 11 | 5 | 7 |
| Paraesthesias and dysaesthesias | 1 | 2 | 1 | 1 | | 1 |
| Paralysis and paresis (excl cranial nerve) | 4 | 4 | | | 4 | 4 |
| Seizures and seizure disorders NEC | 14 | 14 | | | 14 | 14 |
| Speech and language abnormalities | 2 | 2 | 2 | 2 | | |
| Transient cerebrovascular events | 2 | 2 | | | 2 | 2 |
| Tremor (excl congenital) | 4 | 4 | 4 | 4 | | |
| | 128 | 136 | 60 | 65 | 68 | 71 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | | 1 | | | | 1 |
| Confusion and disorientation | 3 | 3 | 1 | 1 | 2 | 2 |
| Emotional and mood disturbances NEC | 1 | 1 | 1 | 1 | | |
| Hallucinations (excl sleep-related) | 1 | 1 | 1 | 1 | | |
| Increased physical activity levels | 1 | 1 | 1 | 1 | | |
| Perception disturbances NEC | 1 | 1 | 1 | 1 | | |
| Psychotic disorder NEC | 1 | 1 | | | 1 | 1 |
| Speech and language usage disturbances | 1 | 1 | 1 | 1 | | |
| | 9 | 10 | 6 | 6 | 3 | 4 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Urinary tract signs and symptoms NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Menopausal effects on the genitourinary tract | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 23 | 24 | 8 | 8 | 15 | 16 |
| Bronchospasm and obstruction | 1 | 1 | | | 1 | 1 |
| Coughing and associated symptoms | 4 | 5 | 1 | 2 | 3 | 3 |
| Lower respiratory tract inflammatory and immunologic conditions | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 6 | 8 | 1 | 1 | 5 | 7 |
| Pulmonary oedemas | 1 | 1 | | | 1 | 1 |
| Respiratory failures (excl neonatal) | 1 | 1 | | | 1 | 1 |
| Respiratory signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Respiratory tract disorders NEC | 2 | 2 | | | 2 | 2 |
| Upper respiratory tract signs and symptoms | 5 | 8 | 1 | 3 | 4 | 5 |
| | 45 | 52 | 12 | 15 | 33 | 37 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 6 | 7 | | | 6 | 7 |
| Apocrine and eccrine gland disorders | 4 | 4 | 2 | 2 | 2 | 2 |
| Dermal and epidermal conditions NEC | 1 | 1 | 1 | 1 | | |
| Erythemas | 1 | 3 | | 1 | 1 | 2 |
| Pruritus NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Rashes, eruptions and exanthems NEC | 4 | 6 | 3 | 4 | 1 | 2 |
| Urticarias | 7 | 9 | 4 | 5 | 3 | 4 |
| | 25 | 33 | 11 | 14 | 14 | 19 |

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System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disability issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 1 | 1 | | | 1 | 1 |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Non-site specific embolism and thrombosis | 2 | 2 | | | 2 | 2 |
| Peripheral vascular disorders NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 2 | 3 | 1 | 2 | 1 | 1 |
| Site specific vascular disorders NEC | 3 | 3 | | | 3 | 3 |
| Vascular hypertensive disorders NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Vascular hypotensive disorders | 3 | 3 | 1 | 1 | 2 | 2 |
| | 18 | 19 | 5 | 6 | 13 | 13 |

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Country Where Event Occurred
NORTHERN MARIANA ISLANDS

System Organ Class

General disorders and administration site conditions

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|-----------------------------|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenic conditions | | 1 | | 1 |
| Feelings and sensations NEC | | 1 | | 1 |
| Pain and discomfort NEC | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Injury, poisoning and procedural complications

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|--|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product administration errors and issues | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> | Spontaneous | |
|---|--|--|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Joint related signs and symptoms | | 1 | | 1 |
| Musculoskeletal and connective tissue pain and discomfort | | 1 | | 1 |
| | | 2 | | 2 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Headaches NEC | | 1 | | 1 |
| Neurological signs and symptoms NEC | | 1 | | 1 |
| Sleep disturbances NEC | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Confusion and disorientation | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

NORWAY

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Leukocytoses NEC | 1 | 1 | 1 | 1 |
| Lymphatic system disorders NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 1 | 1 | | | 1 | 1 |
| Cardiac disorders NEC | | 2 | | | | 2 |
| Coronary artery disorders NEC | 1 | 1 | | | 1 | 1 |
| Heart failures NEC | 2 | 3 | | | 2 | 3 |
| Ischaemic coronary artery disorders | 4 | 6 | | | 4 | 6 |
| Rate and rhythm disorders NEC | 7 | 7 | 2 | 2 | 5 | 5 |
| Supraventricular arrhythmias | 1 | 1 | | | 1 | 1 |
| Ventricular arrhythmias and cardiac arrest | 1 | 1 | | | 1 | 1 |
| | 17 | 22 | 2 | 2 | 15 | 20 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ear disorders NEC | 4 | 4 | 4 | 4 |
| | 4 | 4 | 4 | 4 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid movement disorders | | 1 | | 1 | | |
| Ocular bleeding and vascular disorders NEC | 2 | 2 | | | 2 | 2 |
| Ocular disorders NEC | 1 | 1 | 1 | 1 | | |
| Ocular infections, inflammations and associated manifestations | 2 | 2 | 1 | 1 | 1 | 1 |
| Ocular sensation disorders | 2 | 2 | 2 | 2 | | |
| Pupil disorders | | 2 | | | | 2 |
| | 7 | 10 | 4 | 5 | 3 | 5 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal wall conditions NEC | 1 | 1 | | | 1 | 1 |
| Diarrhoea (excl infective) | 16 | 18 | 13 | 13 | 3 | 5 |
| Faecal abnormalities NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastritis (excl infective) | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 9 | 9 | 6 | 6 | 3 | 3 |
| Gastrointestinal atonic and hypomotility disorders NEC | 1 | 1 | 1 | 1 | | |
| Gastrointestinal signs and symptoms NEC | 7 | 8 | 1 | 1 | 6 | 7 |
| Nausea and vomiting symptoms | 46 | 55 | 30 | 33 | 16 | 22 |
| Non-site specific gastrointestinal haemorrhages | 2 | 3 | | | 2 | 3 |
| Oral dryness and saliva altered | 2 | 2 | 1 | 1 | 1 | 1 |
| Oral soft tissue signs and symptoms | 2 | 2 | 2 | 2 | | |
| | 89 | 102 | 56 | 59 | 33 | 43 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 60 | 69 | 50 | 54 | 10 | 15 |
| Death and sudden death | 20 | 30 | | | 20 | 30 |
| Febrile disorders | 43 | 49 | 22 | 24 | 21 | 25 |
| Feelings and sensations NEC | 25 | 28 | 21 | 23 | 4 | 5 |
| General signs and symptoms NEC | 42 | 55 | 8 | 8 | 34 | 47 |
| Injection site reactions | | 1 | | 1 | | |
| Oedema NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Pain and discomfort NEC | 13 | 14 | 8 | 8 | 5 | 6 |
| Therapeutic and nontherapeutic responses | 2 | 2 | 2 | 2 | | |
| Vaccination site reactions | 30 | 36 | 29 | 32 | 1 | 4 |
| | 238 | 287 | 142 | 154 | 96 | 133 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 3 | 4 | 2 | 2 | 1 | 2 |
| Anaphylactic and anaphylactoid responses | 5 | 5 | | | 5 | 5 |
| | 8 | 9 | 2 | 2 | 6 | 7 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal infections | 2 | 2 | | | 2 | 2 |
| Bacterial infections NEC | 1 | 1 | | | 1 | 1 |
| Eye and eyelid infections | 1 | 1 | 1 | 1 | | |
| Herpes viral infections | 1 | 1 | | | 1 | 1 |
| Infections NEC | 6 | 7 | 1 | 1 | 5 | 6 |
| Influenza viral infections | 2 | 2 | 2 | 2 | | |
| Lower respiratory tract and lung infections | 12 | 15 | | | 12 | 15 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 2 | 2 | 1 | 1 | 1 | 1 |
| Urinary tract infections | 3 | 4 | 2 | 3 | 1 | 1 |
| | 31 | 36 | 7 | 8 | 24 | 28 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cerebral injuries NEC | 1 | 1 | | | 1 | 1 |
| Conditions caused by cold | 1 | 1 | | | 1 | 1 |
| Fractures and dislocations NEC | 1 | 1 | | | 1 | 1 |
| Limb fractures and dislocations | 1 | 1 | | | 1 | 1 |
| Medication errors, product use errors and issues NEC | | 1 | | 1 | | |
| Non-site specific injuries NEC | 7 | 7 | 2 | 2 | 5 | 5 |
| Product administration errors and issues | 3 | 11 | 3 | 11 | | |
| Product preparation errors and issues | 1 | 3 | 1 | 3 | | |
| Skin injuries NEC | 1 | 1 | | | 1 | 1 |
| | 16 | 27 | 6 | 17 | 10 | 10 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bacteria identification and serology (excl mycobacteria) | 1 | 1 | 1 | 1 | | |
| Blood gas and acid base analyses | 7 | 10 | 1 | 1 | 6 | 9 |
| Coagulation and bleeding analyses | 1 | 1 | | | 1 | 1 |
| Heart rate and pulse investigations | 8 | 11 | 2 | 3 | 6 | 8 |
| Physical examination procedures and organ system status | 3 | 8 | 3 | 5 | | 3 |
| Protein analyses NEC | 15 | 15 | 4 | 4 | 11 | 11 |
| Red blood cell analyses | 1 | 1 | | | 1 | 1 |
| Urinalysis NEC | 1 | 1 | 1 | 1 | | |
| Vascular tests NEC (incl blood pressure) | 4 | 7 | 2 | 3 | 2 | 4 |
| White blood cell analyses | 1 | 1 | | | 1 | 1 |
| | 42 | 56 | 14 | 18 | 28 | 38 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 11 | 14 | 4 | 4 | 7 | 10 |
| General nutritional disorders NEC | 1 | 1 | | | 1 | 1 |
| Hyperglycaemic conditions NEC | 1 | 1 | | | 1 | 1 |
| Potassium imbalance | 1 | 1 | | | 1 | 1 |
| Sodium imbalance | 1 | 1 | | | 1 | 1 |
| Total fluid volume decreased | 1 | 1 | | | 1 | 1 |
| | 16 | 19 | 4 | 4 | 12 | 15 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 1 | 1 | 1 | | |
| Joint related signs and symptoms | 6 | 7 | 6 | 7 | | |
| Muscle pains | 13 | 13 | 11 | 11 | 2 | 2 |
| Muscle related signs and symptoms NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Muscle weakness conditions | 2 | 2 | 1 | 1 | 1 | 1 |
| Musculoskeletal and connective tissue conditions NEC | 5 | 5 | 5 | 5 | | |
| Musculoskeletal and connective tissue pain and discomfort | 12 | 13 | 9 | 10 | 3 | 3 |
| Tendon disorders | 1 | 1 | 1 | 1 | | |
| | 44 | 46 | 36 | 38 | 8 | 8 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Metastases to specified sites | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 12 | 15 | | | 12 | 15 |
| Central nervous system vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Coordination and balance disturbances | | 1 | | | | 1 |
| Cortical dysfunction NEC | 1 | 1 | | | 1 | 1 |
| Dementia (excl Alzheimer's type) | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 29 | 36 | 6 | 6 | 23 | 30 |
| Dyskinesias and movement disorders NEC | 3 | 3 | 3 | 3 | | |
| Facial cranial nerve disorders | 4 | 4 | | | 4 | 4 |
| Headaches NEC | 33 | 35 | 29 | 31 | 4 | 4 |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 19 | 21 | 9 | 10 | 10 | 11 |
| Paraesthesias and dysaesthesias | 3 | 4 | 3 | 3 | | 1 |
| Paralysis and paresis (excl cranial nerve) | 4 | 4 | | | 4 | 4 |
| Seizures and seizure disorders NEC | 2 | 2 | | | 2 | 2 |
| Sensory abnormalities NEC | 2 | 2 | 2 | 2 | | |
| Speech and language abnormalities | 5 | 5 | 2 | 2 | 3 | 3 |
| Transient cerebrovascular events | 2 | 2 | | | 2 | 2 |
| Tremor (excl congenital) | 1 | 2 | | | 1 | 2 |
| | 123 | 140 | 54 | 57 | 69 | 83 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product distribution and storage issues | | 6 | | 6 |
| | | 6 | | 6 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 1 | 2 | | 1 | 1 | 1 |
| Communications disorders | 1 | 1 | 1 | 1 | | |
| Confusion and disorientation | 11 | 14 | 5 | 5 | 6 | 9 |
| Deliria | 1 | 2 | | | 1 | 2 |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 | | |
| Hallucinations (excl sleep-related) | 2 | 3 | | | 2 | 3 |
| Increased physical activity levels | 5 | 6 | 1 | 2 | 4 | 4 |
| Mood disorders NEC | 1 | 2 | 1 | 1 | | 1 |
| Sleep disorders NEC | 1 | 1 | 1 | 1 | | |
| | 24 | 32 | 10 | 12 | 14 | 20 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Bladder and urethral symptoms | 2 | 2 | 2 | 2 |
| Renal failure and impairment | 1 | 2 | 1 | 2 |
| | 3 | 4 | 3 | 4 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast disorders NEC | 1 | 1 | 1 | 1 |
| Breast signs and symptoms | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 35 | 42 | 11 | 12 | 24 | 30 |
| Bronchospasm and obstruction | 3 | 3 | | | 3 | 3 |
| Conditions associated with abnormal gas exchange | 1 | 2 | | | 1 | 2 |
| Coughing and associated symptoms | 14 | 15 | 7 | 7 | 7 | 8 |
| Laryngeal spasm, oedema and obstruction | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract inflammatory and immunologic conditions | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 4 | 5 | 3 | 3 | 1 | 2 |
| Nasal congestion and inflammations | 4 | 4 | 4 | 4 | | |
| Nasal disorders NEC | 3 | 3 | 3 | 3 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 1 | 1 | 1 | 1 | | |
| Respiratory failures (excl neonatal) | 4 | 4 | | | 4 | 4 |
| Respiratory tract disorders NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 18 | 18 | 14 | 14 | 4 | 4 |
| | 90 | 100 | 43 | 44 | 47 | 56 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 5 | 8 | 3 | 3 | 2 | 5 |
| Dermal and epidermal conditions NEC | 1 | 1 | 1 | 1 | | |
| Erythemas | 2 | 2 | 1 | 1 | 1 | 1 |
| Pruritus NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Rashes, eruptions and exanthems NEC | 7 | 7 | 4 | 4 | 3 | 3 |
| Skin vasomotor conditions | 1 | 1 | 1 | 1 | | |
| Urticarias | 2 | 2 | | | 2 | 2 |
| | 22 | 25 | 12 | 12 | 10 | 13 |

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System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disability issues | 4 | 4 | 4 | 4 |
| | 4 | 4 | 4 | 4 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 1 | 2 | | | 1 | 2 |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 1 | 2 | 1 | 2 | | |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | 1 | 1 | | |
| Site specific vascular disorders NEC | 3 | 5 | | | 3 | 5 |
| Vascular hypertensive disorders NEC | 2 | 2 | 2 | 2 | | |
| Vascular hypotensive disorders | 6 | 8 | | | 6 | 8 |
| | 15 | 21 | 4 | 5 | 11 | 16 |

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Country Where Event Occurred

OMAN

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea (excl infective) | | 1 | | 1 |
| Gastritis (excl infective) | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenic conditions | | 1 | | 1 |
| Febrile disorders | | 1 | | 1 |
| Pain and discomfort NEC | | 1 | | 1 |
| | | 3 | | 3 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product administration errors and issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Headaches NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product supply and availability issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred
PANAMA

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

POLAND

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coagulopathies | 1 | 1 | 1 | 1 | | |
| Lymphatic system disorders NEC | 38 | 45 | 16 | 23 | 22 | 22 |
| | 39 | 46 | 17 | 24 | 22 | 22 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac disorders NEC | 1 | 1 | | | 1 | 1 |
| Cardiac signs and symptoms NEC | 2 | 2 | 2 | 2 | | |
| Myocardial disorders NEC | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 14 | 17 | 2 | 2 | 12 | 15 |
| Ventricular arrhythmias and cardiac arrest | 3 | 3 | | | 3 | 3 |
| | 21 | 24 | 4 | 4 | 17 | 20 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 1 | 2 | | 1 | 1 | 1 |
| Hearing losses | 2 | 2 | | | 2 | 2 |
| Hyperacusia | 1 | 1 | 1 | 1 | | |
| Inner ear signs and symptoms | 9 | 9 | 5 | 5 | 4 | 4 |
| | 13 | 14 | 6 | 7 | 7 | 7 |

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System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Acute and chronic thyroiditis | 1 | 1 | 1 | 1 |
| Thyroid disorders NEC | 2 | 2 | 2 | 2 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival infections, irritations and inflammations | | 1 | | 1 | | |
| Iris and uveal tract infections, irritations and inflammations | | 1 | | 1 | | |
| Lacrimation disorders | 1 | 1 | | | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 1 | | | 1 | 1 |
| Ocular disorders NEC | 4 | 5 | | 1 | 4 | 4 |
| Ocular sensation disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual disorders NEC | | 1 | | 1 | | |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | 1 | 1 | | |
| | 9 | 13 | 2 | 6 | 7 | 7 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | | 1 | | | | 1 |
| Dental pain and sensation disorders | | 2 | | 2 | | |
| Diarrhoea (excl infective) | 7 | 13 | 3 | 9 | 4 | 4 |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 6 | 10 | 4 | 7 | 2 | 3 |
| Gastrointestinal disorders NEC | 1 | 1 | | | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Nausea and vomiting symptoms | 32 | 48 | 17 | 33 | 15 | 15 |
| Non-site specific gastrointestinal haemorrhages | 1 | 1 | | | 1 | 1 |
| Oral dryness and saliva altered | | 1 | | 1 | | |
| Oral soft tissue signs and symptoms | 5 | 7 | 1 | 2 | 4 | 5 |
| Oral soft tissue swelling and oedema | 1 | 1 | | | 1 | 1 |
| Stomatitis and ulceration | 1 | 1 | 1 | 1 | | |
| Tongue signs and symptoms | 4 | 4 | | | 4 | 4 |
| | 60 | 92 | 27 | 56 | 33 | 36 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 89 | 131 | 64 | 105 | 25 | 26 |
| Death and sudden death | 8 | 8 | | | 8 | 8 |
| Febrile disorders | 79 | 114 | 43 | 74 | 36 | 40 |
| Feelings and sensations NEC | 57 | 79 | 44 | 63 | 13 | 16 |
| Gait disturbances | 1 | 2 | 1 | 2 | | |
| General signs and symptoms NEC | 9 | 18 | 5 | 12 | 4 | 6 |
| Inflamations | | 2 | | 2 | | |
| Mass conditions NEC | 1 | 1 | 1 | 1 | | |
| Oedema NEC | 3 | 4 | | 1 | 3 | 3 |
| Pain and discomfort NEC | 15 | 23 | 11 | 18 | 4 | 5 |
| Therapeutic and nontherapeutic responses | 24 | 36 | 1 | 2 | 23 | 34 |
| Vaccination site reactions | 73 | 142 | 46 | 114 | 27 | 28 |
| | 359 | 560 | 216 | 394 | 143 | 166 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 5 | 7 | 1 | 3 | 4 | 4 |
| Anaphylactic and anaphylactoid responses | 14 | 14 | | | 14 | 14 |
| | 19 | 21 | 1 | 3 | 18 | 18 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 30 | 42 | 6 | 7 | 24 | 35 |
| Dental and oral soft tissue infections | 1 | 2 | 1 | 2 | | |
| Herpes viral infections | | 4 | | 4 | | |
| Infections NEC | 1 | 2 | | 1 | 1 | 1 |
| Influenza viral infections | | 1 | | 1 | | |
| Lower respiratory tract and lung infections | 1 | 2 | | | 1 | 2 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 3 | 4 | 2 | 3 | 1 | 1 |
| Urinary tract infections | | 1 | | 1 | | |
| Viral infections NEC | 1 | 1 | 1 | 1 | | |
| | 38 | 60 | 10 | 20 | 28 | 40 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 2 | 11 | 2 | 11 | | |
| Medication errors, product use errors and issues NEC | 3 | 11 | 3 | 10 | | 1 |
| Non-site specific injuries NEC | 1 | 1 | | | 1 | 1 |
| Off label uses | 2 | 10 | 2 | 9 | | 1 |
| Peripheral nerve injuries | 1 | 1 | | | 1 | 1 |
| Product administration errors and issues | 4 | 10 | 4 | 10 | | |
| Product confusion errors and issues | | 2 | | 2 | | |
| Product preparation errors and issues | 1 | 1 | 1 | 1 | | |
| Skin injuries NEC | 3 | 3 | | | 3 | 3 |
| Vaccination related complications | 1 | 1 | 1 | 1 | | |
| | 18 | 51 | 13 | 44 | 5 | 7 |

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System Organ Class

| Investigations | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|--|
| | | | Nonserious | | Serious | | |
| | | | I | C | I | C | |
| High Level Term | | | | | | | |
| Blood gas and acid base analyses | 5 | 7 | | 1 | 5 | 6 | |
| Carbohydrate tolerance analyses (incl diabetes) | 1 | 1 | | | 1 | 1 | |
| Heart rate and pulse investigations | 3 | 6 | 2 | 3 | 1 | 3 | |
| Immunology analyses NEC | 12 | 12 | 12 | 12 | | | |
| Physical examination procedures and organ system status | 4 | 6 | 3 | 5 | 1 | 1 | |
| Protein analyses NEC | 1 | 1 | | | 1 | 1 | |
| Urinalysis NEC | | 1 | | 1 | | | |
| Vascular tests NEC (incl blood pressure) | 16 | 19 | 2 | 3 | 14 | 16 | |
| Virus identification and serology | 4 | 5 | 4 | 4 | | 1 | |
| | 46 | 58 | 23 | 29 | 23 | 29 | |

System Organ Class

| Metabolism and nutrition disorders | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| High Level Term | | | | | | |
| Appetite disorders | 3 | 5 | 2 | 4 | 1 | 1 |
| Electrolyte imbalance NEC | 1 | 1 | 1 | 1 | | |
| | 4 | 6 | 3 | 5 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 3 | 1 | 3 | | |
| Bone related signs and symptoms | 10 | 16 | 6 | 10 | 4 | 6 |
| Joint related signs and symptoms | 30 | 50 | 24 | 43 | 6 | 7 |
| Muscle pains | 49 | 69 | 35 | 54 | 14 | 15 |
| Muscle related signs and symptoms NEC | | 1 | | 1 | | |
| Muscle weakness conditions | 2 | 2 | 2 | 2 | | |
| Musculoskeletal and connective tissue conditions NEC | 3 | 5 | 3 | 5 | | |
| Musculoskeletal and connective tissue pain and discomfort | 42 | 66 | 31 | 52 | 11 | 14 |
| | 137 | 212 | 102 | 170 | 35 | 42 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 3 | 3 | | | 3 | 3 |
| Choreiform movements | 1 | 1 | 1 | 1 | | |
| Coordination and balance disturbances | 1 | 2 | 1 | 2 | | |
| Disturbances in consciousness NEC | 35 | 38 | 3 | 6 | 32 | 32 |
| Dyskinesias and movement disorders NEC | 1 | 1 | | | 1 | 1 |
| Encephalopathies NEC | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 2 | 2 | | | 2 | 2 |
| Generalised tonic-clonic seizures | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 49 | 76 | 32 | 58 | 17 | 18 |
| Mental impairment (excl dementia and memory loss) | 4 | 4 | 3 | 3 | 1 | 1 |
| Migraine headaches | | 1 | | 1 | | |
| Mononeuropathies | 1 | 1 | 1 | 1 | | |
| Neurological signs and symptoms NEC | 16 | 23 | 8 | 15 | 8 | 8 |
| Neurologic visual problems NEC | 1 | 2 | 1 | 2 | | |
| Neuromuscular disorders NEC | 10 | 10 | 3 | 3 | 7 | 7 |
| Olfactory nerve disorders | 10 | 13 | 7 | 10 | 3 | 3 |
| Paraesthesias and dysaesthesias | 22 | 29 | 11 | 16 | 11 | 13 |
| Paralysis and paresis (excl cranial nerve) | 1 | 5 | | 1 | 1 | 4 |
| Seizures and seizure disorders NEC | 15 | 15 | | | 15 | 15 |
| Sensory abnormalities NEC | 12 | 18 | 7 | 13 | 5 | 5 |
| Sleep disturbances NEC | | 1 | | 1 | | |
| Speech and language abnormalities | 4 | 4 | 1 | 1 | 3 | 3 |
| Transient cerebrovascular events | 1 | 1 | | | 1 | 1 |
| Tremor (excl congenital) | 2 | 4 | 1 | 2 | 1 | 2 |
| | 193 | 256 | 80 | 136 | 113 | 120 |

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System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Device physical property and chemical issues | | 1 | | 1 |
| Product distribution and storage issues | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 3 | 5 | 2 | 4 | 1 | 1 |
| Confusion and disorientation | 4 | 4 | 1 | 1 | 3 | 3 |
| Deliria | 1 | 1 | | | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 8 | 11 | 8 | 11 | | |
| Mental disorders NEC | 1 | 1 | 1 | 1 | | |
| Psychiatric symptoms NEC | | 1 | | | | 1 |
| | 17 | 23 | 12 | 17 | 5 | 6 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Genitourinary tract infections and inflammations NEC | 1 | 1 | 1 | 1 |
| Renal obstructive disorders | 1 | 1 | 1 | 1 |
| Urinary abnormalities | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast signs and symptoms | 1 | 2 | | 1 | 1 | 1 |
| Lactation disorders | | 2 | | 1 | | 1 |
| Pelvis and broad ligament disorders NEC | 1 | 1 | 1 | 1 | | |
| Prostate and seminal vesicles infections and inflammations | 1 | 1 | | | 1 | 1 |
| | 3 | 6 | 1 | 3 | 2 | 3 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 14 | 16 | 3 | 5 | 11 | 11 |
| Bronchospasm and obstruction | 5 | 5 | | | 5 | 5 |
| Conditions associated with abnormal gas exchange | 1 | 1 | | | 1 | 1 |
| Coughing and associated symptoms | 6 | 9 | 3 | 6 | 3 | 3 |
| Laryngeal spasm, oedema and obstruction | 3 | 3 | | | 3 | 3 |
| Nasal congestion and inflammations | 1 | 1 | 1 | 1 | | |
| Nasal disorders NEC | | 2 | | 2 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 2 | 3 | 1 | 2 | 1 | 1 |
| Pulmonary oedemas | 1 | 1 | | | 1 | 1 |
| Respiratory failures (excl neonatal) | 1 | 1 | | | 1 | 1 |
| Respiratory signs and symptoms NEC | | 1 | | 1 | | |
| Respiratory tract disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Tracheal disorders (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 9 | 15 | 7 | 13 | 2 | 2 |
| | 46 | 61 | 16 | 31 | 30 | 30 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 4 | 4 | | | 4 | 4 |
| Apocrine and eccrine gland disorders | 11 | 12 | 7 | 8 | 4 | 4 |
| Bullous conditions | 2 | 2 | | | 2 | 2 |
| Dermal and epidermal conditions NEC | 1 | 2 | | 1 | 1 | 1 |
| Dermatitis and eczema | 1 | 1 | | | 1 | 1 |
| Erythemas | 3 | 4 | 1 | 1 | 2 | 3 |
| Pruritus NEC | 2 | 3 | 1 | 2 | 1 | 1 |
| Purpura and related conditions | 4 | 4 | 1 | 1 | 3 | 3 |
| Rashes, eruptions and exanthems NEC | 5 | 8 | 3 | 6 | 2 | 2 |
| Skin hyperplasias and hypertrophies | 1 | 1 | 1 | 1 | | |
| Skin vasomotor conditions | 2 | 2 | | | 2 | 2 |
| Urticarias | 2 | 4 | | 2 | 2 | 2 |
| | 38 | 47 | 14 | 22 | 24 | 25 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Disability issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aortic aneurysms and dissections | 1 | 1 | | | 1 | 1 |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Haemorrhages NEC | | 1 | | 1 | | |
| Non-site specific embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Non-site specific vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Peripheral vascular disorders NEC | 4 | 7 | 3 | 5 | 1 | 2 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | 1 | 1 | | |
| Site specific vascular disorders NEC | 3 | 5 | | 1 | 3 | 4 |
| Vascular hypertensive disorders NEC | 2 | 3 | | 1 | 2 | 2 |
| Vascular hypotensive disorders | 1 | 1 | | | 1 | 1 |
| | 15 | 22 | 5 | 10 | 10 | 12 |

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Country Where Event Occurred

PORTUGAL

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytoses NEC | 1 | 1 | | | 1 | 1 |
| Lymphatic system disorders NEC | 79 | 88 | 2 | 8 | 77 | 80 |
| Marrow depression and hypoplastic anaemias | 1 | 1 | | | 1 | 1 |
| Thrombocytopenias | 1 | 1 | | | 1 | 1 |
| | 82 | 91 | 2 | 8 | 80 | 83 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 5 | 6 | | 1 | 5 | 5 |
| Noninfectious myocarditis | 2 | 2 | | | 2 | 2 |
| Rate and rhythm disorders NEC | 38 | 43 | 1 | 4 | 37 | 39 |
| Supraventricular arrhythmias | 1 | 2 | | | 1 | 2 |
| Ventricular arrhythmias and cardiac arrest | 2 | 3 | | | 2 | 3 |
| | 48 | 56 | 1 | 5 | 47 | 51 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Ear disorders NEC | 3 | 3 | 3 | 3 |
| Hearing disorders NEC | 1 | 1 | 1 | 1 |
| Hearing losses | 2 | 2 | 2 | 2 |
| Inner ear signs and symptoms | 8 | 9 | 8 | 9 |
| | 14 | 15 | 14 | 15 |

System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Thyroid hypofunction disorders | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conjunctival infections, irritations and inflammations | 1 | 1 | | | 1 | 1 |
| Eyelid movement disorders | 1 | 1 | | | 1 | 1 |
| Lacrimation disorders | 1 | 2 | | 1 | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 3 | 4 | | | 3 | 4 |
| Ocular disorders NEC | 2 | 4 | | 2 | 2 | 2 |
| Ocular infections, inflammations and associated manifestations | 4 | 5 | 1 | 2 | 3 | 3 |
| Ocular nerve and muscle disorders | | 1 | | | | 1 |
| Ocular sensation disorders | 3 | 5 | | 1 | 3 | 4 |
| Retinal, choroid and vitreous infections and inflammations | 1 | 1 | | | 1 | 1 |
| Structural change, deposit and degeneration of eye NEC | | 1 | | | | 1 |
| Visual disorders NEC | 2 | 3 | | 1 | 2 | 2 |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | | | 1 | 1 |
| | 19 | 29 | 1 | 7 | 18 | 22 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Colitis (excl infective) | 2 | 2 | | | 2 | 2 |
| Diarrhoea (excl infective) | 27 | 29 | 2 | 4 | 25 | 25 |
| Dyspeptic signs and symptoms | 1 | 3 | | 2 | 1 | 1 |
| Faecal abnormalities NEC | 2 | 2 | | | 2 | 2 |
| Flatulence, bloating and distension | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 15 | 17 | 1 | 2 | 14 | 15 |
| Gastrointestinal disorders NEC | | 1 | | | | 1 |
| Gastrointestinal signs and symptoms NEC | 10 | 14 | | 2 | 10 | 12 |
| Nausea and vomiting symptoms | 109 | 124 | 5 | 13 | 104 | 111 |
| Oesophageal stenosis and obstruction | 1 | 1 | | | 1 | 1 |
| Oral dryness and saliva altered | 3 | 3 | | | 3 | 3 |
| Oral soft tissue disorders NEC | | 1 | | | | 1 |
| Oral soft tissue signs and symptoms | 24 | 39 | 2 | 5 | 22 | 34 |
| Oral soft tissue swelling and oedema | 11 | 15 | | | 11 | 15 |
| Stomatitis and ulceration | 3 | 5 | | 2 | 3 | 3 |
| Tongue disorders | 1 | 2 | 1 | 2 | | |
| Tongue signs and symptoms | 15 | 21 | | | 15 | 21 |
| | 226 | 281 | 12 | 33 | 214 | 248 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 161 | 177 | 7 | 18 | 154 | 159 |
| Body temperature altered | 6 | 6 | 1 | 1 | 5 | 5 |
| Death and sudden death | 2 | 4 | | | 2 | 4 |
| Febrile disorders | 195 | 207 | 3 | 11 | 192 | 196 |
| Feelings and sensations NEC | 110 | 119 | 4 | 8 | 106 | 111 |
| Gait disturbances | 2 | 2 | 2 | 2 | | |
| General signs and symptoms NEC | 10 | 10 | 2 | 2 | 8 | 8 |
| Inflammatons | 1 | 1 | | | 1 | 1 |
| Injection site reactions | | 1 | | 1 | | |
| Interactions | 1 | 1 | | | 1 | 1 |
| Mucosal findings abnormal | 1 | 1 | | | 1 | 1 |
| Oedema NEC | 22 | 27 | 1 | 3 | 21 | 24 |
| Pain and discomfort NEC | 50 | 55 | 2 | 4 | 48 | 51 |
| Therapeutic and nontherapeutic responses | 15 | 31 | | | 15 | 31 |
| Vaccination site reactions | 174 | 222 | 14 | 52 | 160 | 170 |
| | 750 | 864 | 36 | 102 | 714 | 762 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 3 | 10 | | 4 | 3 | 6 |
| Allergies to foods, food additives, drugs and other chemicals | 2 | 4 | | | 2 | 4 |
| Anaphylactic and anaphylactoid responses | 12 | 13 | | | 12 | 13 |
| | 17 | 27 | | 4 | 17 | 23 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast infections | 1 | 1 | | | 1 | 1 |
| Candida infections | 1 | 1 | | | 1 | 1 |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 25 | 41 | 7 | 8 | 18 | 33 |
| Herpes viral infections | 3 | 3 | | | 3 | 3 |
| Influenza viral infections | 2 | 2 | | | 2 | 2 |
| Lower respiratory tract and lung infections | 1 | 1 | | | 1 | 1 |
| Neisseria infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 3 | 3 | 2 | 2 | 1 | 1 |
| Urinary tract infections | 1 | 1 | | | 1 | 1 |
| | 39 | 55 | 9 | 10 | 30 | 45 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Conditions caused by cold | | 1 | | 1 | | |
| Exposures associated with pregnancy, delivery and lactation | 3 | 8 | 3 | 8 | | |
| Exposures to agents or circumstances NEC | 1 | 1 | | | 1 | 1 |
| Medication errors, product use errors and issues NEC | 7 | 9 | 7 | 9 | | |
| Non-site specific injuries NEC | 2 | 2 | 2 | 2 | | |
| Non-site specific procedural complications | 1 | 1 | | | 1 | 1 |
| Occupational exposures | 1 | 1 | 1 | 1 | | |
| Off label uses | 8 | 11 | 8 | 11 | | |
| Overdoses NEC | 1 | 5 | 1 | 5 | | |
| Product administration errors and issues | 18 | 21 | 18 | 21 | | |
| Skin injuries NEC | | 1 | | 1 | | |
| Vaccination related complications | 2 | 2 | | | 2 | 2 |
| | 44 | 63 | 40 | 59 | 4 | 4 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 5 | 5 | 1 | 1 | 4 | 4 |
| Digestive enzymes | 2 | 2 | | | 2 | 2 |
| Heart rate and pulse investigations | 2 | 2 | 1 | 1 | 1 | 1 |
| Physical examination procedures and organ system status | 2 | 4 | | 2 | 2 | 2 |
| Respiratory and pulmonary function diagnostic procedures | 1 | 1 | | | 1 | 1 |
| Thyroid analyses | | 1 | | 1 | | |
| Vascular tests NEC (incl blood pressure) | 5 | 6 | 1 | 1 | 4 | 5 |
| Virus identification and serology | 4 | 8 | 1 | 1 | 3 | 7 |
| | 21 | 29 | 4 | 7 | 17 | 22 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 10 | 12 | 3 | 5 | 7 | 7 |
| Fluid intake increased | 3 | 3 | | | 3 | 3 |
| Hyperglycaemic conditions NEC | 3 | 4 | 1 | 1 | 2 | 3 |
| Hypoglycaemic conditions NEC | 3 | 3 | | | 3 | 3 |
| Potassium imbalance | 3 | 3 | | | 3 | 3 |
| | 22 | 25 | 4 | 6 | 18 | 19 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | | 2 | | 1 | | 1 |
| Joint related signs and symptoms | 71 | 71 | 3 | 3 | 68 | 68 |
| Muscle pains | 272 | 293 | 12 | 26 | 260 | 267 |
| Muscle related signs and symptoms NEC | 5 | 5 | | | 5 | 5 |
| Muscle tone abnormalities | 1 | 1 | | | 1 | 1 |
| Muscle weakness conditions | 3 | 4 | | | 3 | 4 |
| Musculoskeletal and connective tissue conditions NEC | 1 | 1 | | | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 35 | 37 | 3 | 4 | 32 | 33 |
| Myopathies | 1 | 1 | | | 1 | 1 |
| Soft tissue disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Spondyloarthropathies | | 1 | | | | 1 |
| Synovial disorders | 4 | 4 | | | 4 | 4 |
| Tendon disorders | | 1 | | 1 | | |
| | 395 | 423 | 19 | 36 | 376 | 387 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cerebrovascular venous and sinus thrombosis | 1 | 1 | | | 1 | 1 |
| Coordination and balance disturbances | 6 | 8 | 1 | 1 | 5 | 7 |
| Cortical dysfunction NEC | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 21 | 27 | | 3 | 21 | 24 |
| Dyskinesias and movement disorders NEC | 4 | 4 | | | 4 | 4 |
| Facial cranial nerve disorders | 5 | 6 | | | 5 | 6 |
| Generalised tonic-clonic seizures | 1 | 2 | | | 1 | 2 |
| Headaches NEC | 237 | 258 | 11 | 27 | 226 | 231 |
| Memory loss (excl dementia) | | 1 | | 1 | | |
| Migraine headaches | 4 | 8 | 1 | 2 | 3 | 6 |
| Neurological signs and symptoms NEC | 74 | 81 | 4 | 9 | 70 | 72 |
| Neuromuscular disorders NEC | 1 | 1 | | | 1 | 1 |
| Olfactory nerve disorders | 1 | 1 | | | 1 | 1 |
| Paraesthesias and dysaesthesias | 46 | 54 | 3 | 8 | 43 | 46 |
| Paralysis and paresis (excl cranial nerve) | 1 | 1 | | | 1 | 1 |
| Peripheral neuropathies NEC | 1 | 1 | | | 1 | 1 |
| Seizures and seizure disorders NEC | 3 | 3 | | | 3 | 3 |
| Sensory abnormalities NEC | 18 | 24 | | 4 | 18 | 20 |
| Sleep disturbances NEC | 1 | 1 | | | 1 | 1 |
| Speech and language abnormalities | 4 | 5 | | 1 | 4 | 4 |
| Tremor (excl congenital) | 21 | 23 | | 2 | 21 | 21 |
| | 451 | 511 | 20 | 58 | 431 | 453 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 3 | 4 | | 1 | 3 | 3 |
| Confusion and disorientation | 1 | 1 | | | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 9 | 9 | 1 | 1 | 8 | 8 |
| Fear symptoms and phobic disorders (incl social phobia) | 1 | 1 | | | 1 | 1 |
| Mood alterations with depressive symptoms | 1 | 1 | | | 1 | 1 |
| Sexual desire disorders | 1 | 1 | 1 | 1 | | |
| Sleep disorders NEC | 2 | 2 | | | 2 | 2 |
| Thinking disturbances | 1 | 1 | | | 1 | 1 |
| | 19 | 20 | 2 | 3 | 17 | 17 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Renal disorders NEC | 1 | 1 | | | 1 | 1 |
| Urinary abnormalities | 2 | 2 | 2 | 2 | | |
| Urinary tract signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast signs and symptoms | 4 | 4 | 2 | 2 | 2 | 2 |
| Menstruation and uterine bleeding NEC | 1 | 1 | | | 1 | 1 |
| Reproductive tract signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Vulvovaginal signs and symptoms | 2 | 2 | | | 2 | 2 |
| | 8 | 8 | 2 | 2 | 6 | 6 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 26 | 27 | 2 | 2 | 24 | 25 |
| Bronchospasm and obstruction | 5 | 5 | | | 5 | 5 |
| Coughing and associated symptoms | 19 | 23 | 5 | 5 | 14 | 18 |
| Laryngeal spasm, oedema and obstruction | 8 | 12 | | | 8 | 12 |
| Lower respiratory tract inflammatory and immunologic conditions | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 2 | 2 | | | 2 | 2 |
| Nasal congestion and inflammations | 5 | 5 | 1 | 1 | 4 | 4 |
| Nasal disorders NEC | 1 | 1 | 1 | 1 | | |
| Pharyngeal disorders (excl infections and neoplasms) | 6 | 10 | 1 | 2 | 5 | 8 |
| Respiratory signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Respiratory tract disorders NEC | | 1 | | | | 1 |
| Upper respiratory tract signs and symptoms | 38 | 49 | 7 | 10 | 31 | 39 |
| | 112 | 137 | 17 | 21 | 95 | 116 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 8 | 9 | | | 8 | 9 |
| Apocrine and eccrine gland disorders | 19 | 20 | 1 | 1 | 18 | 19 |
| Dermal and epidermal conditions NEC | 3 | 3 | | | 3 | 3 |
| Dermatitis and eczema | 2 | 3 | | | 2 | 3 |
| Dermatitis ascribed to specific agent | | 1 | | | | 1 |
| Erythemas | 10 | 18 | | 3 | 10 | 15 |
| Exfoliative conditions | 1 | 1 | | | 1 | 1 |
| Pilar disorders NEC | 3 | 3 | | | 3 | 3 |
| Pruritus NEC | 20 | 27 | | 2 | 20 | 25 |
| Purpura and related conditions | 1 | 1 | | | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 38 | 55 | 1 | 12 | 37 | 43 |
| Skin vasculitides | 1 | 1 | | | 1 | 1 |
| Urticarias | 7 | 11 | | 2 | 7 | 9 |
| | 113 | 153 | 2 | 20 | 111 | 133 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disability issues | 4 | 4 | 2 | 2 | 2 | 2 |
| | 4 | 4 | 2 | 2 | 2 | 2 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 2 | 2 | | | 2 | 2 |
| Arterial infections and inflammations | 1 | 1 | | | 1 | 1 |
| Circulatory collapse and shock | 1 | 1 | | | 1 | 1 |
| Haemorrhages NEC | 1 | 1 | | | 1 | 1 |
| Non-site specific embolism and thrombosis | | 1 | | | | 1 |
| Non-site specific vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Peripheral embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 12 | 14 | | | 12 | 14 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 2 | 3 | | | 2 | 3 |
| Phlebitis NEC | 1 | 1 | | | 1 | 1 |
| Site specific vascular disorders NEC | 5 | 8 | | 2 | 5 | 6 |
| Vascular hypertensive disorders NEC | 16 | 16 | | | 16 | 16 |
| Vascular hypotensive disorders | 13 | 13 | | | 13 | 13 |
| Vasculitides NEC | 1 | 1 | | | 1 | 1 |
| | 57 | 64 | | 2 | 57 | 62 |

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Country Where Event Occurred

PUERTO RICO

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | 2 | 4 | 2 | 4 |
| | 2 | 4 | 2 | 4 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | | 1 | | 1 | | |
| Rate and rhythm disorders NEC | 1 | 2 | 1 | 2 | | |
| Supraventricular arrhythmias | | 1 | | | | 1 |
| | 1 | 4 | 1 | 3 | | 1 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Ocular sensation disorders | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Diarrhoea (excl infective) | | 3 | | 3 |
| Dyspeptic signs and symptoms | | 1 | | 1 |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | | 1 | | 1 |
| Gastrointestinal signs and symptoms NEC | 2 | 4 | 2 | 4 |
| Gingival haemorrhages | | 1 | | 1 |
| Nausea and vomiting symptoms | 2 | 5 | 2 | 5 |
| Oral dryness and saliva altered | | 1 | | 1 |
| | 5 | 17 | 5 | 17 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Administration site reactions NEC | | 1 | | 1 |
| Asthenic conditions | 3 | 13 | 3 | 13 |
| Febrile disorders | 3 | 11 | 3 | 11 |
| Feelings and sensations NEC | 1 | 5 | 1 | 5 |
| Gait disturbances | | 1 | | 1 |
| General signs and symptoms NEC | 1 | 2 | 1 | 2 |
| Inflamations | | 1 | | 1 |
| Mass conditions NEC | | 1 | | 1 |
| Pain and discomfort NEC | 5 | 9 | 5 | 9 |
| Vaccination site reactions | 2 | 12 | 2 | 12 |
| | 15 | 56 | 15 | 56 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Exposures associated with pregnancy, delivery and lactation | | 1 | | 1 |
| Off label uses | | 2 | | 2 |
| Product administration errors and issues | 12 | 13 | 12 | 13 |
| | 12 | 16 | 12 | 16 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autoimmunity analyses | 1 | 1 | 1 | 1 | | |
| Haematological analyses NEC | 1 | 1 | 1 | 1 | | |
| Heart rate and pulse investigations | | 1 | | | | 1 |
| Immunology analyses NEC | 1 | 1 | 1 | 1 | | |
| Investigations NEC | 1 | 1 | 1 | 1 | | |
| | 4 | 5 | 4 | 4 | | 1 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Appetite disorders | | 1 | | 1 |
| Total fluid volume decreased | 1 | 1 | 1 | 1 |
| | 1 | 2 | 1 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Bone disorders NEC | | 1 | | 1 |
| Bone related signs and symptoms | | 1 | | 1 |
| Joint related signs and symptoms | 3 | 7 | 3 | 7 |
| Muscle pains | 4 | 6 | 4 | 6 |
| Muscle related signs and symptoms NEC | 1 | 2 | 1 | 2 |
| Musculoskeletal and connective tissue conditions NEC | | 1 | | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 2 | 9 | 2 | 9 |
| | 10 | 27 | 10 | 27 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Bone neoplasms unspecified malignancy | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dyskinesias and movement disorders NEC | | 2 | | 1 | | 1 |
| Facial cranial nerve disorders | 1 | 2 | | | 1 | 2 |
| Headaches NEC | 7 | 17 | 7 | 17 | | |
| Migraine headaches | | 1 | | | | 1 |
| Neurological signs and symptoms NEC | 1 | 2 | 1 | 2 | | |
| Paraesthesias and dysaesthesias | 2 | 10 | 2 | 10 | | |
| Sensory abnormalities NEC | | 3 | | 3 | | |
| Speech and language abnormalities | | 1 | | 1 | | |
| | 11 | 38 | 10 | 34 | 1 | 4 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Anxiety symptoms | 1 | 1 | 1 | 1 |
| Depressive disorders | | 1 | | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breathing abnormalities | | 1 | | 1 |
| Upper respiratory tract signs and symptoms | | 2 | | 2 |
| | | 3 | | 3 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | | 1 | | | | 1 |
| Erythemas | | 1 | | 1 | | |
| Pruritus NEC | | 1 | | 1 | | |
| Rashes, eruptions and exanthems NEC | | 1 | | 1 | | |
| | | 4 | | 3 | | 1 |

System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Disability issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Haemorrhages NEC | | 1 | | 1 |
| Vascular hypertensive disorders NEC | | 1 | | 1 |
| | | 2 | | 2 |

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Country Where Event Occurred

QATAR

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dyspeptic signs and symptoms | 2 | 2 | 2 | 2 | | |
| Nausea and vomiting symptoms | | 1 | | | | 1 |
| | 2 | 3 | 2 | 2 | | 1 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 1 | 1 | 1 | 1 | | |
| Feelings and sensations NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 3 | 3 | 2 | 2 | 1 | 1 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Overdoses NEC | | 1 | | 1 |
| Product preparation errors and issues | | 1 | | 1 |
| | | 2 | | 2 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Heart rate and pulse investigations | 1 | 1 | 1 | 1 |
| Vascular tests NEC (incl blood pressure) | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle pains | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in consciousness NEC | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 2 | 3 | | | 2 | 3 |
| Sensory abnormalities NEC | 1 | 1 | 1 | 1 | | |
| | 4 | 5 | 1 | 1 | 3 | 4 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Emotional and mood disturbances NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Breathing abnormalities | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Apocrine and eccrine gland disorders | 1 | 1 | 1 | 1 |
| Erythemas | | 1 | | 1 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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Country Where Event Occurred

ROMANIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 6 | 16 | 1 | 11 | 5 | 5 |
| | 6 | 16 | 1 | 11 | 5 | 5 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 1 | 1 | | | 1 | 1 |
| Cardiac signs and symptoms NEC | | 2 | | | | 2 |
| Ischaemic coronary artery disorders | 1 | 2 | | | 1 | 2 |
| Noninfectious pericarditis | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 8 | 13 | 3 | 5 | 5 | 8 |
| Supraventricular arrhythmias | 3 | 3 | | | 3 | 3 |
| Ventricular arrhythmias and cardiac arrest | | 1 | | 1 | | |
| | 14 | 23 | 3 | 6 | 11 | 17 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 1 | 3 | 1 | 3 | | |
| Inner ear disorders NEC | | 1 | | 1 | | |
| Inner ear signs and symptoms | 7 | 10 | 1 | 3 | 6 | 7 |
| | 8 | 14 | 2 | 7 | 6 | 7 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Eyelid movement disorders | 2 | 2 | 1 | 1 | 1 | 1 |
| Glaucomas (excl congenital) | | 1 | | | | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 2 | | 1 | 1 | 1 |
| Ocular disorders NEC | 1 | 1 | | | 1 | 1 |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | | | 1 | 1 |
| | 5 | 7 | 1 | 2 | 4 | 5 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | 1 | 1 | | | 1 | 1 |
| Diarrhoea (excl infective) | 3 | 4 | 1 | 2 | 2 | 2 |
| Faecal abnormalities NEC | 1 | 1 | | | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | | 1 | | | | 1 |
| Nausea and vomiting symptoms | 19 | 35 | 6 | 19 | 13 | 16 |
| Oral dryness and saliva altered | | 1 | | | | 1 |
| Oral soft tissue signs and symptoms | | 2 | | 2 | | |
| Oral soft tissue swelling and oedema | 3 | 7 | | 2 | 3 | 5 |
| Tongue disorders | | 1 | | 1 | | |
| Tongue signs and symptoms | 1 | 2 | | | 1 | 2 |
| | 30 | 57 | 8 | 27 | 22 | 30 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Administration site reactions NEC | 1 | 1 | | | 1 | 1 |
| Adverse effect absent | 1 | 1 | 1 | 1 | | |
| Asthenic conditions | 19 | 52 | 7 | 37 | 12 | 15 |
| Body temperature altered | | 1 | | 1 | | |
| Death and sudden death | 1 | 1 | | | 1 | 1 |
| Febrile disorders | 24 | 56 | 8 | 40 | 16 | 16 |
| Feelings and sensations NEC | 22 | 49 | 8 | 30 | 14 | 19 |
| General signs and symptoms NEC | 5 | 8 | 2 | 5 | 3 | 3 |
| Inflamations | 1 | 2 | 1 | 2 | | |
| Injection site reactions | 2 | 5 | 1 | 4 | 1 | 1 |
| Oedema NEC | 3 | 5 | | 1 | 3 | 4 |
| Pain and discomfort NEC | 6 | 18 | 2 | 13 | 4 | 5 |
| Therapeutic and nontherapeutic responses | 30 | 49 | 1 | 1 | 29 | 48 |
| Vaccination site reactions | 39 | 121 | 23 | 105 | 16 | 16 |
| | 154 | 369 | 54 | 240 | 100 | 129 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 3 | 5 | 1 | 3 | 2 | 2 |
| Allergies to foods, food additives, drugs and other chemicals | | 1 | | 1 | | |
| Anaphylactic and anaphylactoid responses | 3 | 6 | | | 3 | 6 |
| | 6 | 12 | 1 | 4 | 5 | 8 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 31 | 43 | 2 | 2 | 29 | 41 |
| | 31 | 43 | 2 | 2 | 29 | 41 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 1 | 3 | 1 | 3 | | |
| Medication errors, product use errors and issues NEC | 1 | 23 | 1 | 23 | | |
| Off label uses | | 3 | | 3 | | |
| Overdoses NEC | 1 | 1 | 1 | 1 | | |
| Product administration errors and issues | 2 | 4 | | 2 | 2 | 2 |
| Product preparation errors and issues | | 17 | | 17 | | |
| Site specific injuries NEC | | 1 | | | | 1 |
| Underdoses NEC | | 1 | | 1 | | |
| Vaccination related complications | 1 | 1 | | | 1 | 1 |
| | 6 | 54 | 3 | 50 | 3 | 4 |

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System Organ Class

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 2 | 2 | | | 2 | 2 |
| Digestive enzymes | 1 | 1 | 1 | 1 | | |
| Heart rate and pulse investigations | 8 | 9 | 1 | 2 | 7 | 7 |
| Liver function analyses | | 1 | | 1 | | |
| Physical examination procedures and organ system status | 1 | 3 | 1 | 3 | | |
| Vascular tests NEC (incl blood pressure) | 5 | 7 | | 2 | 5 | 5 |
| Virus identification and serology | 10 | 18 | 8 | 9 | 2 | 9 |
| | 27 | 41 | 11 | 18 | 16 | 23 |

System Organ Class

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 1 | 2 | | 1 | 1 | 1 |
| Calcium metabolism disorders | | 1 | | | | 1 |
| | 1 | 3 | | 1 | 1 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 2 | 3 | 1 | 2 | 1 | 1 |
| Joint related disorders NEC | | 1 | | | | 1 |
| Joint related signs and symptoms | 10 | 24 | 3 | 15 | 7 | 9 |
| Muscle pains | 19 | 45 | 3 | 27 | 16 | 18 |
| Muscle related signs and symptoms NEC | | 1 | | 1 | | |
| Muscle weakness conditions | | 2 | | 2 | | |
| Musculoskeletal and connective tissue pain and discomfort | 2 | 31 | 1 | 29 | 1 | 2 |
| | 33 | 107 | 8 | 76 | 25 | 31 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autonomic nervous system disorders | | 1 | | | | 1 |
| Coordination and balance disturbances | | 2 | | 1 | | 1 |
| Disturbances in consciousness NEC | 11 | 17 | 1 | 6 | 10 | 11 |
| Dyskinesias and movement disorders NEC | 1 | 1 | 1 | 1 | | |
| Facial cranial nerve disorders | 2 | 5 | | | 2 | 5 |
| Headaches NEC | 28 | 61 | 9 | 39 | 19 | 22 |
| Increased intracranial pressure disorders | 1 | 1 | | | 1 | 1 |
| Memory loss (excl dementia) | 1 | 1 | | | 1 | 1 |
| Mental impairment (excl dementia and memory loss) | 1 | 2 | | 1 | 1 | 1 |
| Migraine headaches | | 2 | | 1 | | 1 |
| Nervous system disorders NEC | 3 | 3 | 3 | 3 | | |
| Neurological signs and symptoms NEC | 13 | 23 | 5 | 15 | 8 | 8 |
| Neuromuscular disorders NEC | | 1 | | 1 | | |
| Olfactory nerve disorders | 1 | 3 | 1 | 2 | | 1 |
| Paraesthesias and dysaesthesias | 15 | 25 | 7 | 15 | 8 | 10 |
| Paralysis and paresis (excl cranial nerve) | 3 | 3 | | | 3 | 3 |
| Seizures and seizure disorders NEC | | 1 | | | | 1 |
| Sensory abnormalities NEC | 2 | 6 | 2 | 4 | | 2 |
| Speech and language abnormalities | 1 | 1 | | | 1 | 1 |
| Tremor (excl congenital) | 1 | 3 | | 1 | 1 | 2 |
| Trigeminal disorders | 1 | 1 | | | 1 | 1 |
| | 85 | 163 | 29 | 90 | 56 | 73 |

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System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Device physical property and chemical issues | | 1 | | 1 |
| Product quality issues NEC | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 1 | 7 | | 4 | 1 | 3 |
| Confusion and disorientation | 1 | 1 | 1 | 1 | | |
| Disturbances in initiating and maintaining sleep | 1 | 2 | | 1 | 1 | 1 |
| Emotional and mood disturbances NEC | | 1 | | 1 | | |
| Fear symptoms and phobic disorders (incl social phobia) | | 1 | | 1 | | |
| Panic attacks and disorders | | 2 | | 2 | | |
| | 3 | 14 | 1 | 10 | 2 | 4 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Nephropathies and tubular disorders NEC | 1 | 1 | 1 | 1 |
| Urinary tract signs and symptoms NEC | 3 | 3 | 3 | 3 |
| | 4 | 4 | 4 | 4 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Breast signs and symptoms | | 1 | | 1 |
| Lactation disorders | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 8 | 10 | 1 | 1 | 7 | 9 |
| Bronchospasm and obstruction | 3 | 3 | | | 3 | 3 |
| Conditions associated with abnormal gas exchange | 1 | 1 | | | 1 | 1 |
| Coughing and associated symptoms | 3 | 6 | | 1 | 3 | 5 |
| Laryngeal spasm, oedema and obstruction | | 2 | | | | 2 |
| Nasal disorders NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Respiratory signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 3 | 6 | 1 | 3 | 2 | 3 |
| | 21 | 32 | 3 | 6 | 18 | 26 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 2 | 2 | | | 2 | 2 |
| Apocrine and eccrine gland disorders | 6 | 10 | 3 | 6 | 3 | 4 |
| Bullous conditions | 1 | 1 | | | 1 | 1 |
| Dermal and epidermal conditions NEC | 1 | 3 | | 2 | 1 | 1 |
| Dermatitis and eczema | 2 | 2 | | | 2 | 2 |
| Dermatitis ascribed to specific agent | 2 | 2 | | | 2 | 2 |
| Erythemas | 7 | 17 | 2 | 11 | 5 | 6 |
| Panniculitides | 1 | 2 | | 1 | 1 | 1 |
| Pruritus NEC | 5 | 10 | 1 | 5 | 4 | 5 |
| Rashes, eruptions and exanthems NEC | 7 | 17 | | 8 | 7 | 9 |
| Urticarias | 4 | 8 | | 4 | 4 | 4 |
| | 38 | 74 | 6 | 37 | 32 | 37 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | | 1 | | | | 1 |
| Blood pressure disorders NEC | 1 | 1 | | | 1 | 1 |
| Non-site specific vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Peripheral vascular disorders NEC | 2 | 3 | 1 | 2 | 1 | 1 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 2 | | 1 | 1 | 1 |
| Site specific vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Vascular hypertensive disorders NEC | 7 | 13 | 1 | 1 | 6 | 12 |
| Vascular hypotensive disorders | 4 | 4 | | | 4 | 4 |
| | 17 | 26 | 3 | 5 | 14 | 21 |

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Country Where Event Occurred

SAUDI ARABIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Gastrointestinal and abdominal pains (excl oral and throat) | | 1 | | 1 |
| Stomatitis and ulceration | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 4 | 9 | 4 | 9 | | |
| Febrile disorders | 2 | 5 | 2 | 5 | | |
| Feelings and sensations NEC | 1 | 2 | 1 | 2 | | |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| Injection site reactions | | 1 | | 1 | | |
| Pain and discomfort NEC | 3 | 4 | 3 | 4 | | |
| Therapeutic and nontherapeutic responses | 1 | 1 | | | 1 | 1 |
| Vaccination site reactions | 5 | 7 | 5 | 7 | | |
| | 17 | 30 | 16 | 29 | 1 | 1 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 2 | 2 | | | 2 | 2 |
| Female reproductive tract infections | | 1 | | 1 | | |
| Herpes viral infections | | 1 | | 1 | | |
| Upper respiratory tract infections | | 1 | | 1 | | |
| | 2 | 5 | | 3 | 2 | 2 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product administration errors and issues | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Haematological analyses NEC | 1 | 1 | 1 | 1 |
| Protein analyses NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | 1 | 1 | 1 | 1 | | |
| Joint related signs and symptoms | 2 | 3 | 2 | 3 | | |
| Muscle pains | 2 | 4 | 2 | 4 | | |
| Musculoskeletal and connective tissue conditions NEC | 5 | 6 | 5 | 6 | | |
| Musculoskeletal and connective tissue pain and discomfort | 3 | 4 | 1 | 2 | 2 | 2 |
| | 13 | 18 | 11 | 16 | 2 | 2 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in consciousness NEC | 1 | 2 | 1 | 1 | | 1 |
| Dyskinesias and movement disorders NEC | | 1 | | 1 | | |
| Headaches NEC | 2 | 4 | 2 | 4 | | |
| Lumbar spinal cord and nerve root disorders | 2 | 2 | 2 | 2 | | |
| Neurological signs and symptoms NEC | | 1 | | 1 | | |
| | 5 | 10 | 5 | 9 | | 1 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Bladder and urethral symptoms | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Upper respiratory tract signs and symptoms | 1 | 2 | 1 | 2 |
| | 1 | 2 | 1 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Apocrine and eccrine gland disorders | 1 | 3 | 1 | 3 |
| Dermal and epidermal conditions NEC | | 1 | | 1 |
| | 1 | 4 | 1 | 4 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 2 | 1 | 2 | | |
| Vascular hypotensive disorders | | 1 | | | | 1 |
| | 1 | 3 | 1 | 2 | | 1 |

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Country Where Event Occurred

SERBIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | | 3 | | 1 | | 2 |
| | | 3 | | 1 | | 2 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | | 1 | | 1 | | |
| Rate and rhythm disorders NEC | 1 | 2 | 1 | 1 | | 1 |
| | 1 | 3 | 1 | 2 | | 1 |

System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Neurological disorders congenital NEC | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inner ear signs and symptoms | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Eyelid movement disorders | 1 | 1 | 1 | 1 |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 2 | 1 | 2 |
| | 2 | 3 | 2 | 3 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic pancreatitis | 1 | 1 | | | 1 | 1 |
| Diarrhoea (excl infective) | | 1 | | 1 | | |
| Nausea and vomiting symptoms | 3 | 12 | 1 | 10 | 2 | 2 |
| Non-site specific gastrointestinal haemorrhages | 1 | 1 | | | 1 | 1 |
| Oral dryness and saliva altered | | 1 | | 1 | | |
| Tongue signs and symptoms | 1 | 1 | | | 1 | 1 |
| | 6 | 17 | 1 | 12 | 5 | 5 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 5 | 19 | 5 | 19 | | |
| Febrile disorders | 10 | 28 | 8 | 25 | 2 | 3 |
| Feelings and sensations NEC | 1 | 6 | 1 | 5 | | 1 |
| General signs and symptoms NEC | 1 | 5 | 1 | 3 | | 2 |
| Mucosal findings abnormal | | 1 | | | | 1 |
| Oedema NEC | 1 | 2 | | 1 | 1 | 1 |
| Pain and discomfort NEC | 1 | 6 | 1 | 4 | | 2 |
| Vaccination site reactions | 8 | 24 | 8 | 23 | | 1 |
| | 27 | 91 | 24 | 80 | 3 | 11 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | | 2 | | 1 | | 1 |
| Anaphylactic and anaphylactoid responses | | 1 | | | | 1 |
| | | 3 | | 1 | | 2 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 2 | 2 | 1 | 1 | 1 | 1 |
| Eye and eyelid infections | 1 | 1 | 1 | 1 | | |
| Herpes viral infections | | 1 | | 1 | | |
| Infections NEC | | 1 | | | | 1 |
| | 3 | 5 | 2 | 3 | 1 | 2 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Non-site specific injuries NEC | | 1 | | 1 |
| Vaccination related complications | 2 | 2 | 2 | 2 |
| | 2 | 3 | 2 | 3 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Chemistry analyses NEC | | 1 | | 1 | | |
| Ophthalmic function diagnostic procedures | | 1 | | | | 1 |
| Physical examination procedures and organ system status | 1 | 5 | 1 | 4 | | 1 |
| Vascular tests NEC (incl blood pressure) | | 1 | | 1 | | |
| Virus identification and serology | | 1 | | 1 | | |
| White blood cell analyses | | 1 | | 1 | | |
| | 1 | 10 | 1 | 8 | | 2 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Appetite disorders | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone related signs and symptoms | | 3 | | 3 | | |
| Joint related signs and symptoms | 6 | 10 | 6 | 10 | | |
| Muscle pains | 4 | 11 | 3 | 10 | 1 | 1 |
| Muscle weakness conditions | | 2 | | 2 | | |
| Musculoskeletal and connective tissue conditions NEC | 1 | 1 | 1 | 1 | | |
| Musculoskeletal and connective tissue pain and discomfort | 1 | 9 | 1 | 9 | | |
| | 12 | 36 | 11 | 35 | 1 | 1 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in consciousness NEC | | 1 | | | | 1 |
| Facial cranial nerve disorders | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 8 | 14 | 7 | 13 | 1 | 1 |
| Neurological signs and symptoms NEC | | 1 | | 1 | | |
| Olfactory nerve disorders | | 1 | | 1 | | |
| Paraesthesias and dysaesthesias | | 2 | | 2 | | |
| Sensory abnormalities NEC | | 1 | | 1 | | |
| | 9 | 21 | 7 | 18 | 2 | 3 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Anxiety symptoms | | 1 | | 1 |
| Confusion and disorientation | | 1 | | 1 |
| Disturbances in initiating and maintaining sleep | | 1 | | 1 |
| Fear symptoms and phobic disorders (incl social phobia) | | 1 | | 1 |
| Sleep disorders NEC | | 1 | | 1 |
| | | 5 | | 5 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 1 | 1 | | | 1 | 1 |
| Bronchospasm and obstruction | 1 | 2 | 1 | 1 | | 1 |
| Conditions associated with abnormal gas exchange | | 1 | | | | 1 |
| Coughing and associated symptoms | 1 | 2 | 1 | 1 | | 1 |
| Nasal congestion and inflammations | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | | 1 | | 1 | | |
| | 4 | 8 | 3 | 4 | 1 | 4 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 1 | 3 | 1 | 3 | | |
| Dermal and epidermal conditions NEC | | 1 | | | | 1 |
| Erythemas | 1 | 4 | 1 | 4 | | |
| Pruritus NEC | | 1 | | 1 | | |
| Rashes, eruptions and exanthems NEC | | 5 | | 2 | | 3 |
| Urticarias | 1 | 2 | 1 | 2 | | |
| | 3 | 16 | 3 | 12 | | 4 |

System Organ Class

SOC Not Yet Coded

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Non-site specific vascular disorders NEC | | 1 | | 1 | | |
| Phlebitis NEC | | 1 | | | | 1 |
| Site specific vascular disorders NEC | 1 | 1 | 1 | 1 | | |
| Vascular hypertensive disorders NEC | 1 | 3 | 1 | 2 | | 1 |
| | 2 | 6 | 2 | 4 | | 2 |

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Country Where Event Occurred

SINGAPORE

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | | 2 | | 1 | | 1 |
| | | 2 | | 1 | | 1 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ocular disorders NEC | | 2 | | 1 | | 1 |
| | | 2 | | 1 | | 1 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | | 2 | | 1 | | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | | 1 | | | | 1 |
| Nausea and vomiting symptoms | | 2 | | 1 | | 1 |
| Oral soft tissue disorders NEC | | 2 | | 1 | | 1 |
| Oral soft tissue swelling and oedema | | 2 | | | | 2 |
| | | 9 | | 3 | | 6 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | | 1 | | 1 | | |
| Febrile disorders | | 1 | | 1 | | |
| Feelings and sensations NEC | | 2 | | 2 | | |
| Pain and discomfort NEC | | 1 | | | | 1 |
| Vaccination site reactions | 3 | 3 | 3 | 3 | | |
| | 3 | 8 | 3 | 7 | | 1 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Anaphylactic and anaphylactoid responses | | 7 | | 7 |
| | | 7 | | 7 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Heart rate and pulse investigations | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Neurological signs and symptoms NEC | | 2 | | 1 | | 1 |
| Sensory abnormalities NEC | 2 | 2 | 2 | 2 | | |
| | 2 | 4 | 2 | 3 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | | 2 | | 1 | | 1 |
| Coughing and associated symptoms | | 2 | | 1 | | 1 |
| Upper respiratory tract signs and symptoms | | 3 | | 1 | | 2 |
| | | 7 | | 3 | | 4 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | | 2 | | | | 2 |
| Pruritus NEC | | 1 | | | | 1 |
| Rashes, eruptions and exanthems NEC | | 2 | | | | 2 |
| Urticarias | | 3 | | 2 | | 1 |
| | | 8 | | 2 | | 6 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vascular hypertensive disorders NEC | | 1 | | 1 |
| | | 1 | | 1 |

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Country Where Event Occurred

SLOVAKIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | | 2 | | 2 |
| | | 2 | | 2 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 1 | 2 | 1 | 2 | | |
| Heart failures NEC | 1 | 1 | | | 1 | 1 |
| Ischaemic coronary artery disorders | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | | 1 | | 1 | | |
| Supraventricular arrhythmias | 1 | 1 | | | 1 | 1 |
| | 4 | 6 | 1 | 3 | 3 | 3 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Inner ear signs and symptoms | 3 | 3 | 3 | 3 |
| | 3 | 3 | 3 | 3 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ocular disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Ocular infections, inflammations and associated manifestations | 4 | 4 | 4 | 4 | | |
| Pupil disorders | 1 | 1 | 1 | 1 | | |
| Visual disorders NEC | | 1 | | 1 | | |
| | 7 | 8 | 6 | 7 | 1 | 1 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 2 | 2 | 2 | 2 | | |
| Flatulence, bloating and distension | 1 | 1 | 1 | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Nausea and vomiting symptoms | 8 | 9 | 5 | 6 | 3 | 3 |
| Oral dryness and saliva altered | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 1 | 1 | 1 | 1 | | |
| Oral soft tissue swelling and oedema | 1 | 1 | 1 | 1 | | |
| | 17 | 18 | 11 | 12 | 6 | 6 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Adverse effect absent | 1 | 1 | 1 | 1 | | |
| Asthenic conditions | 22 | 24 | 19 | 21 | 3 | 3 |
| Febrile disorders | 11 | 15 | 9 | 13 | 2 | 2 |
| Feelings and sensations NEC | 16 | 23 | 13 | 19 | 3 | 4 |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Oedema NEC | 2 | 2 | 2 | 2 | | |
| Pain and discomfort NEC | 4 | 5 | 4 | 5 | | |
| Therapeutic and nontherapeutic responses | 1 | 3 | | | 1 | 3 |
| Vaccination site reactions | 13 | 22 | 13 | 20 | | 2 |
| | 72 | 97 | 63 | 83 | 9 | 14 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Allergic conditions NEC | 1 | 1 | 1 | 1 |
| Anaphylactic and anaphylactoid responses | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 3 | 7 | | 2 | 3 | 5 |
| Streptococcal infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | | 1 | | 1 | | |
| | 4 | 9 | | 3 | 4 | 6 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Exposures associated with pregnancy, delivery and lactation | | 1 | | 1 |
| Medication errors, product use errors and issues NEC | 1 | 1 | 1 | 1 |
| Product administration errors and issues | 2 | 3 | 2 | 3 |
| | 3 | 5 | 3 | 5 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Immunology analyses NEC | 1 | 1 | 1 | 1 | | |
| Physical examination procedures and organ system status | 4 | 6 | 3 | 4 | 1 | 2 |
| Vascular tests NEC (incl blood pressure) | 5 | 5 | 1 | 1 | 4 | 4 |
| Virus identification and serology | | 3 | | 1 | | 2 |
| | 10 | 15 | 5 | 7 | 5 | 8 |

System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 1 | 1 | 1 | 1 | | |
| Hyperglycaemic conditions NEC | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Joint related signs and symptoms | 3 | 3 | 3 | 3 |
| Muscle pains | 8 | 9 | 8 | 9 |
| Musculoskeletal and connective tissue pain and discomfort | 6 | 12 | 6 | 12 |
| Synovial disorders | 1 | 1 | 1 | 1 |
| | 18 | 25 | 18 | 25 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in consciousness NEC | 4 | 5 | | | 4 | 5 |
| Dyskinesias and movement disorders NEC | 1 | 1 | 1 | 1 | | |
| Headaches NEC | 11 | 16 | 11 | 15 | | 1 |
| Neurological signs and symptoms NEC | 10 | 12 | 5 | 7 | 5 | 5 |
| Paraesthesias and dysaesthesias | 5 | 8 | 3 | 5 | 2 | 3 |
| Tremor (excl congenital) | 1 | 1 | | | 1 | 1 |
| | 32 | 43 | 20 | 28 | 12 | 15 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 | | |
| Increased physical activity levels | 1 | 1 | | | 1 | 1 |
| Parasomnias | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 2 | 2 | 1 | 1 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Bladder and urethral symptoms | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 3 | 4 | 1 | 2 | 2 | 2 |
| Coughing and associated symptoms | 1 | 3 | 1 | 3 | | |
| Upper respiratory tract signs and symptoms | 1 | 4 | 1 | 4 | | |
| | 5 | 11 | 3 | 9 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 1 | 1 | | | 1 | 1 |
| Apocrine and eccrine gland disorders | 4 | 5 | 1 | 2 | 3 | 3 |
| Dermal and epidermal conditions NEC | 1 | 1 | 1 | 1 | | |
| Erythemas | 3 | 4 | 3 | 3 | | 1 |
| Pruritus NEC | 3 | 4 | 3 | 3 | | 1 |
| Purpura and related conditions | 1 | 1 | 1 | 1 | | |
| Rashes, eruptions and exanthems NEC | 2 | 4 | 2 | 4 | | |
| Skin vasculitides | 1 | 1 | 1 | 1 | | |
| Urticarias | 1 | 1 | 1 | 1 | | |
| | 17 | 22 | 13 | 16 | 4 | 6 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral embolism and thrombosis | 3 | 3 | | | 3 | 3 |
| Peripheral vascular disorders NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 2 | 2 | 2 | 2 | | |
| Site specific vascular disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Vascular hypertensive disorders NEC | 2 | 4 | 1 | 3 | 1 | 1 |
| | 13 | 15 | 6 | 8 | 7 | 7 |

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Country Where Event Occurred

SLOVENIA

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 5 | 5 | 5 | 5 | | |
| Neutropenias | 1 | 1 | | | 1 | 1 |
| Thrombocytopenias | 1 | 1 | | | 1 | 1 |
| | 7 | 7 | 5 | 5 | 2 | 2 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Heart failures NEC | | 1 | | | | 1 |
| Ischaemic coronary artery disorders | 1 | 2 | | | 1 | 2 |
| Rate and rhythm disorders NEC | 2 | 2 | 2 | 2 | | |
| Supraventricular arrhythmias | 2 | 2 | | | 2 | 2 |
| | 5 | 7 | 2 | 2 | 3 | 5 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Ear disorders NEC | 1 | 1 | 1 | 1 |
| Inner ear signs and symptoms | 1 | 2 | 1 | 2 |
| | 2 | 3 | 2 | 3 |

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System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Acute and chronic thyroiditis | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lid, lash and lacrimal infections, irritations and inflammations | 1 | 1 | 1 | 1 | | |
| Pupil disorders | 1 | 1 | | | 1 | 1 |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | | | 1 | 1 |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 4 | 4 | 4 | 4 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 4 | 4 | 4 | 4 | | |
| Nausea and vomiting symptoms | 5 | 7 | 4 | 4 | 1 | 3 |
| Oral soft tissue signs and symptoms | 2 | 2 | 1 | 1 | 1 | 1 |
| | 15 | 17 | 13 | 13 | 2 | 4 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 18 | 21 | 13 | 16 | 5 | 5 |
| Death and sudden death | 1 | 2 | | | 1 | 2 |
| Febrile disorders | 5 | 5 | 4 | 4 | 1 | 1 |
| Feelings and sensations NEC | 6 | 6 | 5 | 5 | 1 | 1 |
| General signs and symptoms NEC | | 1 | | | | 1 |
| Oedema NEC | 1 | 1 | | | 1 | 1 |
| Pain and discomfort NEC | 5 | 5 | 2 | 2 | 3 | 3 |
| Therapeutic and nontherapeutic responses | 2 | 2 | | | 2 | 2 |
| Vaccination site reactions | 50 | 53 | 47 | 50 | 3 | 3 |
| | 88 | 96 | 71 | 77 | 17 | 19 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Allergic conditions NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 3 | 3 | | | 3 | 3 |
| Herpes viral infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 2 | 2 | 2 | 2 | | |
| | 6 | 6 | 2 | 2 | 4 | 4 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Medication errors, product use errors and issues NEC | | 1 | | 1 |
| Off label uses | 1 | 1 | 1 | 1 |
| Product administration errors and issues | 1 | 1 | 1 | 1 |
| | 2 | 3 | 2 | 3 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 1 | 1 | | | 1 | 1 |
| Physical examination procedures and organ system status | 4 | 4 | 3 | 3 | 1 | 1 |
| Vascular tests NEC (incl blood pressure) | 1 | 1 | 1 | 1 | | |
| White blood cell analyses | | 1 | | 1 | | |
| | 6 | 7 | 4 | 5 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint related signs and symptoms | 2 | 2 | 2 | 2 | | |
| Muscle pains | 7 | 7 | 6 | 6 | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 2 | 2 | 1 | 1 | 1 | 1 |
| | 11 | 11 | 9 | 9 | 2 | 2 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| B-cell lymphomas NEC | 1 | 1 | 1 | 1 |
| Leukaemias acute lymphocytic | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 1 | | | 1 | 1 |
| Cortical dysfunction NEC | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 8 | 8 | 3 | 3 | 5 | 5 |
| Facial cranial nerve disorders | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 14 | 14 | 12 | 12 | 2 | 2 |
| Neurological signs and symptoms NEC | 8 | 8 | 3 | 3 | 5 | 5 |
| Olfactory nerve disorders | 2 | 2 | 2 | 2 | | |
| Paraesthesias and dysaesthesias | 3 | 3 | 3 | 3 | | |
| Seizures and seizure disorders NEC | 2 | 2 | | | 2 | 2 |
| Sensory abnormalities NEC | 4 | 4 | 4 | 4 | | |
| Speech and language abnormalities | 1 | 1 | 1 | 1 | | |
| Transient cerebrovascular events | 1 | 1 | | | 1 | 1 |
| | 46 | 46 | 28 | 28 | 18 | 18 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Confusion and disorientation | 1 | 1 | | | 1 | 1 |
| Increased physical activity levels | 1 | 1 | 1 | 1 | | |
| Parasomnias | 1 | 1 | 1 | 1 | | |
| Thinking disturbances | 1 | 1 | 1 | 1 | | |
| | 4 | 4 | 3 | 3 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Pulmonary thrombotic and embolic conditions | 1 | 1 | | | 1 | 1 |
| Respiratory signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract signs and symptoms | 1 | 1 | 1 | 1 | | |
| | 3 | 3 | 1 | 1 | 2 | 2 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Apocrine and eccrine gland disorders | 1 | 1 | | | 1 | 1 |
| Dermal and epidermal conditions NEC | 1 | 1 | | | 1 | 1 |
| Erythemas | 1 | 1 | 1 | 1 | | |
| Rashes, eruptions and exanthems NEC | 2 | 2 | 2 | 2 | | |
| | 5 | 5 | 3 | 3 | 2 | 2 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Peripheral embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 1 | 1 | 1 | 1 | | |
| Vascular hypertensive disorders NEC | 1 | 2 | | | 1 | 2 |
| Vascular hypotensive disorders | 1 | 1 | | | 1 | 1 |
| | 4 | 5 | 1 | 1 | 3 | 4 |

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Country Where Event Occurred

SPAIN

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bleeding tendencies | 1 | 1 | | | 1 | 1 |
| Coagulopathies | 1 | 1 | | | 1 | 1 |
| Leukopenias NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Lymphatic system disorders NEC | 28 | 30 | 3 | 5 | 25 | 25 |
| Marrow depression and hypoplastic anaemias | 1 | 1 | | | 1 | 1 |
| Neutropenias | 1 | 1 | | | 1 | 1 |
| Thrombocytopenias | 2 | 2 | | | 2 | 2 |
| | 36 | 38 | 4 | 6 | 32 | 32 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac signs and symptoms NEC | 8 | 12 | | 2 | 8 | 10 |
| Heart failures NEC | 7 | 8 | | | 7 | 8 |
| Ischaemic coronary artery disorders | 3 | 3 | | | 3 | 3 |
| Noninfectious myocarditis | 1 | 1 | | | 1 | 1 |
| Noninfectious pericarditis | 1 | 1 | | | 1 | 1 |
| Rate and rhythm disorders NEC | 43 | 46 | 5 | 6 | 38 | 40 |
| Supraventricular arrhythmias | 4 | 4 | 1 | 1 | 3 | 3 |
| Ventricular arrhythmias and cardiac arrest | 5 | 5 | | | 5 | 5 |
| | 72 | 80 | 6 | 9 | 66 | 71 |

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System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Neurological disorders congenital NEC | 1 | 1 | 1 | 1 |
| Tongue disorders congenital | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 2 | 2 | | | 2 | 2 |
| Hearing losses | 5 | 5 | | | 5 | 5 |
| Inner ear signs and symptoms | 9 | 9 | 2 | 2 | 7 | 7 |
| | 16 | 16 | 2 | 2 | 14 | 14 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Choroid and vitreous structural change, deposit and degeneration | 2 | 2 | | | 2 | 2 |
| Conjunctival and corneal bleeding and vascular disorders | 5 | 5 | | | 5 | 5 |
| Lacrimation disorders | 3 | 3 | | | 3 | 3 |
| Lid, lash and lacrimal infections, irritations and inflammations | 4 | 4 | 1 | 1 | 3 | 3 |
| Ocular disorders NEC | 1 | 2 | | 1 | 1 | 1 |
| Ocular infections, inflammations and associated manifestations | 3 | 4 | | 1 | 3 | 3 |
| Ocular sensation disorders | 3 | 3 | | | 3 | 3 |
| Visual disorders NEC | 9 | 9 | 3 | 3 | 6 | 6 |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | | | 1 | 1 |
| | 31 | 33 | 4 | 6 | 27 | 27 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anal and rectal disorders NEC | 1 | 1 | | | 1 | 1 |
| Colitis (excl infective) | 1 | 1 | | | 1 | 1 |
| Diarrhoea (excl infective) | 33 | 50 | 7 | 22 | 26 | 28 |
| Dyspeptic signs and symptoms | 1 | 1 | | | 1 | 1 |
| Flatulence, bloating and distension | | 1 | | | | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 7 | 11 | 2 | 5 | 5 | 6 |
| Gastrointestinal atonic and hypomotility disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 4 | 6 | 1 | 2 | 3 | 4 |
| Gastrointestinal stenosis and obstruction NEC | 3 | 3 | | | 3 | 3 |
| Gastrointestinal vascular occlusion and infarction | | 1 | | | | 1 |
| Gingival disorders, signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Intestinal haemorrhages | 1 | 2 | | | 1 | 2 |
| Nausea and vomiting symptoms | 72 | 96 | 17 | 34 | 55 | 62 |
| Non-mechanical ileus | 1 | 1 | | | 1 | 1 |
| Non-site specific gastrointestinal haemorrhages | 2 | 2 | | | 2 | 2 |
| Oral dryness and saliva altered | 1 | 3 | | 1 | 1 | 2 |
| Oral soft tissue disorders NEC | 3 | 3 | | | 3 | 3 |
| Oral soft tissue infections | | 1 | | 1 | | |
| Oral soft tissue signs and symptoms | 21 | 25 | 2 | 6 | 19 | 19 |
| Oral soft tissue swelling and oedema | 24 | 26 | | 1 | 24 | 25 |
| Stomatitis and ulceration | 1 | 5 | | 3 | 1 | 2 |
| Tongue disorders | 1 | 3 | | 1 | 1 | 2 |
| Tongue signs and symptoms | 11 | 17 | | 4 | 11 | 13 |
| | 191 | 262 | 30 | 81 | 161 | 181 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 101 | 129 | 26 | 48 | 75 | 81 |
| Body temperature altered | 12 | 14 | 4 | 6 | 8 | 8 |
| Death and sudden death | 7 | 11 | | | 7 | 11 |
| Febrile disorders | 110 | 157 | 24 | 68 | 86 | 89 |
| Feelings and sensations NEC | 44 | 56 | 8 | 19 | 36 | 37 |
| Gait disturbances | 3 | 3 | | | 3 | 3 |
| General signs and symptoms NEC | 18 | 22 | 4 | 6 | 14 | 16 |
| Inflamations | 2 | 2 | | | 2 | 2 |
| Interactions | 1 | 2 | | 1 | 1 | 1 |
| Mucosal findings abnormal | 1 | 1 | | | 1 | 1 |
| Necrosis NEC | 1 | 1 | | | 1 | 1 |
| Oedema NEC | 23 | 24 | 2 | 2 | 21 | 22 |
| Pain and discomfort NEC | 39 | 51 | 7 | 16 | 32 | 35 |
| Therapeutic and nontherapeutic responses | 31 | 37 | | | 31 | 37 |
| Vaccination site reactions | 79 | 121 | 16 | 56 | 63 | 65 |
| | 472 | 631 | 91 | 222 | 381 | 409 |

System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hepatic enzymes and function abnormalities | 1 | 1 | 1 | 1 |
| Hepatic failure and associated disorders | 1 | 1 | 1 | 1 |
| Hepatocellular damage and hepatitis NEC | 3 | 3 | 3 | 3 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 14 | 15 | 1 | 1 | 13 | 14 |
| Allergies to foods, food additives, drugs and other chemicals | 8 | 8 | | | 8 | 8 |
| Anaphylactic and anaphylactoid responses | 33 | 38 | | | 33 | 38 |
| Immune and associated conditions NEC | 1 | 2 | | 1 | 1 | 1 |
| | 56 | 63 | 1 | 2 | 55 | 61 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal infections | 2 | 3 | 1 | 1 | 1 | 2 |
| Bacterial infections NEC | 8 | 8 | | | 8 | 8 |
| Bordetella infections | 2 | 2 | | | 2 | 2 |
| Candida infections | 1 | 1 | | | 1 | 1 |
| Central nervous system and spinal infections | 3 | 3 | | | 3 | 3 |
| Coronavirus infections | 54 | 59 | 6 | 6 | 48 | 53 |
| Dental and oral soft tissue infections | 3 | 3 | 1 | 1 | 2 | 2 |
| Ear infections | 1 | 1 | | | 1 | 1 |
| Herpes viral infections | 25 | 25 | | | 25 | 25 |
| Infections NEC | 4 | 4 | | | 4 | 4 |
| Influenza viral infections | 3 | 3 | | | 3 | 3 |
| Lower respiratory tract and lung infections | 7 | 8 | | | 7 | 8 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | 1 | | | | 1 |
| Skin structures and soft tissue infections | 1 | 1 | | | 1 | 1 |
| Upper respiratory tract infections | 3 | 6 | | 3 | 3 | 3 |
| Urinary tract infections | 2 | 3 | | 1 | 2 | 2 |
| Vascular infections | 1 | 1 | | | 1 | 1 |
| | 120 | 132 | 8 | 12 | 112 | 120 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Exposures associated with pregnancy, delivery and lactation | 1 | 3 | 1 | 3 | | |
| Medication errors, product use errors and issues NEC | 8 | 11 | 8 | 11 | | |
| Non-site specific injuries NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Off label uses | 9 | 11 | 9 | 11 | | |
| Overdoses NEC | 1 | 2 | 1 | 2 | | |
| Peripheral nerve injuries | 1 | 1 | | | 1 | 1 |
| Product administration errors and issues | 4 | 7 | 4 | 7 | | |
| Site specific injuries NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Skin injuries NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Skull fractures, facial bone fractures and dislocations | 2 | 2 | | | 2 | 2 |
| Spinal cord injuries NEC | 1 | 1 | | | 1 | 1 |
| Underdoses NEC | | 1 | | 1 | | |
| Vaccination related complications | 5 | 7 | | 1 | 5 | 6 |
| | 39 | 53 | 27 | 40 | 12 | 13 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Autoimmunity analyses | 1 | 1 | | | 1 | 1 |
| Blood gas and acid base analyses | 6 | 6 | | | 6 | 6 |
| Carbohydrate tolerance analyses (incl diabetes) | 1 | 1 | 1 | 1 | | |
| Coagulation and bleeding analyses | 3 | 3 | 2 | 2 | 1 | 1 |
| ECG investigations | 3 | 3 | | | 3 | 3 |
| Haematological analyses NEC | 1 | 1 | 1 | 1 | | |
| Heart rate and pulse investigations | 2 | 2 | 1 | 1 | 1 | 1 |
| Liver function analyses | 2 | 2 | 1 | 1 | 1 | 1 |
| Mineral and electrolyte analyses | 2 | 2 | 2 | 2 | | |
| Physical examination procedures and organ system status | 2 | 3 | | 1 | 2 | 2 |
| Platelet analyses | 1 | 1 | 1 | 1 | | |
| Protein analyses NEC | 3 | 3 | 3 | 3 | | |
| Red blood cell analyses | 2 | 2 | 2 | 2 | | |
| Skeletal and cardiac muscle analyses | | 1 | | | | 1 |
| Urinalysis NEC | 1 | 1 | 1 | 1 | | |
| Vascular auscultatory investigations | 2 | 2 | | | 2 | 2 |
| Vascular tests NEC (incl blood pressure) | 12 | 13 | 9 | 9 | 3 | 4 |
| Virus identification and serology | 5 | 6 | 5 | 5 | | 1 |
| White blood cell analyses | 7 | 7 | 6 | 6 | 1 | 1 |
| | 56 | 60 | 35 | 36 | 21 | 24 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 3 | 3 | | | 3 | 3 |
| Calcium metabolism disorders | 1 | 1 | 1 | 1 | | |
| Diabetes mellitus (incl subtypes) | 1 | 1 | | | 1 | 1 |
| Diabetic complications NEC | 1 | 1 | | | 1 | 1 |
| Hyperglycaemic conditions NEC | | 2 | | 2 | | |
| Hypoglycaemic conditions NEC | 2 | 2 | | | 2 | 2 |
| Iron deficiencies | 1 | 1 | 1 | 1 | | |
| Phosphorus metabolism disorders | 1 | 1 | 1 | 1 | | |
| Potassium imbalance | 1 | 1 | | | 1 | 1 |
| Sodium imbalance | 2 | 2 | | | 2 | 2 |
| Total fluid volume decreased | 2 | 2 | 1 | 1 | 1 | 1 |
| | 15 | 17 | 4 | 6 | 11 | 11 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bone disorders NEC | | 1 | | 1 | | |
| Bone related signs and symptoms | 1 | 1 | 1 | 1 | | |
| Bursal disorders | 1 | 1 | | | 1 | 1 |
| Joint related disorders NEC | | 1 | | 1 | | |
| Joint related signs and symptoms | 22 | 29 | 5 | 10 | 17 | 19 |
| Muscle infections and inflammations | 1 | 1 | | | 1 | 1 |
| Muscle pains | 42 | 56 | 9 | 23 | 33 | 33 |
| Muscle related signs and symptoms NEC | 2 | 4 | 1 | 2 | 1 | 2 |
| Muscle tone abnormalities | 1 | 2 | | | 1 | 2 |
| Muscle weakness conditions | 4 | 6 | 1 | 3 | 3 | 3 |
| Musculoskeletal and connective tissue conditions NEC | 5 | 9 | 3 | 5 | 2 | 4 |
| Musculoskeletal and connective tissue pain and discomfort | 33 | 45 | 9 | 18 | 24 | 27 |
| Soft tissue disorders NEC | 1 | 1 | | | 1 | 1 |
| | 113 | 157 | 29 | 64 | 84 | 93 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukaemias acute NEC | 1 | 1 | | | 1 | 1 |
| Neoplasms unspecified malignancy and site unspecified NEC | 1 | 1 | 1 | 1 | | |
| | 2 | 2 | 1 | 1 | 1 | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal reflexes | 1 | 1 | 1 | 1 | | |
| Absence seizures | 2 | 2 | | | 2 | 2 |
| Acute polyneuropathies | 1 | 1 | | | 1 | 1 |
| Central nervous system haemorrhages and cerebrovascular accidents | 11 | 11 | | | 11 | 11 |
| Cervical spinal cord and nerve root disorders | 1 | 1 | | | 1 | 1 |
| Coordination and balance disturbances | 4 | 5 | | 1 | 4 | 4 |
| Cortical dysfunction NEC | 3 | 3 | | | 3 | 3 |
| Demyelinating disorders NEC | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 51 | 56 | 2 | 6 | 49 | 50 |
| Dyskinesias and movement disorders NEC | 3 | 5 | 1 | 3 | 2 | 2 |
| Dystonias | 1 | 1 | | | 1 | 1 |
| Encephalopathies NEC | 2 | 2 | | | 2 | 2 |
| Facial cranial nerve disorders | 19 | 20 | | | 19 | 20 |
| Generalised tonic-clonic seizures | 2 | 2 | | | 2 | 2 |
| Headaches NEC | 91 | 128 | 21 | 53 | 70 | 75 |
| Memory loss (excl dementia) | 2 | 2 | | | 2 | 2 |
| Mental impairment (excl dementia and memory loss) | 6 | 6 | | | 6 | 6 |
| Migraine headaches | 4 | 6 | | 1 | 4 | 5 |
| Mononeuropathies | 1 | 1 | | | 1 | 1 |
| Nervous system disorders NEC | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 69 | 82 | 14 | 23 | 55 | 59 |
| Neurologic visual problems NEC | 1 | 1 | | | 1 | 1 |
| Neuromuscular disorders NEC | | 1 | | 1 | | |
| Olfactory nerve disorders | 3 | 3 | | | 3 | 3 |
| Paraesthesias and dysaesthesias | 44 | 55 | 5 | 16 | 39 | 39 |
| Paralysis and paresis (excl cranial nerve) | 3 | 3 | | | 3 | 3 |
| Peripheral neuropathies NEC | 1 | 1 | | | 1 | 1 |
| Seizures and seizure disorders NEC | 10 | 10 | | | 10 | 10 |
| Sensory abnormalities NEC | 9 | 13 | 1 | 4 | 8 | 9 |
| Speech and language abnormalities | 6 | 8 | 2 | 3 | 4 | 5 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|----------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Transient cerebrovascular events | 2 | 2 | | | 2 | 2 |
| Tremor (excl congenital) | 8 | 8 | 1 | 1 | 7 | 7 |
| Trigeminal disorders | 1 | 1 | | | 1 | 1 |
| | 364 | 443 | 48 | 113 | 316 | 330 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 3 | 6 | 3 | 6 | | |
| Confusion and disorientation | 5 | 6 | 2 | 2 | 3 | 4 |
| Depressive disorders | 1 | 1 | | | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 | | |
| Emotional and mood disturbances NEC | 1 | 2 | | 1 | 1 | 1 |
| Increased physical activity levels | 1 | 1 | 1 | 1 | | |
| Mood alterations with depressive symptoms | | 2 | | 2 | | |
| Panic attacks and disorders | 1 | 1 | | | 1 | 1 |
| Sexual desire disorders | 1 | 1 | | | 1 | 1 |
| Stereotypies and automatisms | | 1 | | 1 | | |
| Thinking disturbances | 3 | 3 | 1 | 1 | 2 | 2 |
| Tic disorders | 1 | 1 | | | 1 | 1 |
| | 18 | 26 | 8 | 15 | 10 | 11 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 1 | 1 | | | 1 | 1 |
| Renal failure and impairment | 6 | 6 | | | 6 | 6 |
| Urinary abnormalities | 1 | 1 | 1 | 1 | | |
| | 8 | 8 | 1 | 1 | 7 | 7 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast signs and symptoms | 1 | 1 | | | 1 | 1 |
| Reproductive tract disorders NEC (excl neoplasms) | 1 | 1 | | | 1 | 1 |
| Reproductive tract signs and symptoms NEC | | 1 | | 1 | | |
| Uterine disorders NEC | 2 | 2 | | | 2 | 2 |
| Vulvovaginal disorders NEC | | 1 | | 1 | | |
| | 4 | 6 | | 2 | 4 | 4 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 54 | 64 | 2 | 2 | 52 | 62 |
| Bronchospasm and obstruction | 20 | 20 | | | 20 | 20 |
| Conditions associated with abnormal gas exchange | 13 | 14 | | | 13 | 14 |
| Coughing and associated symptoms | 18 | 20 | 4 | 6 | 14 | 14 |
| Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 |
| Laryngeal spasm, oedema and obstruction | 6 | 8 | | | 6 | 8 |
| Lower respiratory tract signs and symptoms | 2 | 2 | | | 2 | 2 |
| Nasal congestion and inflammations | 5 | 7 | 1 | 3 | 4 | 4 |
| Parenchymal lung disorders NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Pharyngeal disorders (excl infections and neoplasms) | 6 | 6 | | | 6 | 6 |
| Pneumothorax and pleural effusions NEC | | 1 | | | | 1 |
| Pulmonary thrombotic and embolic conditions | 3 | 3 | | | 3 | 3 |
| Respiratory failures (excl neonatal) | 5 | 9 | | | 5 | 9 |
| Respiratory signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Respiratory tract disorders NEC | 1 | 2 | | | 1 | 2 |
| Upper respiratory tract signs and symptoms | 26 | 34 | 3 | 10 | 23 | 24 |
| | 165 | 196 | 12 | 23 | 153 | 173 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 20 | 23 | | 1 | 20 | 22 |
| Apocrine and eccrine gland disorders | 11 | 12 | 2 | 3 | 9 | 9 |
| Bullous conditions | 3 | 3 | | | 3 | 3 |
| Dermal and epidermal conditions NEC | 6 | 7 | | 1 | 6 | 6 |
| Dermatitis and eczema | 2 | 2 | | | 2 | 2 |
| Erythemas | 26 | 29 | 1 | 4 | 25 | 25 |
| Exfoliative conditions | 1 | 1 | | | 1 | 1 |
| Panniculitides | 2 | 2 | | | 2 | 2 |
| Papulosquamous conditions | 1 | 1 | | | 1 | 1 |
| Pruritus NEC | 37 | 43 | 1 | 5 | 36 | 38 |
| Psoriatic conditions | 1 | 1 | | | 1 | 1 |
| Purpura and related conditions | 4 | 5 | 1 | 2 | 3 | 3 |
| Rashes, eruptions and exanthems NEC | 31 | 39 | 2 | 9 | 29 | 30 |
| Skin and subcutaneous tissue ulcerations | 1 | 1 | | | 1 | 1 |
| Skin vasomotor conditions | 1 | 1 | | | 1 | 1 |
| Urticarias | 22 | 24 | 2 | 3 | 20 | 21 |
| | 169 | 194 | 9 | 28 | 160 | 166 |

System Organ Class

Surgical and medical procedures

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Limb therapeutic procedures | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 13 | 13 | | | 13 | 13 |
| Aortic aneurysms and dissections | 1 | 1 | | | 1 | 1 |
| Circulatory collapse and shock | 2 | 2 | | | 2 | 2 |
| Haemorrhages NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Peripheral embolism and thrombosis | 4 | 4 | 1 | 1 | 3 | 3 |
| Peripheral vascular disorders NEC | 5 | 5 | 1 | 1 | 4 | 4 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 3 | 4 | | | 3 | 4 |
| Phlebitis NEC | 1 | 1 | 1 | 1 | | |
| Site specific vascular disorders NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Vascular hypertensive disorders NEC | 22 | 22 | 6 | 6 | 16 | 16 |
| Vascular hypotensive disorders | 9 | 14 | 2 | 4 | 7 | 10 |
| Vasculitides NEC | 1 | 1 | | | 1 | 1 |
| | 70 | 76 | 13 | 15 | 57 | 61 |

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Country Where Event Occurred

SWEDEN

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Leukocytoses NEC | 1 | 1 | | | 1 | 1 |
| Lymphatic system disorders NEC | 10 | 11 | 9 | 9 | 1 | 2 |
| Marrow depression and hypoplastic anaemias | 1 | 1 | | | 1 | 1 |
| | 12 | 13 | 9 | 9 | 3 | 4 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 3 | 3 | | | 3 | 3 |
| Cardiac disorders NEC | | 1 | | | | 1 |
| Cardiac signs and symptoms NEC | 8 | 11 | 1 | 4 | 7 | 7 |
| Coronary artery disorders NEC | | 1 | | | | 1 |
| Heart failures NEC | 8 | 10 | | | 8 | 10 |
| Ischaemic coronary artery disorders | 5 | 8 | | | 5 | 8 |
| Left ventricular failures | 1 | 1 | | | 1 | 1 |
| Myocardial disorders NEC | | 1 | | | | 1 |
| Noninfectious myocarditis | 1 | 1 | | | 1 | 1 |
| Pericardial disorders NEC | | 1 | | | | 1 |
| Rate and rhythm disorders NEC | 6 | 7 | 2 | 2 | 4 | 5 |
| Supraventricular arrhythmias | 4 | 4 | | | 4 | 4 |
| Ventricular arrhythmias and cardiac arrest | 4 | 8 | | | 4 | 8 |
| | 40 | 57 | 3 | 6 | 37 | 51 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 2 | 2 | | | 2 | 2 |
| Inner ear signs and symptoms | 2 | 3 | 1 | 2 | 1 | 1 |
| | 4 | 5 | 1 | 2 | 3 | 3 |

System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Thyroid disorders NEC | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lacrimation disorders | 1 | 1 | | | 1 | 1 |
| Ocular disorders NEC | 9 | 9 | 2 | 2 | 7 | 7 |
| Ocular infections, inflammations and associated manifestations | 2 | 2 | | | 2 | 2 |
| Visual disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Visual impairment and blindness (excl colour blindness) | 4 | 4 | 1 | 1 | 3 | 3 |
| | 18 | 18 | 4 | 4 | 14 | 14 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 18 | 23 | 11 | 15 | 7 | 8 |
| Dyspeptic signs and symptoms | | 1 | | 1 | | |
| Flatulence, bloating and distension | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 8 | 11 | 6 | 9 | 2 | 2 |
| Gastrointestinal atonic and hypomotility disorders NEC | 2 | 2 | 2 | 2 | | |
| Gastrointestinal signs and symptoms NEC | 7 | 8 | 2 | 3 | 5 | 5 |
| Gastrointestinal vascular occlusion and infarction | | 1 | | | | 1 |
| Intestinal haemorrhages | | 1 | | | | 1 |
| Nausea and vomiting symptoms | 66 | 76 | 29 | 38 | 37 | 38 |
| Non-site specific gastrointestinal haemorrhages | 2 | 2 | | | 2 | 2 |
| Oral dryness and saliva altered | 1 | 1 | | | 1 | 1 |
| Oral soft tissue signs and symptoms | 22 | 25 | 8 | 10 | 14 | 15 |
| Oral soft tissue swelling and oedema | 6 | 7 | 1 | 1 | 5 | 6 |
| Peritoneal and retroperitoneal disorders | | 1 | | | | 1 |
| Tongue signs and symptoms | 12 | 13 | 2 | 2 | 10 | 11 |
| | 146 | 174 | 62 | 82 | 84 | 92 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 126 | 139 | 72 | 82 | 54 | 57 |
| Body temperature altered | 1 | 1 | | | 1 | 1 |
| Death and sudden death | 21 | 29 | | | 21 | 29 |
| Febrile disorders | 109 | 125 | 70 | 81 | 39 | 44 |
| Feelings and sensations NEC | 65 | 78 | 37 | 48 | 28 | 30 |
| Gait disturbances | 2 | 2 | | | 2 | 2 |
| General signs and symptoms NEC | 39 | 49 | 11 | 16 | 28 | 33 |
| Inflammations | | 1 | | | | 1 |
| Injection site reactions | 1 | 2 | 1 | 2 | | |
| Mass conditions NEC | 1 | 1 | 1 | 1 | | |
| Oedema NEC | 1 | 1 | | | 1 | 1 |
| Pain and discomfort NEC | 47 | 52 | 24 | 27 | 23 | 25 |
| Therapeutic and nontherapeutic responses | 7 | 8 | | | 7 | 8 |
| Vaccination site reactions | 147 | 168 | 117 | 134 | 30 | 34 |
| | 567 | 656 | 333 | 391 | 234 | 265 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 27 | 28 | 4 | 4 | 23 | 24 |
| Allergies to foods, food additives, drugs and other chemicals | 2 | 2 | | | 2 | 2 |
| Anaphylactic and anaphylactoid responses | 12 | 14 | | | 12 | 14 |
| Immune and associated conditions NEC | 1 | 1 | | | 1 | 1 |
| | 42 | 45 | 4 | 4 | 38 | 41 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal infections | 1 | 1 | | | 1 | 1 |
| Bacterial infections NEC | | 1 | | | | 1 |
| Central nervous system and spinal infections | 1 | 1 | | | 1 | 1 |
| Coronavirus infections | 25 | 26 | 18 | 18 | 7 | 8 |
| Escherichia infections | 1 | 2 | | | 1 | 2 |
| Herpes viral infections | 8 | 8 | 3 | 3 | 5 | 5 |
| Infections NEC | 4 | 7 | | | 4 | 7 |
| Lower respiratory tract and lung infections | 4 | 6 | | | 4 | 6 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 6 | 9 | | | 6 | 9 |
| Staphylococcal infections | 1 | 1 | | | 1 | 1 |
| Streptococcal infections | 4 | 5 | | | 4 | 5 |
| Upper respiratory tract infections | 5 | 7 | 1 | 2 | 4 | 5 |
| Urinary tract infections | 1 | 2 | | | 1 | 2 |
| Viral infections NEC | | 1 | | 1 | | |
| | 61 | 77 | 22 | 24 | 39 | 53 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Medication errors, product use errors and issues NEC | 1 | 30 | 1 | 30 | | |
| Non-site specific injuries NEC | 2 | 2 | | | 2 | 2 |
| Non-site specific procedural complications | 1 | 1 | | | 1 | 1 |
| Off label uses | 1 | 1 | 1 | 1 | | |
| Overdoses NEC | 1 | 1 | 1 | 1 | | |
| Product administration errors and issues | 6 | 42 | 6 | 42 | | |
| Product preparation errors and issues | 4 | 4 | 4 | 4 | | |
| Site specific injuries NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Underdoses NEC | 3 | 5 | 3 | 5 | | |
| | 22 | 89 | 17 | 84 | 5 | 5 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 9 | 13 | 1 | 3 | 8 | 10 |
| Carbohydrate tolerance analyses (incl diabetes) | 2 | 2 | | | 2 | 2 |
| Heart rate and pulse investigations | 13 | 15 | 9 | 9 | 4 | 6 |
| Physical examination procedures and organ system status | 10 | 11 | 2 | 2 | 8 | 9 |
| Protein analyses NEC | 2 | 3 | 2 | 2 | | 1 |
| Red blood cell analyses | 1 | 1 | | | 1 | 1 |
| Urinalysis NEC | 1 | 1 | 1 | 1 | | |
| Urinary tract function analyses NEC | 1 | 1 | | | 1 | 1 |
| Vascular tests NEC (incl blood pressure) | 11 | 14 | 4 | 5 | 7 | 9 |
| White blood cell analyses | 1 | 1 | 1 | 1 | | |
| | 51 | 62 | 20 | 23 | 31 | 39 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 11 | 11 | 4 | 4 | 7 | 7 |
| Fluid intake decreased | 1 | 1 | | | 1 | 1 |
| General nutritional disorders NEC | 1 | 1 | | | 1 | 1 |
| Hyperglycaemic conditions NEC | 1 | 1 | | | 1 | 1 |
| Hypoglycaemic conditions NEC | 2 | 2 | | | 2 | 2 |
| Metabolic acidoses (excl diabetic acidoses) | 1 | 1 | | | 1 | 1 |
| Potassium imbalance | 1 | 1 | | | 1 | 1 |
| Sodium imbalance | 1 | 1 | | | 1 | 1 |
| Total fluid volume decreased | 2 | 3 | | | 2 | 3 |
| Total fluid volume increased | 1 | 1 | | | 1 | 1 |
| | 22 | 23 | 4 | 4 | 18 | 19 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 1 | 1 | | | 1 | 1 |
| Bone disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Bone related signs and symptoms | 1 | 1 | | | 1 | 1 |
| Joint related signs and symptoms | 21 | 26 | 16 | 20 | 5 | 6 |
| Muscle pains | 39 | 50 | 25 | 33 | 14 | 17 |
| Muscle related signs and symptoms NEC | 5 | 5 | | | 5 | 5 |
| Muscle weakness conditions | 4 | 5 | 2 | 3 | 2 | 2 |
| Musculoskeletal and connective tissue conditions NEC | 6 | 6 | 4 | 4 | 2 | 2 |
| Musculoskeletal and connective tissue pain and discomfort | 52 | 64 | 40 | 52 | 12 | 12 |
| | 131 | 160 | 88 | 113 | 43 | 47 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Neoplasms unspecified malignancy and site unspecified NEC | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal reflexes | 1 | 1 | | | 1 | 1 |
| Abnormal sleep-related events | 1 | 1 | | | 1 | 1 |
| Acute polyneuropathies | 1 | 1 | | | 1 | 1 |
| Autonomic nervous system disorders | 1 | 1 | | | 1 | 1 |
| Central nervous system haemorrhages and cerebrovascular accidents | 6 | 9 | | | 6 | 9 |
| Coordination and balance disturbances | 2 | 3 | | | 2 | 3 |
| Dementia (excl Alzheimer's type) | 2 | 2 | | | 2 | 2 |
| Disturbances in consciousness NEC | 29 | 31 | 1 | 1 | 28 | 30 |
| Dyskinesias and movement disorders NEC | 2 | 2 | | | 2 | 2 |
| Encephalopathies NEC | 1 | 1 | | | 1 | 1 |
| Facial cranial nerve disorders | 13 | 15 | | | 13 | 15 |
| Headaches NEC | 90 | 104 | 69 | 82 | 21 | 22 |
| Memory loss (excl dementia) | 3 | 4 | 1 | 1 | 2 | 3 |
| Mental impairment (excl dementia and memory loss) | 3 | 3 | 2 | 2 | 1 | 1 |
| Migraine headaches | 1 | 3 | 1 | 3 | | |
| Muscle tone abnormal | 1 | 1 | | | 1 | 1 |
| Narcolepsy and hypersomnia | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 39 | 43 | 17 | 20 | 22 | 23 |
| Neurologic visual problems NEC | 2 | 2 | | | 2 | 2 |
| Neuromuscular disorders NEC | 1 | 1 | | | 1 | 1 |
| Olfactory nerve disorders | 4 | 4 | 2 | 2 | 2 | 2 |
| Paraesthesias and dysaesthesias | 41 | 47 | 15 | 19 | 26 | 28 |
| Paralysis and paresis (excl cranial nerve) | 6 | 6 | | | 6 | 6 |
| Seizures and seizure disorders NEC | 7 | 7 | | | 7 | 7 |
| Sensory abnormalities NEC | 14 | 14 | 6 | 6 | 8 | 8 |
| Speech and language abnormalities | 4 | 4 | | | 4 | 4 |
| Transient cerebrovascular events | 3 | 3 | | | 3 | 3 |
| Tremor (excl congenital) | 6 | 6 | 1 | 1 | 5 | 5 |
| Trigeminal disorders | 1 | 1 | | | 1 | 1 |
| | 286 | 321 | 115 | 137 | 171 | 184 |

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System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| Product physical issues | | 36 | | 36 |
| | | 36 | | 36 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal behaviour NEC | 1 | 2 | | 1 | 1 | 1 |
| Anxiety symptoms | 12 | 13 | 6 | 6 | 6 | 7 |
| Behaviour and socialisation disturbances | 1 | 1 | | | 1 | 1 |
| Cognitive and attention disorders and disturbances NEC | 1 | 1 | | | 1 | 1 |
| Confusion and disorientation | 9 | 10 | | | 9 | 10 |
| Delusional disorders | 1 | 1 | | | 1 | 1 |
| Dissociative states | 1 | 1 | | | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 2 | 4 | 2 | 4 | | |
| Hallucinations (excl sleep-related) | 3 | 4 | | | 3 | 4 |
| Learning disorders | 1 | 1 | | | 1 | 1 |
| Mood alterations with depressive symptoms | 1 | 1 | | | 1 | 1 |
| Panic attacks and disorders | 1 | 1 | | | 1 | 1 |
| Parasomnias | 1 | 2 | | | 1 | 2 |
| Sleep disorders NEC | 1 | 1 | | | 1 | 1 |
| Speech and language usage disturbances | 1 | 1 | | | 1 | 1 |
| | 37 | 44 | 8 | 11 | 29 | 33 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 3 | 3 | 1 | 1 | 2 | 2 |
| Renal failure and impairment | | 2 | | | | 2 |
| Urinary tract signs and symptoms NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| | 5 | 7 | 2 | 2 | 3 | 5 |

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Vulvovaginal disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 52 | 63 | 7 | 8 | 45 | 55 |
| Bronchospasm and obstruction | 12 | 14 | | 1 | 12 | 13 |
| Coughing and associated symptoms | 16 | 21 | 8 | 9 | 8 | 12 |
| Lower respiratory tract inflammatory and immunologic conditions | 1 | 1 | | | 1 | 1 |
| Lower respiratory tract signs and symptoms | 1 | 1 | | | 1 | 1 |
| Nasal congestion and inflammations | 6 | 6 | 1 | 1 | 5 | 5 |
| Nasal disorders NEC | 1 | 2 | 1 | 2 | | |
| Paranasal sinus disorders (excl infections and neoplasms) | 2 | 2 | 2 | 2 | | |
| Parenchymal lung disorders NEC | 1 | 1 | | | 1 | 1 |
| Pharyngeal disorders (excl infections and neoplasms) | 12 | 14 | 1 | 2 | 11 | 12 |
| Pleural infections and inflammations | 1 | 1 | | | 1 | 1 |
| Pneumothorax and pleural effusions NEC | 2 | 2 | | | 2 | 2 |
| Pulmonary oedemas | 4 | 7 | | | 4 | 7 |
| Pulmonary thrombotic and embolic conditions | 4 | 4 | | | 4 | 4 |
| Respiratory failures (excl neonatal) | 1 | 2 | | | 1 | 2 |
| Respiratory signs and symptoms NEC | 1 | 1 | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 43 | 49 | 35 | 38 | 8 | 11 |
| | 160 | 191 | 56 | 64 | 104 | 127 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acnes | 1 | 1 | 1 | 1 | | |
| Angioedemas | 4 | 4 | | | 4 | 4 |
| Apocrine and eccrine gland disorders | 10 | 10 | 8 | 8 | 2 | 2 |
| Bullous conditions | 3 | 3 | 1 | 1 | 2 | 2 |
| Dermal and epidermal conditions NEC | 5 | 5 | 3 | 3 | 2 | 2 |
| Dermatitis and eczema | 2 | 3 | 1 | 2 | 1 | 1 |
| Dermatitis ascribed to specific agent | 1 | 1 | 1 | 1 | | |
| Erythemas | 20 | 21 | 12 | 13 | 8 | 8 |
| Nail and nail bed conditions (excl infections and infestations) | 1 | 1 | | | 1 | 1 |
| Pruritus NEC | 13 | 14 | 6 | 6 | 7 | 8 |
| Psoriatic conditions | 1 | 1 | 1 | 1 | | |
| Purpura and related conditions | 1 | 1 | | | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 21 | 21 | 10 | 10 | 11 | 11 |
| Skin and subcutaneous tissue ulcerations | 1 | 2 | | | 1 | 2 |
| Skin injuries and mechanical dermatoses | | 1 | | 1 | | |
| Urticarias | 18 | 19 | 9 | 10 | 9 | 9 |
| | 102 | 108 | 53 | 57 | 49 | 51 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood pressure disorders NEC | | 1 | | | | 1 |
| Circulatory collapse and shock | 2 | 4 | | | 2 | 4 |
| Haemorrhages NEC | 2 | 2 | | | 2 | 2 |
| Non-site specific embolism and thrombosis | 1 | 1 | | | 1 | 1 |
| Non-site specific necrosis and vascular insufficiency NEC | | 1 | | | | 1 |
| Peripheral embolism and thrombosis | 3 | 3 | | | 3 | 3 |
| Peripheral vascular disorders NEC | 4 | 4 | 1 | 1 | 3 | 3 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 2 | 3 | | 1 | 2 | 2 |
| Site specific vascular disorders NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Vascular hypertensive disorders NEC | 4 | 5 | 3 | 3 | 1 | 2 |
| Vascular hypotensive disorders | 8 | 10 | 2 | 2 | 6 | 8 |
| | 29 | 37 | 7 | 8 | 22 | 29 |

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Country Where Event Occurred

SWITZERLAND

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Lymphatic system disorders NEC | 1 | 1 | 1 | 1 | | |
| Thrombocytopenias | 1 | 1 | | | 1 | 1 |
| | 2 | 2 | 1 | 1 | 1 | 1 |

System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronary artery disorders NEC | | 1 | | | | 1 |
| Heart failures NEC | 1 | 1 | | | 1 | 1 |
| Ischaemic coronary artery disorders | 1 | 2 | | | 1 | 2 |
| Rate and rhythm disorders NEC | 1 | 2 | 1 | 1 | | 1 |
| | 3 | 6 | 1 | 1 | 2 | 5 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Visual impairment and blindness (excl colour blindness) | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | 2 | 2 | 1 | 1 | 1 | 1 |
| Gastrointestinal and abdominal pains (excl oral and throat) | | 2 | | 1 | | 1 |
| Gastrointestinal disorders NEC | | 1 | | | | 1 |
| Intestinal haemorrhages | | 1 | | 1 | | |
| Nausea and vomiting symptoms | 6 | 8 | | 1 | 6 | 7 |
| Tongue signs and symptoms | | 1 | | | | 1 |
| | 8 | 15 | 1 | 4 | 7 | 11 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 6 | 11 | 2 | 6 | 4 | 5 |
| Body temperature altered | 1 | 1 | 1 | 1 | | |
| Death and sudden death | 1 | 3 | | | 1 | 3 |
| Febrile disorders | 5 | 6 | 1 | 1 | 4 | 5 |
| Feelings and sensations NEC | 4 | 6 | 2 | 4 | 2 | 2 |
| Gait disturbances | 2 | 2 | | | 2 | 2 |
| General signs and symptoms NEC | 3 | 4 | 1 | 1 | 2 | 3 |
| Interactions | 1 | 1 | 1 | 1 | | |
| Pain and discomfort NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Therapeutic and nontherapeutic responses | 3 | 3 | | | 3 | 3 |
| Trophic disorders | | 1 | | | | 1 |
| Vaccination site reactions | 10 | 13 | 4 | 7 | 6 | 6 |
| | 38 | 53 | 13 | 22 | 25 | 31 |

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System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hepatic fibrosis and cirrhosis | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 2 | 3 | 1 | 1 | 1 | 2 |
| Anaphylactic and anaphylactoid responses | 4 | 5 | | | 4 | 5 |
| | 6 | 8 | 1 | 1 | 5 | 7 |

System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Central nervous system and spinal infections | 1 | 1 | 1 | 1 |
| Coronavirus infections | 2 | 2 | 2 | 2 |
| Infections NEC | 1 | 1 | 1 | 1 |
| Lower respiratory tract and lung infections | | 1 | | 1 |
| | 4 | 5 | 4 | 5 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Non-site specific injuries NEC | | 1 | | | | 1 |
| Product administration errors and issues | 1 | 1 | 1 | 1 | | |
| Underdoses NEC | 1 | 1 | 1 | 1 | | |
| | 2 | 3 | 2 | 2 | | 1 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Blood gas and acid base analyses | 1 | 2 | | | 1 | 2 |
| Carbohydrate tolerance analyses (incl diabetes) | 1 | 1 | 1 | 1 | | |
| Heart rate and pulse investigations | | 1 | | | | 1 |
| Platelet analyses | 1 | 1 | 1 | 1 | | |
| Protein analyses NEC | | 1 | | | | 1 |
| Vascular tests NEC (incl blood pressure) | 2 | 3 | 2 | 2 | | 1 |
| Virus identification and serology | 2 | 2 | | | 2 | 2 |
| | 7 | 11 | 4 | 4 | 3 | 7 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Joint related signs and symptoms | 1 | 1 | | | 1 | 1 |
| Muscle pains | 2 | 3 | | | 2 | 3 |
| Muscle related signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | | 2 | | 2 | | |
| | 4 | 7 | | 2 | 4 | 5 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Central nervous system haemorrhages and cerebrovascular accidents | 1 | 2 | | | 1 | 2 |
| Coma states | 1 | 2 | | | 1 | 2 |
| Cortical dysfunction NEC | 2 | 3 | | | 2 | 3 |
| Dementia (excl Alzheimer's type) | 1 | 1 | | | 1 | 1 |
| Disturbances in consciousness NEC | 2 | 4 | | | 2 | 4 |
| Encephalopathies NEC | 1 | 1 | | | 1 | 1 |
| Headaches NEC | 4 | 4 | 2 | 2 | 2 | 2 |
| Mental impairment (excl dementia and memory loss) | 1 | 1 | | | 1 | 1 |
| Nervous system disorders NEC | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 5 | 6 | 1 | 2 | 4 | 4 |
| Paraesthesias and dysaesthesias | 2 | 2 | 1 | 1 | 1 | 1 |
| Paralysis and paresis (excl cranial nerve) | | 1 | | | | 1 |
| Sensory abnormalities NEC | | 1 | | 1 | | |
| | 21 | 29 | 4 | 6 | 17 | 23 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anxiety symptoms | 1 | 1 | | | 1 | 1 |
| Confusion and disorientation | 1 | 1 | | | 1 | 1 |
| Disturbances in initiating and maintaining sleep | 1 | 1 | 1 | 1 | | |
| Sleep disorders NEC | 1 | 1 | 1 | 1 | | |
| | 4 | 4 | 2 | 2 | 2 | 2 |

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System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Bladder and urethral symptoms | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 4 | 5 | 1 | 1 | 3 | 4 |
| Bronchospasm and obstruction | 2 | 3 | | | 2 | 3 |
| Nasal disorders NEC | 1 | 1 | 1 | 1 | | |
| Pulmonary oedemas | 1 | 1 | | | 1 | 1 |
| Respiratory failures (excl neonatal) | | 1 | | | | 1 |
| | 8 | 11 | 2 | 2 | 6 | 9 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Angioedemas | 2 | 2 | | | 2 | 2 |
| Erythemas | 3 | 3 | 1 | 1 | 2 | 2 |
| Pruritus NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| Urticarias | 2 | 3 | 1 | 1 | 1 | 2 |
| | 10 | 11 | 4 | 4 | 6 | 7 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 1 | 1 | | | 1 | 1 |
| Non-site specific embolism and thrombosis | | 1 | | | | 1 |
| Non-site specific necrosis and vascular insufficiency NEC | | 1 | | | | 1 |
| Peripheral vascular disorders NEC | 1 | 1 | | | 1 | 1 |
| Vascular hypertensive disorders NEC | 1 | 1 | 1 | 1 | | |
| | 3 | 5 | 1 | 1 | 2 | 4 |

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Country Where Event Occurred
TURKS AND CAICOS ISLANDS

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Asthenic conditions | 1 | 1 | 1 | 1 |
| Mass conditions NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Muscle pains | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Seizures and seizure disorders NEC | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |

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Country Where Event Occurred

UNITED ARAB EMIRATES

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Lymphatic system disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Hearing losses | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Visual disorders NEC | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Diarrhoea (excl infective) | | 1 | | 1 | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | 2 | 2 | 2 | 2 | | |
| Intestinal haemorrhages | 1 | 1 | | | 1 | 1 |
| Nausea and vomiting symptoms | 5 | 6 | 5 | 5 | | 1 |
| | 8 | 10 | 7 | 8 | 1 | 2 |

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Asthenic conditions | 1 | 2 | 1 | 2 | | |
| Febrile disorders | 3 | 5 | 3 | 5 | | |
| Feelings and sensations NEC | 2 | 2 | 2 | 2 | | |
| Gait disturbances | 1 | 1 | 1 | 1 | | |
| General signs and symptoms NEC | 1 | 1 | | | 1 | 1 |
| Injection site reactions | 1 | 1 | 1 | 1 | | |
| Pain and discomfort NEC | 2 | 3 | 2 | 2 | | 1 |
| Therapeutic and nontherapeutic responses | 4 | 6 | | | 4 | 6 |
| Vaccination site reactions | 1 | 3 | 1 | 3 | | |
| | 16 | 24 | 11 | 16 | 5 | 8 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coronavirus infections | 4 | 6 | | | 4 | 6 |
| Upper respiratory tract infections | 1 | 1 | 1 | 1 | | |
| | 5 | 7 | 1 | 1 | 4 | 6 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Medication errors, product use errors and issues NEC | | 1 | | 1 |
| Off label uses | | 1 | | 1 |
| | | 2 | | 2 |

System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Vascular tests NEC (incl blood pressure) | 1 | 1 | 1 | 1 |
| | 1 | 1 | 1 | 1 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Joint related signs and symptoms | 1 | 2 | 1 | 2 |
| Musculoskeletal and connective tissue pain and discomfort | 1 | 1 | 1 | 1 |
| | 2 | 3 | 2 | 3 |

System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disturbances in consciousness NEC | 1 | 2 | 1 | 1 | | 1 |
| Facial cranial nerve disorders | | 1 | | | | 1 |
| Headaches NEC | 2 | 4 | 2 | 3 | | 1 |
| Lumbar spinal cord and nerve root disorders | 1 | 1 | 1 | 1 | | |
| Nervous system disorders NEC | 1 | 1 | | | 1 | 1 |
| Neurological signs and symptoms NEC | 2 | 3 | 2 | 2 | | 1 |
| Paraesthesias and dysaesthesias | | 1 | | | | 1 |
| | 7 | 13 | 6 | 7 | 1 | 6 |

System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Mood alterations with depressive symptoms | | 1 | | 1 |
| | | 1 | | 1 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Erection and ejaculation conditions and disorders | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Dermatitis and eczema | 1 | 1 | 1 | 1 |
| Pruritus NEC | 1 | 1 | 1 | 1 |
| Rashes, eruptions and exanthems NEC | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Vascular hypertensive disorders NEC | | 2 | | 1 | | 1 |
| | | 2 | | 1 | | 1 |

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Country Where Event Occurred

UNITED KINGDOM

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Anaemias haemolytic immune | 1 | 1 | | | | | 1 | 1 |
| Anaemias NEC | 4 | 4 | | | 2 | 2 | 2 | 2 |
| Bleeding tendencies | 3 | 3 | | | 1 | 1 | 2 | 2 |
| Eosinophilic disorders | | 1 | | | | 1 | | |
| Haematological disorders | 1 | 2 | | | | | 1 | 2 |
| Leukocytoses NEC | 1 | 1 | | | 1 | 1 | | |
| Leukopenias NEC | 1 | 1 | | | 1 | 1 | | |
| Lymphatic system disorders NEC | 508 | 923 | 2 | 2 | 73 | 275 | 435 | 648 |
| Marrow depression and hypoplastic anaemias | 1 | 2 | | | | | 1 | 2 |
| Neutropenias | 6 | 6 | | | | | 6 | 6 |
| Platelet disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Red blood cell abnormal findings NEC | 1 | 1 | | | | | 1 | 1 |
| Spleen disorders | 1 | 1 | | | | | 1 | 1 |
| Thrombocytopenias | 10 | 15 | | | | | 10 | 15 |
| Thrombocytoses | | 1 | | | | | | 1 |
| | 539 | 963 | 2 | 2 | 78 | 281 | 461 | 682 |

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System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Cardiac conduction disorders | 2 | 3 | | | | 1 | 2 | 2 |
| Cardiac disorders NEC | 2 | 4 | | | | | 2 | 4 |
| Cardiac signs and symptoms NEC | 156 | 249 | | | 13 | 44 | 143 | 205 |
| Coronary artery disorders NEC | 2 | 5 | | | | | 2 | 5 |
| Heart failures NEC | 5 | 9 | | | | | 5 | 9 |
| Ischaemic coronary artery disorders | 28 | 52 | | | | | 28 | 52 |
| Left ventricular failures | 1 | 1 | | | | | 1 | 1 |
| Myocardial disorders NEC | 1 | 3 | | | | 1 | 1 | 2 |
| Noninfectious myocarditis | 1 | 5 | | | | | 1 | 5 |
| Noninfectious pericarditis | 4 | 6 | | | | | 4 | 6 |
| Rate and rhythm disorders NEC | 132 | 265 | 1 | 1 | 10 | 48 | 122 | 217 |
| Right ventricular failures | 1 | 1 | | | | | 1 | 1 |
| Supraventricular arrhythmias | 43 | 79 | | | 2 | 8 | 41 | 71 |
| Ventricular arrhythmias and cardiac arrest | 23 | 52 | | | 1 | 2 | 22 | 50 |
| | 401 | 734 | 1 | 1 | 26 | 104 | 375 | 630 |

System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Musculoskeletal disorders congenital NEC | 1 | 1 | 1 | 1 |
| Neurological disorders congenital NEC | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Ear disorders NEC | 74 | 124 | | | 8 | 34 | 66 | 90 |
| Eustachian tube disorders | 1 | 1 | | | | | 1 | 1 |
| External ear disorders NEC | 4 | 5 | | | 1 | 1 | 3 | 4 |
| Hearing disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Hearing losses | 26 | 34 | | | 2 | 4 | 24 | 30 |
| Hyperacusia | 7 | 10 | | | 2 | 3 | 5 | 7 |
| Inner ear disorders NEC | 6 | 6 | | | | | 6 | 6 |
| Inner ear signs and symptoms | 161 | 245 | 1 | 1 | 12 | 40 | 149 | 205 |
| Middle ear infections and inflammations | | 1 | | | | | | 1 |
| | 280 | 427 | 1 | 1 | 25 | 82 | 255 | 345 |

System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Serious | |
| | | | I | C |
| Adrenal cortical hypofunctions | 1 | 1 | 1 | 1 |
| Female gonadal function disorders | 1 | 1 | 1 | 1 |
| Thyroid disorders NEC | 1 | 1 | 1 | 1 |
| Thyroid hypofunction disorders | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|---|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Amblyopic vision impairment | | 1 | | | | 1 | | | |
| Choroid and vitreous haemorrhages and vascular disorders | 2 | 2 | | | | | 2 | 2 | |
| Choroid and vitreous structural change, deposit and degeneration | 4 | 6 | | | 1 | 3 | 3 | 3 | |
| Conjunctival and corneal bleeding and vascular disorders | 5 | 9 | | | | | 5 | 9 | |
| Corneal infections, oedemas and inflammations | 2 | 2 | | | | | 2 | 2 | |
| Eyelid movement disorders | 6 | 10 | | | 1 | 2 | 5 | 8 | |
| Glaucomas (excl congenital) | 1 | 1 | | | | | 1 | 1 | |
| Iris and uveal tract infections, irritations and inflammations | 10 | 12 | | | 1 | 1 | 9 | 11 | |
| Lacrimation disorders | 25 | 45 | | | 3 | 10 | 22 | 35 | |
| Lid, lash and lacrimal infections, irritations and inflammations | 18 | 30 | | | 1 | 6 | 17 | 24 | |
| Lid, lash and lacrimal structural disorders | | 1 | | | | | | | 1 |
| Ocular bleeding and vascular disorders NEC | 4 | 5 | | | | 1 | 4 | 4 | |
| Ocular disorders NEC | 177 | 277 | 2 | 2 | 24 | 57 | 153 | 220 | |
| Ocular infections, inflammations and associated manifestations | 47 | 86 | 2 | 2 | 6 | 15 | 41 | 71 | |
| Ocular nerve and muscle disorders | 4 | 7 | | | | | 4 | 7 | |
| Ocular sensation disorders | 59 | 100 | | | 6 | 19 | 53 | 81 | |
| Optic disc abnormalities NEC | 1 | 1 | | | | | 1 | 1 | |
| Pupil disorders | 3 | 7 | | | | | 3 | 7 | |
| Retinal bleeding and vascular disorders (excl retinopathy) | 4 | 4 | | | | | 4 | 4 | |
| Retinal structural change, deposit and degeneration | 1 | 3 | | | | | 1 | 3 | |
| Scleral infections, irritations and inflammations | 1 | 3 | | | | 1 | 1 | 2 | |
| Scleral structural change, deposit and degeneration | 1 | 1 | | | 1 | 1 | | | |
| Visual disorders NEC | 88 | 159 | | | 10 | 43 | 78 | 116 | |
| Visual impairment and blindness (excl colour blindness) | 41 | 63 | | | 6 | 10 | 35 | 53 | |
| Visual pathway disorders | 2 | 2 | | | | | 2 | 2 | |

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System Organ Class

Eye disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| 4 | 4 | 60 | 170 | 446 | 667 |

506

837

4

4

60

170

446

667

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal findings abnormal | 3 | 3 | | | | | 3 | 3 |
| Acute and chronic pancreatitis | 2 | 2 | | | | | 2 | 2 |
| Anal and rectal disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Anal and rectal pains | 1 | 1 | | | 1 | 1 | | |
| Anal and rectal signs and symptoms | 1 | 1 | | | 1 | 1 | | |
| Benign oral cavity neoplasms | | 1 | | | | 1 | | |
| Colitis (excl infective) | 11 | 12 | | | | | 11 | 12 |
| Dental pain and sensation disorders | 7 | 13 | | | 2 | 5 | 5 | 8 |
| Diarrhoea (excl infective) | 507 | 767 | | | 47 | 142 | 460 | 625 |
| Duodenal and small intestinal stenosis and obstruction | | 1 | | | | | | 1 |
| Dyspeptic signs and symptoms | 30 | 43 | | | 2 | 7 | 28 | 36 |
| Faecal abnormalities NEC | 9 | 15 | | | 5 | 9 | 4 | 6 |
| Flatulence, bloating and distension | 38 | 50 | | | 7 | 12 | 31 | 38 |
| Gastric and oesophageal haemorrhages | 4 | 4 | | | | | 4 | 4 |
| Gastritis (excl infective) | 5 | 8 | | | | 1 | 5 | 7 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 327 | 487 | | | 37 | 104 | 290 | 383 |
| Gastrointestinal atonic and hypomotility disorders NEC | 30 | 40 | | | 2 | 5 | 28 | 35 |
| Gastrointestinal disorders NEC | 9 | 12 | | | 3 | 5 | 6 | 7 |
| Gastrointestinal dyskinetic disorders | 2 | 3 | | | | 1 | 2 | 2 |
| Gastrointestinal inflammatory disorders NEC | | 1 | | | | 1 | | |
| Gastrointestinal mucosal dystrophies and secretion disorders | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Gastrointestinal signs and symptoms NEC | 105 | 150 | 3 | 3 | 14 | 29 | 91 | 121 |
| Gastrointestinal spastic and hypermotility disorders | 13 | 26 | | | | 5 | 13 | 21 |
| Gastrointestinal stenosis and obstruction NEC | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal vascular malformations | 1 | 1 | | | | | 1 | 1 |
| Gastrointestinal vascular occlusion and infarction | 1 | 1 | | | | | 1 | 1 |
| Gingival disorders, signs and symptoms NEC | 12 | 23 | | | 2 | 8 | 10 | 15 |
| Gingival haemorrhages | | 3 | | | | 1 | | 2 |

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System Organ Class

Gastrointestinal disorders

| <i>High Level Term</i> | <i>Interval Total # Spontaneous AE</i> | <i>Cumulative Total # Spontaneous AE</i> |
|--|--|--|
| Haemorrhoids and gastrointestinal varices (excl oesophageal) | 3 | 3 |
| Intestinal haemorrhages | 18 | 21 |
| Intestinal ulcers and perforation NEC | 1 | 1 |
| Nausea and vomiting symptoms | 1,696 | 2,881 |
| Non-site specific gastrointestinal haemorrhages | 17 | 32 |
| Oesophageal stenosis and obstruction | 1 | 1 |
| Oral dryness and saliva altered | 59 | 109 |
| Oral soft tissue disorders NEC | 12 | 20 |
| Oral soft tissue haemorrhages | 1 | 3 |
| Oral soft tissue signs and symptoms | 187 | 369 |
| Oral soft tissue swelling and oedema | 95 | 151 |
| Peritoneal and retroperitoneal disorders | 2 | 2 |
| Peritoneal and retroperitoneal fibrosis and adhesions | | 1 |
| Rectal inflammations NEC | | 1 |
| Salivary gland disorders NEC | | 1 |
| Salivary gland enlargements | | 2 |
| Salivary gland stenosis and obstruction | 1 | 1 |
| Stomatitis and ulceration | 39 | 58 |
| Tongue disorders | 8 | 14 |
| Tongue signs and symptoms | 104 | 174 |
| | 3,367 | 5,519 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|------|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | | | 3 | 3 |
| | | | | 18 | 21 |
| | | | | 1 | 1 |
| 9 | 13 | 209 | 665 | 1487 | 2216 |
| | | | | 17 | 32 |
| | | | | 1 | 1 |
| 1 | 1 | 10 | 35 | 49 | 74 |
| | | 3 | 7 | 9 | 13 |
| | | | 1 | 1 | 2 |
| 1 | 1 | 38 | 133 | 149 | 236 |
| | | 7 | 26 | 88 | 125 |
| | | | | 2 | 2 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 2 | | |
| | | | | 1 | 1 |
| 1 | 1 | 10 | 20 | 29 | 38 |
| | | 1 | 3 | 7 | 11 |
| | | 14 | 38 | 90 | 136 |
| 15 | 19 | 416 | 1270 | 2951 | 4249 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|-------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Administration site reactions NEC | 3 | 3 | | | | | 3 | 3 |
| Adverse effect absent | 4 | 7 | | | 4 | 7 | | |
| Asthenic conditions | 3,020 | 4,832 | 36 | 41 | 474 | 1180 | 2546 | 3652 |
| Body temperature altered | 8 | 17 | | | 1 | 1 | 7 | 16 |
| Complications associated with device NEC | | 1 | | | | 1 | | |
| Death and sudden death | 46 | 104 | | | | | 46 | 104 |
| Eye complications associated with device | 1 | 1 | | | | | 1 | 1 |
| Febrile disorders | 1,363 | 2,560 | 6 | 9 | 143 | 548 | 1220 | 2012 |
| Feelings and sensations NEC | 1,551 | 2,751 | 7 | 9 | 247 | 725 | 1304 | 2026 |
| Gait disturbances | 85 | 118 | 1 | 1 | 10 | 20 | 75 | 98 |
| General signs and symptoms NEC | 1,013 | 1,584 | 3 | 3 | 146 | 367 | 867 | 1217 |
| Healing abnormal NEC | 1 | 1 | | | | | 1 | 1 |
| Inflammations | 20 | 38 | | | 2 | 9 | 18 | 29 |
| Injection site reactions | 16 | 66 | | | | 44 | 16 | 22 |
| Interactions | 1 | 2 | | | | | 1 | 2 |
| Mass conditions NEC | 4 | 8 | | | 2 | 4 | 2 | 4 |
| Oedema NEC | 20 | 25 | | | 3 | 4 | 17 | 21 |
| Pain and discomfort NEC | 1,196 | 1,993 | 13 | 13 | 227 | 551 | 969 | 1442 |
| Therapeutic and nontherapeutic responses | 197 | 443 | 2 | 2 | 4 | 9 | 193 | 434 |
| Ulcers NEC | 1 | 1 | | | | | 1 | 1 |
| Vaccination site reactions | 1,167 | 2,483 | 4 | 9 | 234 | 892 | 933 | 1591 |
| Withdrawal and rebound effects | 1 | 1 | | | | | 1 | 1 |
| | 9,718 | 17,039 | 72 | 87 | 1497 | 4362 | 8221 | 12677 |

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System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Cholestasis and jaundice | 1 | 2 | 1 | 2 |
| Hepatic vascular disorders | | 1 | | 1 |
| Hepatobiliary signs and symptoms | 3 | 4 | 3 | 4 |
| Hepatocellular damage and hepatitis NEC | 2 | 4 | 2 | 4 |
| Obstructive bile duct disorders (excl neoplasms) | | 1 | | 1 |
| | 6 | 12 | 6 | 12 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic sarcoidosis | 2 | 2 | | | 2 | 2 |
| Allergic conditions NEC | 71 | 133 | 7 | 26 | 64 | 107 |
| Allergies to foods, food additives, drugs and other chemicals | 21 | 44 | 3 | 14 | 18 | 30 |
| Anaphylactic and anaphylactoid responses | 112 | 187 | | | 112 | 187 |
| Atopic disorders | 2 | 3 | | 1 | 2 | 2 |
| Autoimmune disorders NEC | 4 | 4 | | | 4 | 4 |
| Immune and associated conditions NEC | 7 | 9 | 1 | 2 | 6 | 7 |
| | 219 | 382 | 11 | 43 | 208 | 339 |

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System Organ Class

Infections and infestations

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| | | Non Interventional Study | | Spontaneous | | | | |
|---|-----|--------------------------|---|-------------|----|---------|-----|-----|
| | | Serious | | Nonserious | | Serious | | |
| | | I | C | I | C | I | C | |
| Abdominal and gastrointestinal infections | 11 | 15 | | | 1 | | 11 | 14 |
| Aspergillus infections | 1 | 1 | | | | | 1 | 1 |
| Bacterial infections NEC | 51 | 80 | | | 2 | 4 | 49 | 76 |
| Breast infections | 2 | 5 | | | | | 2 | 5 |
| Candida infections | 6 | 10 | | | | 2 | 6 | 8 |
| Central nervous system and spinal infections | 6 | 7 | | | | | 6 | 7 |
| Clostridia infections | 1 | 2 | | | | | 1 | 2 |
| Coronavirus infections | 269 | 515 | 1 | 1 | 31 | 39 | 238 | 476 |
| Coxiella infections | 4 | 5 | | | | | 4 | 5 |
| Dental and oral soft tissue infections | 6 | 9 | | | 1 | 2 | 5 | 7 |
| Ear infections | 13 | 21 | | | 1 | 4 | 12 | 17 |
| Epstein-Barr viral infections | 2 | 2 | | | | | 2 | 2 |
| Eye and eyelid infections | 10 | 16 | | | | 1 | 10 | 15 |
| Female reproductive tract infections | 1 | 1 | | | | | 1 | 1 |
| Fungal infections NEC | 1 | 1 | | | | | 1 | 1 |
| Hepatobiliary and spleen infections | | 2 | | | | | | 2 |
| Herpes viral infections | 101 | 135 | | | 8 | 21 | 93 | 114 |
| Infections NEC | 23 | 37 | | | 4 | 5 | 19 | 32 |
| Influenza viral infections | 151 | 204 | | | 18 | 40 | 133 | 164 |
| Lower respiratory tract and lung infections | 33 | 54 | | | | | 33 | 54 |
| Male reproductive tract infections | 3 | 3 | | | | | 3 | 3 |
| Muscle and soft tissue infections | 2 | 2 | | | | | 2 | 2 |
| Neisseria infections | 1 | 1 | | | | | 1 | 1 |
| Prion-associated disorders | 1 | 1 | | | | | 1 | 1 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 7 | 13 | | | 1 | 1 | 6 | 12 |
| Skin structures and soft tissue infections | 6 | 10 | | | 1 | 2 | 5 | 8 |
| Staphylococcal infections | 4 | 5 | | | 1 | 2 | 3 | 3 |
| Streptococcal infections | | 2 | | | | | | 2 |
| Trypanosomal infections | | 1 | | | | | | 1 |
| Upper respiratory tract infections | 91 | 143 | | | 19 | 43 | 72 | 100 |
| Urinary tract infections | 35 | 42 | | | 3 | 3 | 32 | 39 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|----------------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Vascular infections | 1 | 1 | | | | | 1 | 1 |
| Viral infections NEC | 33 | 58 | | | 3 | 7 | 30 | 51 |
| | 876 | 1,404 | 1 | 1 | 93 | 177 | 783 | 1227 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|----|----|
| | | | Serious | | Nonserious | | Serious | | |
| | | | I | C | I | C | I | C | |
| Abdominal and gastrointestinal injuries NEC | 2 | 2 | | | | | 2 | 2 | |
| Bone and joint injuries NEC | 3 | 4 | | | 1 | 2 | 2 | 2 | |
| Chest and respiratory tract injuries NEC | 1 | 1 | | | | | 1 | 1 | |
| Conditions caused by cold | | 1 | | | | | | 1 | |
| Exposures associated with pregnancy, delivery and lactation | 46 | 59 | | | 37 | 48 | 9 | 11 | |
| Exposures to agents or circumstances NEC | 3 | 4 | | | 1 | 1 | 2 | 3 | |
| Eye injuries NEC | 5 | 11 | 1 | 1 | | 1 | 5 | 10 | |
| Fractures and dislocations NEC | 1 | 1 | | | | | 1 | 1 | |
| Gastrointestinal and hepatobiliary procedural complications | 2 | 4 | | | | | 2 | 4 | |
| Heat injuries (excl thermal burns) | 1 | 4 | | | | 2 | 1 | 2 | |
| Limb fractures and dislocations | 6 | 8 | | | | | 6 | 8 | |
| Medication errors, product use errors and issues NEC | 273 | 327 | | | | 269 | 320 | 4 | 7 |
| Muscle, tendon and ligament injuries | 7 | 11 | | | | | 7 | 11 | |
| Musculoskeletal procedural complications | 1 | 1 | | | | | 1 | 1 | |
| Nerve injuries NEC | 2 | 2 | | | | | 2 | 2 | |
| Neurological and psychiatric procedural complications | 1 | 2 | | | | | 1 | 2 | |
| Non-site specific injuries NEC | 59 | 85 | | | | 14 | 20 | 45 | 65 |
| Non-site specific procedural complications | 10 | 13 | | | | | 1 | 10 | 12 |
| Occupational exposures | | 3 | | | | | 3 | | |
| Off label uses | 278 | 331 | | | | 273 | 323 | 5 | 8 |
| Overdoses NEC | 3 | 10 | | | | 2 | 9 | 1 | 1 |
| Peripheral nerve injuries | 3 | 3 | | | | | | 3 | 3 |
| Poisoning and toxicity | | 1 | | | | | | | 1 |
| Product administration errors and issues | 68 | 129 | | | | 61 | 118 | 7 | 11 |
| Product confusion errors and issues | | 1 | | | | | 1 | | |
| Product preparation errors and issues | 1 | 6 | | | | 1 | 6 | | |
| Radiation injuries | 1 | 1 | | | | | | 1 | 1 |
| Site specific injuries NEC | 14 | 24 | | | | 3 | 8 | 11 | 16 |
| Skin injuries NEC | 43 | 62 | | | | 12 | 18 | 31 | 44 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Skull fractures, facial bone fractures and dislocations | 1 | 1 | | | | | 1 | 1 |
| Stoma complications | | 4 | | | | 1 | | 3 |
| Thermal burns | 7 | 7 | | | 1 | 1 | 6 | 6 |
| Underdoses NEC | 1 | 6 | | | 1 | 6 | | |
| Vaccination related complications | 7 | 11 | | | | 2 | 7 | 9 |
| | 850 | 1,140 | 1 | 1 | 676 | 891 | 174 | 249 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Adrenal cortex tests | | 1 | | | | | | 1 |
| Blood counts NEC | 1 | 1 | | | | | 1 | 1 |
| Blood gas and acid base analyses | 23 | 45 | | | 3 | 6 | 20 | 39 |
| Carbohydrate tolerance analyses (incl diabetes) | 14 | 26 | | | 1 | 3 | 13 | 23 |
| Cardiac auscultatory investigations | 1 | 1 | | | | | 1 | 1 |
| Chemistry analyses NEC | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Coagulation and bleeding analyses | 14 | 19 | | | | | 14 | 19 |
| ECG investigations | 3 | 5 | | | | | 3 | 5 |
| Endocrine analyses and imaging NEC | 1 | 1 | | | | | 1 | 1 |
| Haematological analyses NEC | 2 | 3 | | | 1 | 1 | 1 | 2 |
| Heart rate and pulse investigations | 115 | 198 | | | 16 | 46 | 99 | 152 |
| Immunology analyses NEC | 2 | 3 | | | 2 | 3 | | |
| Investigations NEC | 2 | 4 | | | 1 | 1 | 1 | 3 |
| Liver function analyses | 5 | 14 | | | 2 | 5 | 3 | 9 |
| Metabolism tests NEC | 1 | 2 | | | | | 1 | 2 |
| Microbiology and serology tests NEC | | 1 | | | | | | 1 |
| Mineral and electrolyte analyses | 5 | 7 | | | 2 | 3 | 3 | 4 |
| Musculoskeletal and soft tissue tests NEC | 1 | 1 | | | | | 1 | 1 |
| Neurologic diagnostic procedures | | 3 | | | | | | 3 |
| Ophthalmic function diagnostic procedures | 1 | 2 | | | 1 | 1 | | 1 |
| Physical examination procedures and organ system status | 118 | 213 | | 1 | 26 | 59 | 92 | 154 |
| Pituitary analyses anterior | | 1 | | | | 1 | | |
| Platelet analyses | 2 | 2 | | | | | 2 | 2 |
| Protein analyses NEC | 5 | 7 | | | 2 | 3 | 3 | 4 |
| Red blood cell analyses | 5 | 7 | | | | 1 | 5 | 6 |
| Renal function analyses | 3 | 4 | | | 1 | 2 | 2 | 2 |
| Reproductive hormone analyses | 1 | 1 | | | 1 | 1 | | |
| Respiratory and pulmonary function diagnostic procedures | 3 | 3 | | | | | 3 | 3 |
| Respiratory tract and thoracic histopathology procedures | 2 | 2 | | | | | 2 | 2 |

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System Organ Class

Investigations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|---|------------------------------------|--------------------------------------|
| Respiratory tract and thoracic imaging procedures | 1 | 1 |
| Skeletal and cardiac muscle analyses | 2 | 6 |
| Therapeutic drug monitoring analyses | | 1 |
| Thyroid analyses | | 1 |
| Tissue enzyme analyses NEC | | 2 |
| Urinalysis NEC | 6 | 9 |
| Urinary tract function analyses NEC | 1 | 3 |
| Vascular tests NEC (incl blood pressure) | 71 | 133 |
| Virus identification and serology | 36 | 55 |
| Water and electrolyte analyses NEC | | 1 |
| White blood cell analyses | 7 | 8 |
| | 456 | 800 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|---|-------------|-----|---------|-----|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 1 | 1 | | |
| | | | 1 | 2 | 5 |
| | | | | | 1 |
| | | | | | 1 |
| | | | 1 | | 1 |
| | | | 3 | 6 | 6 |
| | | | 1 | 1 | 2 |
| 1 | 1 | 18 | 48 | 53 | 85 |
| | | 16 | 21 | 20 | 34 |
| | | | 1 | | |
| | | 2 | 2 | 5 | 6 |
| | | 97 | 216 | 359 | 584 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Appetite disorders | 212 | 331 | 3 | 3 | 41 | 72 | 171 | 259 |
| Diabetes mellitus (incl subtypes) | 6 | 8 | | | | | 6 | 8 |
| Diabetic complications NEC | 1 | 5 | | | | | 1 | 5 |
| Disorders of purine metabolism | 10 | 12 | | | | | 10 | 12 |
| Fluid intake decreased | | 2 | | | | | | 2 |
| Food malabsorption and intolerance syndromes (excl sugar intolerance) | 1 | 1 | | | | | 1 | 1 |
| General nutritional disorders NEC | 22 | 29 | | | 6 | 11 | 16 | 18 |
| Hyperglycaemic conditions NEC | 8 | 16 | | | 2 | 3 | 6 | 13 |
| Hypoglycaemic conditions NEC | 14 | 22 | | | | 2 | 14 | 20 |
| Metabolic acidoses (excl diabetic acidoses) | 3 | 3 | | | | | 3 | 3 |
| Mixed acid-base disorders | | 2 | | | | 1 | | 1 |
| Potassium imbalance | 2 | 2 | | | | | 2 | 2 |
| Sodium imbalance | 1 | 3 | | | | | 1 | 3 |
| Total fluid volume decreased | 18 | 35 | | | 1 | 10 | 17 | 25 |
| Total fluid volume increased | 3 | 4 | | | 1 | 2 | 2 | 2 |
| | 301 | 475 | 3 | 3 | 51 | 101 | 250 | 374 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE |
|--|------------------------------------|--------------------------------------|
| Arthropathies NEC | 28 | 40 |
| Bone disorders NEC | 1 | 2 |
| Bone related signs and symptoms | 78 | 128 |
| Bursal disorders | 4 | 4 |
| Cartilage disorders | 5 | 7 |
| Connective tissue disorders NEC | 6 | 8 |
| Crystal arthropathic disorders | 1 | 1 |
| Epiphyseal disorders | 1 | 1 |
| Joint related disorders NEC | 4 | 9 |
| Joint related signs and symptoms | 898 | 1,517 |
| Ligament disorders | | 1 |
| Lupus erythematosus (incl subtypes) | 1 | 2 |
| Metabolic bone disorders | 1 | 1 |
| Muscle infections and inflammations | 1 | 2 |
| Muscle pains | 1,012 | 1,844 |
| Muscle related signs and symptoms NEC | 144 | 212 |
| Muscle tone abnormalities | 8 | 14 |
| Muscle weakness conditions | 102 | 167 |
| Musculoskeletal and connective tissue conditions NEC | 175 | 282 |
| Musculoskeletal and connective tissue deformities of skull, face and buccal cavity | 1 | 1 |
| Musculoskeletal and connective tissue infections and inflammations NEC | 1 | 1 |
| Musculoskeletal and connective tissue pain and discomfort | 1,531 | 2,534 |
| Myopathies | 1 | 4 |
| Osteoarthropathies | 3 | 4 |
| Psoriatic arthropathies | 1 | 2 |
| Rheumatoid arthropathies | 9 | 11 |
| Soft tissue disorders NEC | 19 | 41 |
| Spondyloarthropathies | 6 | 9 |
| Synovial disorders | 4 | 6 |

| Non Interventional Study | | Spontaneous | | | |
|--------------------------|----|-------------|-----|---------|------|
| Serious | | Nonserious | | Serious | |
| I | C | I | C | I | C |
| | | 3 | 6 | 25 | 34 |
| | | | 1 | 1 | 1 |
| | | 13 | 37 | 65 | 91 |
| | | | | 4 | 4 |
| | | 1 | 1 | 4 | 6 |
| | | | | 6 | 8 |
| | | | | 1 | 1 |
| | | | 3 | 4 | 6 |
| 7 | 8 | 112 | 322 | 786 | 1195 |
| | | | | | 1 |
| | | | | 1 | 2 |
| | | | | 1 | 1 |
| | | | 1 | 1 | 1 |
| 6 | 9 | 116 | 422 | 896 | 1422 |
| | | 18 | 44 | 126 | 168 |
| | | | | 8 | 14 |
| | | 17 | 37 | 85 | 130 |
| 2 | 2 | 38 | 80 | 137 | 202 |
| | | 1 | 1 | | |
| | | | | 1 | 1 |
| 20 | 23 | 287 | 743 | 1244 | 1791 |
| | | | | 1 | 4 |
| | | | 1 | 3 | 3 |
| | | | | 1 | 2 |
| | | | | 9 | 11 |
| 1 | 1 | 1 | 14 | 18 | 27 |
| | | | | 6 | 9 |
| | | | 1 | 4 | 5 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|------------------|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Tendon disorders | 3 | 4 | | | | | 3 | 4 |
| | 4,049 | 6,859 | 36 | 43 | 607 | 1714 | 3442 | 5145 |

System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Breast and nipple neoplasms malignant | 1 | 1 | 1 | 1 |
| Leukaemias NEC | | 1 | | 1 |
| Lymphomas unspecified NEC | 3 | 3 | 3 | 3 |
| Metastases to specified sites | 5 | 5 | 5 | 5 |
| Neoplasms malignant site unspecified NEC | 2 | 2 | 2 | 2 |
| Plasma cell myelomas | 1 | 1 | 1 | 1 |
| Skin neoplasms benign | 2 | 2 | 2 | 2 |
| Skin neoplasms malignant and unspecified (excl melanoma) | | 1 | | 1 |
| Soft tissue sarcomas histology unspecified | 1 | 1 | 1 | 1 |
| | 15 | 17 | 15 | 17 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|----|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal reflexes | 3 | 5 | | | | | 3 | 5 |
| Abnormal sleep-related events | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Absence seizures | 4 | 6 | | | | | 4 | 6 |
| Acute polyneuropathies | 1 | 2 | | | | | 1 | 2 |
| Autonomic nervous system disorders | 1 | 2 | | | | | 1 | 2 |
| Central nervous system haemorrhages and cerebrovascular accidents | 48 | 90 | | | | | 48 | 90 |
| Central nervous system inflammatory disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Cerebrovascular venous and sinus thrombosis | | 1 | | | | | | 1 |
| Cervical spinal cord and nerve root disorders | 1 | 1 | | | | | 1 | 1 |
| Choreiform movements | 1 | 1 | | | | | 1 | 1 |
| Coma states | 1 | 1 | | | | | 1 | 1 |
| Coordination and balance disturbances | 82 | 117 | | 1 | 13 | 22 | 69 | 95 |
| Cortical dysfunction NEC | 9 | 13 | | | 3 | 3 | 6 | 10 |
| Cranial nerve disorders NEC | 1 | 1 | | | | | 1 | 1 |
| Dementia (excl Alzheimer's type) | 3 | 5 | | | | | 3 | 5 |
| Disturbances in consciousness NEC | 581 | 957 | 4 | 4 | 56 | 145 | 525 | 812 |
| Dyskinesias and movement disorders NEC | 37 | 52 | | | 5 | 9 | 32 | 43 |
| Dystonias | 3 | 5 | | | | | 3 | 5 |
| Encephalopathies NEC | 1 | 2 | | | | | 1 | 2 |
| Eye movement disorders | 5 | 5 | | | | | 5 | 5 |
| Facial cranial nerve disorders | 96 | 145 | 1 | 1 | 2 | 10 | 94 | 135 |
| Generalised tonic-clonic seizures | 4 | 10 | | | | | 4 | 10 |
| Headaches NEC | 2,377 | 4,039 | 17 | 22 | 315 | 955 | 2062 | 3084 |
| Increased intracranial pressure disorders | 1 | 2 | | | | | 1 | 2 |
| Lumbar spinal cord and nerve root disorders | 3 | 5 | | | 1 | 1 | 2 | 4 |
| Memory loss (excl dementia) | 25 | 31 | | | 3 | 6 | 22 | 25 |
| Mental impairment (excl dementia and memory loss) | 54 | 83 | | | 6 | 14 | 48 | 69 |
| Migraine headaches | 209 | 341 | | | 14 | 61 | 195 | 280 |
| Mononeuropathies | 9 | 11 | | | 2 | 2 | 7 | 9 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|----|-------------|------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Multiple sclerosis acute and progressive | 5 | 9 | | | | | 5 | 9 |
| Muscle tone abnormal | 2 | 7 | | | | | 2 | 7 |
| Myelitis (incl infective) | 7 | 7 | | | | | 7 | 7 |
| Narcolepsy and hypersomnia | 38 | 54 | | | 10 | 15 | 28 | 39 |
| Nervous system disorders NEC | 6 | 6 | | | 1 | 1 | 5 | 5 |
| Neurological signs and symptoms NEC | 966 | 1,597 | 5 | 6 | 123 | 376 | 843 | 1221 |
| Neurologic visual problems NEC | 6 | 9 | | | | 1 | 6 | 8 |
| Neuromuscular disorders NEC | 4 | 6 | | | 1 | 2 | 3 | 4 |
| Neuromuscular junction dysfunction | 2 | 2 | | | | | 2 | 2 |
| Olfactory nerve disorders | 37 | 63 | | | 5 | 18 | 32 | 45 |
| Optic nerve disorders NEC | 3 | 4 | | | | | 3 | 4 |
| Paraesthesias and dysaesthesias | 436 | 748 | 2 | 2 | 76 | 221 | 360 | 527 |
| Paralysis and paresis (excl cranial nerve) | 35 | 59 | | | 1 | 2 | 34 | 57 |
| Parkinson's disease and parkinsonism | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Partial complex seizures | 2 | 2 | | | | | 2 | 2 |
| Peripheral neuropathies NEC | 16 | 19 | | | | | 16 | 19 |
| Seizures and seizure disorders NEC | 78 | 104 | | | 1 | 1 | 77 | 103 |
| Sensory abnormalities NEC | 184 | 334 | | | 39 | 126 | 145 | 208 |
| Sleep disturbances NEC | 28 | 41 | | | 6 | 11 | 22 | 30 |
| Speech and language abnormalities | 33 | 49 | 1 | 1 | 6 | 7 | 27 | 42 |
| Spinal cord and nerve root disorders NEC | | 1 | | | | | | 1 |
| Structural brain disorders NEC | | 1 | | | | | | 1 |
| Transient cerebrovascular events | 14 | 20 | | | | | 14 | 20 |
| Tremor (excl congenital) | 203 | 321 | 2 | 2 | 32 | 65 | 171 | 256 |
| Trigeminal disorders | 8 | 10 | | | 1 | 2 | 7 | 8 |
| | 5,679 | 9,413 | 32 | 39 | 724 | 2078 | 4955 | 7335 |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|----|
| | | | Serious | |
| | | | I | C |
| Abortions spontaneous | 6 | 8 | 6 | 8 |
| Gestational age and weight conditions | 2 | 2 | 2 | 2 |
| Maternal complications of pregnancy NEC | 2 | 3 | 2 | 3 |
| | 10 | 13 | 10 | 13 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Device malfunction events NEC | 3 | 4 | | 1 | 3 | 3 |
| Device physical property and chemical issues | 1 | 1 | | | 1 | 1 |
| Product distribution and storage issues | | 3 | | 3 | | |
| Product packaging issues | | 4 | | 4 | | |
| Product physical issues | 1 | 3 | 1 | 3 | | |
| Product quality issues NEC | 3 | 3 | 2 | 2 | 1 | 1 |
| | 8 | 18 | 3 | 13 | 5 | 5 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abnormal behaviour NEC | 2 | 2 | | | | | 2 | 2 |
| Anxiety symptoms | 104 | 167 | | | 22 | 46 | 82 | 121 |
| Behaviour and socialisation disturbances | 7 | 9 | | | | | 7 | 9 |
| Cognitive and attention disorders and disturbances NEC | 18 | 25 | | | 3 | 6 | 15 | 19 |
| Communications disorders | 6 | 7 | | | 3 | 3 | 3 | 4 |
| Confusion and disorientation | 140 | 197 | | | 17 | 30 | 123 | 167 |
| Decreased physical activity levels | 1 | 1 | | | | | 1 | 1 |
| Deliria | 21 | 37 | | | | | 21 | 37 |
| Delusional symptoms | 1 | 2 | | | 1 | 1 | | 1 |
| Depressive disorders | 10 | 14 | | | | | 10 | 14 |
| Dissociative states | 4 | 8 | | | 2 | 5 | 2 | 3 |
| Disturbances in initiating and maintaining sleep | 182 | 280 | 1 | 1 | 40 | 89 | 142 | 191 |
| Eating disorders NEC | 6 | 7 | | | 3 | 3 | 3 | 4 |
| Emotional and mood disturbances NEC | 33 | 44 | | | 8 | 13 | 25 | 31 |
| Fear symptoms and phobic disorders (incl social phobia) | 3 | 9 | | | 1 | 4 | 2 | 5 |
| Fluctuating mood symptoms | 5 | 5 | | | 2 | 2 | 3 | 3 |
| Hallucinations (excl sleep-related) | 34 | 60 | | | | | 34 | 60 |
| Increased physical activity levels | 14 | 32 | | | | 10 | 14 | 22 |
| Mental disorders due to a general medical condition NEC | 1 | 1 | | | 1 | 1 | | |
| Mental disorders NEC | 1 | 2 | | | 1 | 2 | | |
| Mood alterations with depressive symptoms | 27 | 36 | | | 4 | 7 | 23 | 29 |
| Mood disorders NEC | 9 | 11 | | | 2 | 2 | 7 | 9 |
| Narcolepsy and associated conditions | | 2 | | | | | | 2 |
| Obsessive-compulsive disorders and symptoms | | 1 | | | | | | 1 |
| Orgasmic disorders and disturbances | | 1 | | | | | | 1 |
| Panic attacks and disorders | 14 | 18 | | | 2 | 2 | 12 | 16 |
| Parasomnias | 20 | 41 | | | 4 | 17 | 16 | 24 |
| Perception disturbances NEC | 2 | 3 | | | | | 2 | 3 |
| Psychiatric elimination disorders | | 3 | | | | 1 | | 2 |

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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Psychiatric symptoms NEC | 2 | 2 | | | | | 2 | 2 |
| Psychotic disorder NEC | 5 | 6 | | | 1 | 1 | 4 | 5 |
| Sleep disorders NEC | 50 | 91 | | | 18 | 41 | 32 | 50 |
| Somatic symptom disorders | | 2 | | | | | | 2 |
| Speech and language usage disturbances | 2 | 3 | | | | 1 | 2 | 2 |
| Speech articulation and rhythm disturbances | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Stereotypies and automatisms | 2 | 2 | | | 1 | 1 | 1 | 1 |
| Suicidal and self-injurious behaviour | 3 | 4 | | | | | 3 | 4 |
| Thinking disturbances | 9 | 11 | | | | | 9 | 11 |
| | 740 | 1,148 | 1 | 1 | 137 | 289 | 603 | 859 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 50 | 71 | 6 | 12 | 44 | 59 |
| Bladder disorders NEC | 4 | 4 | | | 4 | 4 |
| Genital and urinary tract disorders NEC | 1 | 2 | | | 1 | 2 |
| Glomerulonephritis and nephrotic syndrome | 1 | 2 | | | 1 | 2 |
| Myoneurogenic bladder disorders | 2 | 3 | 1 | 2 | 1 | 1 |
| Nephritis NEC | 1 | 1 | | | 1 | 1 |
| Renal failure and impairment | 8 | 16 | | | 8 | 16 |
| Urinary abnormalities | 12 | 17 | 7 | 9 | 5 | 8 |
| Urinary tract signs and symptoms NEC | 20 | 35 | 3 | 12 | 17 | 23 |
| | 99 | 151 | 17 | 35 | 82 | 116 |

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System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Benign and malignant breast neoplasms | 1 | 1 | | | 1 | 1 |
| Breast disorders NEC | 5 | 6 | 1 | 1 | 4 | 5 |
| Breast signs and symptoms | 41 | 63 | 7 | 20 | 34 | 43 |
| Erection and ejaculation conditions and disorders | 4 | 5 | | | 4 | 5 |
| Menopausal effects NEC | | 2 | | 2 | | |
| Menopausal effects on the genitourinary tract | 1 | 1 | | | 1 | 1 |
| Menstruation and uterine bleeding NEC | 14 | 20 | 6 | 10 | 8 | 10 |
| Menstruation with decreased bleeding | 11 | 12 | 1 | 2 | 10 | 10 |
| Menstruation with increased bleeding | 12 | 19 | | 3 | 12 | 16 |
| Ovarian and fallopian tube disorders NEC | 1 | 1 | | | 1 | 1 |
| Pelvis and broad ligament disorders NEC | 4 | 4 | | | 4 | 4 |
| Penile disorders NEC (excl erection and ejaculation) | | 1 | | | | 1 |
| Prostatic signs, symptoms and disorders NEC | 1 | 2 | 1 | 2 | | |
| Reproductive tract disorders NEC (excl neoplasms) | 1 | 1 | | | 1 | 1 |
| Reproductive tract signs and symptoms NEC | 10 | 11 | 1 | 2 | 9 | 9 |
| Scrotal disorders NEC | 1 | 6 | | 1 | 1 | 5 |
| Sexual function and fertility disorders NEC | 1 | 1 | | | 1 | 1 |
| Testicular and epididymal disorders NEC | 2 | 2 | | | 2 | 2 |
| Uterine disorders NEC | 2 | 2 | | | 2 | 2 |
| Vulvovaginal disorders NEC | 10 | 14 | 2 | 2 | 8 | 12 |
| Vulvovaginal signs and symptoms | | 1 | | 1 | | |
| | 122 | 175 | 19 | 46 | 103 | 129 |

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System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Breathing abnormalities | 425 | 668 | 1 | 1 | 43 | 107 | 382 | 561 |
| Bronchial conditions NEC | 3 | 3 | | | | | 3 | 3 |
| Bronchospasm and obstruction | 99 | 156 | | | 11 | 29 | 88 | 127 |
| Conditions associated with abnormal gas exchange | 7 | 11 | | | | | 7 | 11 |
| Coughing and associated symptoms | 233 | 387 | 1 | 1 | 34 | 88 | 199 | 299 |
| Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) | 1 | 2 | | | | | 1 | 2 |
| Laryngeal spasm, oedema and obstruction | 6 | 7 | | | | | 6 | 7 |
| Lower respiratory tract inflammatory and immunologic conditions | 6 | 11 | | | | | 6 | 11 |
| Lower respiratory tract signs and symptoms | 20 | 29 | | | 3 | 5 | 17 | 24 |
| Nasal congestion and inflammations | 27 | 40 | | | 8 | 15 | 19 | 25 |
| Nasal disorders NEC | 48 | 75 | | | 5 | 17 | 43 | 58 |
| Paranasal sinus disorders (excl infections and neoplasms) | 7 | 13 | | | 1 | 3 | 6 | 10 |
| Parenchymal lung disorders NEC | | 2 | | | | | | 2 |
| Pharyngeal disorders (excl infections and neoplasms) | 70 | 117 | | | 4 | 17 | 66 | 100 |
| Pleural infections and inflammations | 2 | 4 | | | | | 2 | 4 |
| Pneumothorax and pleural effusions NEC | 1 | 2 | | | | | 1 | 2 |
| Pulmonary oedemas | 3 | 6 | 1 | 1 | | | 3 | 6 |
| Pulmonary thrombotic and embolic conditions | 17 | 21 | 1 | 1 | | | 17 | 21 |
| Respiratory failures (excl neonatal) | 1 | 3 | | | | | 1 | 3 |
| Respiratory signs and symptoms NEC | 11 | 16 | 1 | 1 | 3 | 5 | 8 | 11 |
| Respiratory tract disorders NEC | 12 | 19 | | | | 2 | 12 | 17 |
| Tracheal disorders (excl infections and neoplasms) | 1 | 1 | | | 1 | 1 | | |
| Upper respiratory tract signs and symptoms | 465 | 781 | 1 | 1 | 55 | 187 | 410 | 594 |
| | 1,465 | 2,374 | 6 | 6 | 168 | 476 | 1297 | 1898 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Acnes | 2 | 2 | | | | | 2 | 2 |
| Alopecias | 6 | 8 | | | 2 | 3 | 4 | 5 |
| Angioedemas | 33 | 55 | | | | | 33 | 55 |
| Apocrine and eccrine gland disorders | 340 | 570 | 5 | 5 | 61 | 152 | 279 | 418 |
| Bullous conditions | 38 | 51 | 1 | 1 | 2 | 7 | 36 | 44 |
| Dermal and epidermal conditions NEC | 131 | 232 | | | 20 | 58 | 111 | 174 |
| Dermatitis and eczema | 46 | 76 | | | 6 | 20 | 40 | 56 |
| Dermatitis ascribed to specific agent | 1 | 6 | | | 1 | 2 | | 4 |
| Erythemas | 142 | 274 | | | 28 | 99 | 114 | 175 |
| Exfoliative conditions | 9 | 16 | | | 2 | 3 | 7 | 13 |
| Nail and nail bed conditions (excl infections and infestations) | 1 | 3 | | | | | 1 | 3 |
| Panniculitides | 2 | 2 | | | | | 2 | 2 |
| Papulosquamous conditions | 1 | 1 | | | | | 1 | 1 |
| Photosensitivity and photodermatosis conditions | 11 | 12 | | | 4 | 4 | 7 | 8 |
| Pilar disorders NEC | 2 | 6 | | | | 1 | 2 | 5 |
| Pruritus NEC | 250 | 455 | 1 | 1 | 46 | 150 | 204 | 305 |
| Psoriatic conditions | 4 | 5 | 1 | 1 | 2 | 2 | 2 | 3 |
| Purpura and related conditions | 11 | 19 | | | | 3 | 11 | 16 |
| Rashes, eruptions and exanthems NEC | 453 | 818 | 1 | 1 | 63 | 244 | 390 | 574 |
| Rosaceas | 1 | 1 | | | | | 1 | 1 |
| Skin and subcutaneous conditions NEC | 6 | 9 | | | | 2 | 6 | 7 |
| Skin and subcutaneous tissue ulcerations | 5 | 8 | | | | 1 | 5 | 7 |
| Skin haemorrhages | 1 | 2 | | | | | 1 | 2 |
| Skin vasculitides | 3 | 4 | | | 1 | 1 | 2 | 3 |
| Skin vasomotor conditions | 7 | 9 | | | | 1 | 7 | 8 |
| Urticarias | 124 | 212 | | | 13 | 58 | 111 | 154 |
| | 1,630 | 2,856 | 9 | 9 | 251 | 811 | 1379 | 2045 |

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System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disability issues | 45 | 62 | 9 | 12 | 36 | 50 |
| | 45 | 62 | 9 | 12 | 36 | 50 |

System Organ Class

SOC Not Yet Coded

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|-----------------|------------------------------------|--------------------------------------|-------------|----|
| | | | Nonserious | |
| | | | I | C |
| | 5 | 14 | 5 | 14 |
| | 5 | 14 | 5 | 14 |

System Organ Class

Surgical and medical procedures

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dietary and nutritional therapies | 1 | 2 | | | 1 | 2 |
| Gastrointestinal therapeutic procedures NEC | 1 | 1 | | | 1 | 1 |
| Limb therapeutic procedures | 1 | 2 | 1 | 2 | | |
| Respiratory tract therapeutic procedures NEC | | 1 | | | | 1 |
| | 3 | 6 | 1 | 2 | 2 | 4 |

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System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Accelerated and malignant hypertension | | 1 | | | | | | 1 |
| Aortic aneurysms and dissections | 1 | 2 | | | | | 1 | 2 |
| Aortic necrosis and vascular insufficiency | 1 | 1 | | | | | 1 | 1 |
| Arterial infections and inflammations | 3 | 3 | | | | | 3 | 3 |
| Blood pressure disorders NEC | 3 | 4 | | | | | 3 | 4 |
| Circulatory collapse and shock | 19 | 43 | | | | | 19 | 43 |
| Haemorrhages NEC | 19 | 23 | 1 | 1 | | 1 | 19 | 22 |
| Lymphoedemas | 6 | 12 | | | | 1 | 6 | 11 |
| Non-site specific embolism and thrombosis | 4 | 8 | 1 | 1 | | | 4 | 8 |
| Non-site specific necrosis and vascular insufficiency NEC | 1 | 2 | | | | | 1 | 2 |
| Non-site specific vascular disorders NEC | 5 | 11 | | | 1 | 3 | 4 | 8 |
| Peripheral embolism and thrombosis | 7 | 12 | | | | | 7 | 12 |
| Peripheral vascular disorders NEC | 121 | 235 | | | 12 | 64 | 109 | 171 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 45 | 77 | | | 9 | 22 | 36 | 55 |
| Phlebitis NEC | 1 | 1 | | | | | 1 | 1 |
| Site specific vascular disorders NEC | 28 | 61 | | | 5 | 17 | 23 | 44 |
| Varicose veins NEC | 1 | 2 | | | 1 | 2 | | |
| Vascular hypertensive disorders NEC | 68 | 127 | 1 | 1 | 5 | 26 | 63 | 101 |
| Vascular hypotensive disorders | 48 | 92 | | | 8 | 21 | 40 | 71 |
| Vasculitides NEC | 7 | 8 | | | | | 7 | 8 |
| Vena caval embolism and thrombosis | | 2 | | | | | | 2 |
| | 388 | 727 | 3 | 3 | 41 | 157 | 347 | 570 |

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Country Where Event Occurred

UNITED STATES

System Organ Class

Blood and lymphatic system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Anaemias haemolytic immune | 1 | 1 | | | 1 | 1 |
| Anaemias haemolytic NEC | 1 | 2 | | | 1 | 2 |
| Anaemias NEC | 3 | 3 | 1 | 1 | 2 | 2 |
| Bleeding tendencies | 1 | 1 | 1 | 1 | | |
| Coagulopathies | | 1 | | | | 1 |
| Eosinophilic disorders | | 1 | | 1 | | |
| Haematological disorders | | 1 | | 1 | | |
| Leukocytoses NEC | 1 | 4 | 1 | 3 | | 1 |
| Lymphatic system disorders NEC | 223 | 731 | 215 | 693 | 8 | 38 |
| Marrow depression and hypoplastic anaemias | 1 | 2 | | | 1 | 2 |
| Neutropenias | 2 | 3 | | | 2 | 3 |
| Platelet disorders NEC | 1 | 1 | 1 | 1 | | |
| Polycythaemia (excl rubra vera) | 1 | 1 | 1 | 1 | | |
| Spleen disorders | 3 | 3 | 1 | 1 | 2 | 2 |
| Thrombocytopenias | 14 | 21 | | | 14 | 21 |
| | 252 | 776 | 221 | 703 | 31 | 73 |

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System Organ Class

Cardiac disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cardiac conduction disorders | 1 | 1 | 1 | 1 | | |
| Cardiac disorders NEC | 7 | 14 | 2 | 8 | 5 | 6 |
| Cardiac signs and symptoms NEC | 82 | 239 | 69 | 186 | 13 | 53 |
| Cardiac valve disorders NEC | | 1 | | | | 1 |
| Cardiomyopathies | 1 | 1 | | | 1 | 1 |
| Heart failures NEC | 6 | 8 | | | 6 | 8 |
| Ischaemic coronary artery disorders | 21 | 35 | | | 21 | 35 |
| Myocardial disorders NEC | | 2 | | | | 2 |
| Noninfectious myocarditis | 1 | 2 | | | 1 | 2 |
| Noninfectious pericarditis | 3 | 8 | | | 3 | 8 |
| Pericardial disorders NEC | 2 | 4 | | | 2 | 4 |
| Rate and rhythm disorders NEC | 49 | 223 | 22 | 135 | 27 | 88 |
| Supraventricular arrhythmias | 25 | 44 | 1 | 6 | 24 | 38 |
| Ventricular arrhythmias and cardiac arrest | 13 | 32 | 2 | 6 | 11 | 26 |
| | 211 | 614 | 97 | 342 | 114 | 272 |

System Organ Class

Congenital, familial and genetic disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Coagulation disorders congenital | | 1 | | | | 1 |
| Skin and subcutaneous tissue disorders congenital NEC | 1 | 1 | 1 | 1 | | |
| Tongue disorders congenital | 1 | 1 | | | 1 | 1 |
| | 2 | 3 | 1 | 1 | 1 | 2 |

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System Organ Class

Ear and labyrinth disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|------------------------------|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Ear disorders NEC | 47 | 135 | 39 | 123 | 8 | 12 |
| Eustachian tube disorders | 1 | 1 | 1 | 1 | | |
| External ear disorders NEC | 3 | 5 | 3 | 5 | | |
| Hearing losses | 38 | 74 | 10 | 25 | 28 | 49 |
| Hyperacusia | | 5 | | 4 | | 1 |
| Inner ear signs and symptoms | 81 | 222 | 66 | 188 | 15 | 34 |
| Mastoid disorders | 1 | 1 | | | 1 | 1 |
| | 171 | 443 | 119 | 346 | 52 | 97 |

System Organ Class

Endocrine disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acute and chronic thyroiditis | 2 | 3 | | | 2 | 3 |
| Adrenal cortical hypofunctions | 2 | 2 | | | 2 | 2 |
| Adrenal gland disorders NEC | 1 | 1 | | | 1 | 1 |
| Thyroid disorders NEC | 1 | 4 | 1 | 4 | | |
| Thyroid hypofunction disorders | 1 | 3 | | | 1 | 3 |
| | 7 | 13 | 1 | 4 | 6 | 9 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cataract conditions | 2 | 2 | | | 2 | 2 |
| Chambers (anterior and posterior) and lens infections and inflammations | 1 | 1 | | | 1 | 1 |
| Choroid and vitreous structural change, deposit and degeneration | 3 | 3 | 3 | 3 | | |
| Colour blindness (incl acquired) | 1 | 1 | 1 | 1 | | |
| Conjunctival and corneal bleeding and vascular disorders | 1 | 2 | | | 1 | 2 |
| Conjunctival infections, irritations and inflammations | | 4 | | 4 | | |
| Corneal disorders NEC | 2 | 2 | | | 2 | 2 |
| Corneal infections, oedemas and inflammations | | 1 | | 1 | | |
| Corneal structural change, deposit and degeneration | 1 | 1 | | | 1 | 1 |
| Eyelid movement disorders | 3 | 10 | 1 | 7 | 2 | 3 |
| Glaucomas (excl congenital) | 1 | 3 | | | 1 | 3 |
| Iris and uveal tract infections, irritations and inflammations | | 1 | | 1 | | |
| Lacrimation disorders | 17 | 32 | 14 | 28 | 3 | 4 |
| Lid, lash and lacrimal infections, irritations and inflammations | 6 | 38 | 3 | 35 | 3 | 3 |
| Ocular bleeding and vascular disorders NEC | 4 | 10 | | | 4 | 10 |
| Ocular disorders NEC | 76 | 227 | 59 | 191 | 17 | 36 |
| Ocular infections, inflammations and associated manifestations | 37 | 109 | 34 | 98 | 3 | 11 |
| Ocular nerve and muscle disorders | 5 | 8 | 2 | 4 | 3 | 4 |
| Ocular sensation disorders | 11 | 52 | 11 | 49 | | 3 |
| Pupil disorders | 1 | 3 | 1 | 3 | | |
| Refractive and accommodative disorders | | 1 | | 1 | | |
| Retinal structural change, deposit and degeneration | 1 | 1 | | | 1 | 1 |
| Scleral infections, irritations and inflammations | | 3 | | 2 | | 1 |
| Visual colour distortions | 1 | 1 | 1 | 1 | | |
| Visual disorders NEC | 36 | 108 | 29 | 87 | 7 | 21 |

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System Organ Class

Eye disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Visual impairment and blindness (excl colour blindness) | 43 | 68 | 23 | 41 | 20 | 27 |
| | 253 | 692 | 182 | 557 | 71 | 135 |

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System Organ Class

Gastrointestinal disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 3 | | |
| | | 2 | 2 |
| | | 3 | 5 |
| 1 | 1 | | |
| 1 | 1 | | |
| 3 | 3 | | |
| | | 4 | 5 |
| 2 | 2 | | |
| 13 | 31 | 3 | 3 |
| 176 | 509 | 18 | 33 |
| | | 1 | 1 |
| | | 1 | 2 |
| 14 | 36 | 1 | 1 |
| 8 | 13 | | |
| 11 | 32 | 1 | 2 |
| | | 1 | 1 |
| | 3 | | |
| 79 | 235 | 11 | 27 |
| 18 | 26 | 1 | 2 |
| 10 | 30 | | 1 |
| 2 | 5 | | |
| 1 | 1 | | |
| 65 | 150 | 11 | 32 |
| 4 | 11 | 1 | 1 |
| | | 2 | 3 |
| | | 1 | 1 |
| 9 | 26 | 1 | 5 |
| 1 | 5 | | |

| | | |
|---|-----|-----|
| Abdominal findings abnormal | 1 | 3 |
| Abdominal wall conditions NEC | 2 | 2 |
| Acute and chronic pancreatitis | 3 | 5 |
| Anal and rectal disorders NEC | 1 | 1 |
| Anal and rectal pains | 1 | 1 |
| Anal and rectal signs and symptoms | 3 | 3 |
| Colitis (excl infective) | 4 | 5 |
| Dental disorders NEC | 2 | 2 |
| Dental pain and sensation disorders | 16 | 34 |
| Diarrhoea (excl infective) | 194 | 542 |
| Diverticula | 1 | 1 |
| Duodenal and small intestinal stenosis and obstruction | 1 | 2 |
| Dyspeptic signs and symptoms | 15 | 37 |
| Faecal abnormalities NEC | 8 | 13 |
| Flatulence, bloating and distension | 12 | 34 |
| Gastric ulcers and perforation | 1 | 1 |
| Gastritis (excl infective) | | 3 |
| Gastrointestinal and abdominal pains (excl oral and throat) | 90 | 262 |
| Gastrointestinal atonic and hypomotility disorders NEC | 19 | 28 |
| Gastrointestinal disorders NEC | 10 | 31 |
| Gastrointestinal dyskinetic disorders | 2 | 5 |
| Gastrointestinal inflammatory disorders NEC | 1 | 1 |
| Gastrointestinal signs and symptoms NEC | 76 | 182 |
| Gastrointestinal spastic and hypermotility disorders | 5 | 12 |
| Gastrointestinal stenosis and obstruction NEC | 2 | 3 |
| Gastrointestinal vascular occlusion and infarction | 1 | 1 |
| Gingival disorders, signs and symptoms NEC | 10 | 31 |
| Gingival haemorrhages | 1 | 5 |

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System Organ Class

Gastrointestinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Haemorrhoids and gastrointestinal varices (excl oesophageal) | 1 | 2 | 1 | 2 | | |
| Intestinal haemorrhages | 4 | 5 | 1 | 1 | 3 | 4 |
| Intestinal ulcers and perforation NEC | 1 | 1 | | | 1 | 1 |
| Nausea and vomiting symptoms | 627 | 1,964 | 579 | 1829 | 48 | 135 |
| Non-site specific gastrointestinal haemorrhages | 12 | 19 | | | 12 | 19 |
| Oral dryness and saliva altered | 23 | 69 | 21 | 62 | 2 | 7 |
| Oral soft tissue disorders NEC | 14 | 37 | 11 | 30 | 3 | 7 |
| Oral soft tissue haemorrhages | 5 | 5 | 3 | 3 | 2 | 2 |
| Oral soft tissue signs and symptoms | 112 | 372 | 84 | 301 | 28 | 71 |
| Oral soft tissue swelling and oedema | 38 | 118 | 26 | 81 | 12 | 37 |
| Salivary gland disorders NEC | | 1 | | 1 | | |
| Stomatitis and ulceration | 5 | 22 | 4 | 20 | 1 | 2 |
| Tongue disorders | 5 | 22 | 5 | 20 | | 2 |
| Tongue signs and symptoms | 49 | 140 | 34 | 98 | 15 | 42 |
| | 1,378 | 4,027 | 1188 | 3571 | 190 | 456 |

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System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-------|---------|------|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Administration site reactions NEC | 1 | 3 | | | 1 | 3 | | |
| Adverse effect absent | 13 | 13 | | | 13 | 13 | | |
| Application and instillation site reactions | 1 | 1 | | | 1 | 1 | | |
| Asthenic conditions | 1,172 | 3,570 | | | 1097 | 3392 | 75 | 178 |
| Body temperature altered | 5 | 8 | | | 2 | 4 | 3 | 4 |
| Death and sudden death | 27 | 57 | | | | | 27 | 57 |
| Febrile disorders | 666 | 2,287 | | | 620 | 2160 | 46 | 127 |
| Feelings and sensations NEC | 1,060 | 3,256 | | | 986 | 3066 | 74 | 190 |
| Gait disturbances | 74 | 141 | | | 54 | 110 | 20 | 31 |
| General signs and symptoms NEC | 394 | 1,138 | | | 331 | 1016 | 63 | 122 |
| Inflamations | 9 | 26 | | | 9 | 22 | | 4 |
| Injection site reactions | 15 | 85 | | | 14 | 83 | 1 | 2 |
| Interactions | 3 | 13 | | | 2 | 11 | 1 | 2 |
| Mass conditions NEC | 7 | 15 | | | 7 | 15 | | |
| Mucosal findings abnormal | 2 | 5 | | | | 3 | 2 | 2 |
| Oedema NEC | 5 | 21 | | | 4 | 17 | 1 | 4 |
| Pain and discomfort NEC | 793 | 2,503 | | | 715 | 2290 | 78 | 213 |
| Therapeutic and nontherapeutic responses | 323 | 1,025 | 2 | 2 | 19 | 46 | 304 | 979 |
| Ulcers NEC | 1 | 2 | | | 1 | 2 | | |
| Vaccination site reactions | 968 | 3,028 | | | 929 | 2938 | 39 | 90 |
| | 5,539 | 17,197 | 2 | 2 | 4805 | 15192 | 734 | 2005 |

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System Organ Class

Hepatobiliary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Cholecystitis and cholelithiasis | | 1 | | | | 1 |
| Cholestasis and jaundice | 1 | 3 | | 2 | 1 | 1 |
| Gal bladder disorders NEC | 1 | 4 | 1 | 3 | | 1 |
| Hepatic and hepatobiliary disorders NEC | 1 | 1 | 1 | 1 | | |
| Hepatic failure and associated disorders | | 1 | | | | 1 |
| Hepatic fibrosis and cirrhosis | 1 | 1 | | | 1 | 1 |
| Hepatobiliary signs and symptoms | 3 | 4 | 2 | 3 | 1 | 1 |
| Hepatocellular damage and hepatitis NEC | 3 | 5 | | | 3 | 5 |
| | 10 | 20 | 4 | 9 | 6 | 11 |

System Organ Class

Immune system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Allergic conditions NEC | 48 | 145 | 32 | 102 | 16 | 43 |
| Allergies to foods, food additives, drugs and other chemicals | 26 | 80 | 20 | 61 | 6 | 19 |
| Amyloidoses | 1 | 1 | | | 1 | 1 |
| Anaphylactic and anaphylactoid responses | 42 | 144 | 1 | 4 | 41 | 140 |
| Atopic disorders | 1 | 4 | 1 | 4 | | |
| Autoimmune disorders NEC | 3 | 7 | | | 3 | 7 |
| Immune and associated conditions NEC | 4 | 10 | 2 | 6 | 2 | 4 |
| Immunodeficiency disorders NEC | 4 | 6 | | | 4 | 6 |
| Transplant rejections | 1 | 1 | | | 1 | 1 |
| | 130 | 398 | 56 | 177 | 74 | 221 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| Abdominal and gastrointestinal infections | 12 | 18 | | | 1 | 1 | 11 | 17 |
| Bacterial infections NEC | 18 | 28 | | | 1 | 3 | 17 | 25 |
| Bordetella infections | | 1 | | | | | | 1 |
| Breast infections | | 1 | | | | | | 1 |
| Candida infections | 1 | 3 | | | 1 | 3 | | |
| Central nervous system and spinal infections | 5 | 6 | | | | | 5 | 6 |
| Coccidioides infections | 1 | 1 | | | | | 1 | 1 |
| Coronavirus infections | 301 | 833 | 2 | 2 | 18 | 57 | 283 | 776 |
| Dental and oral soft tissue infections | 3 | 5 | | | 2 | 4 | 1 | 1 |
| Ear infections | 3 | 6 | | | 2 | 4 | 1 | 2 |
| Ectoparasitic infestations | 1 | 2 | | | | 1 | 1 | 1 |
| Escherichia infections | | 1 | | | | | | 1 |
| Eye and eyelid infections | 7 | 16 | | | 5 | 14 | 2 | 2 |
| Female reproductive tract infections | | 1 | | | | 1 | | |
| Fungal infections NEC | 2 | 6 | | | 2 | 6 | | |
| Helicobacter infections | 1 | 1 | | | | | 1 | 1 |
| Herpes viral infections | 50 | 119 | | | 40 | 107 | 10 | 12 |
| Infections NEC | 8 | 22 | | | 5 | 17 | 3 | 5 |
| Influenza viral infections | 17 | 52 | | | 16 | 49 | 1 | 3 |
| Lower respiratory tract and lung infections | 22 | 39 | | | 2 | 6 | 20 | 33 |
| Male reproductive tract infections | | 1 | | | | 1 | | |
| Rhinoviral infections | | 1 | | | | 1 | | |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | 4 | 7 | | | | | 4 | 7 |
| Skin structures and soft tissue infections | 6 | 10 | | | 5 | 8 | 1 | 2 |
| Staphylococcal infections | 1 | 4 | | | | 1 | 1 | 3 |
| Streptococcal infections | 3 | 5 | | | 3 | 4 | | 1 |
| Tuberculous infections | | 2 | | | | | | 2 |
| Upper respiratory tract infections | 55 | 145 | | | 54 | 141 | 1 | 4 |
| Urinary tract infections | 32 | 44 | | | 17 | 26 | 15 | 18 |
| Vascular infections | 1 | 1 | | | | | 1 | 1 |
| Viral infections NEC | 6 | 15 | | | 2 | 8 | 4 | 7 |

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System Organ Class

Infections and infestations

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Non Interventional Study | | Spontaneous | | | |
|-----------------|------------------------------------|--------------------------------------|--------------------------|---|-------------|-----|---------|-----|
| | | | Serious | | Nonserious | | Serious | |
| | | | I | C | I | C | I | C |
| | 560 | 1,396 | 2 | 2 | 176 | 463 | 384 | 933 |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abdominal and gastrointestinal injuries NEC | 1 | 4 | 1 | 3 | | 1 |
| Accidental exposures to product | 13 | 29 | 13 | 28 | | 1 |
| Bone and joint injuries NEC | 1 | 3 | 1 | 3 | | |
| Cerebral injuries NEC | 1 | 1 | | | 1 | 1 |
| Chest and respiratory tract injuries NEC | 2 | 3 | | | 2 | 3 |
| Conditions caused by cold | | 2 | | 2 | | |
| Exposures associated with pregnancy, delivery and lactation | 30 | 192 | 30 | 190 | | 2 |
| Exposures to agents or circumstances NEC | 11 | 53 | 10 | 42 | 1 | 11 |
| Eye injuries NEC | | 4 | | 4 | | |
| Fractures and dislocations NEC | 2 | 4 | | | 2 | 4 |
| Gastrointestinal and hepatobiliary procedural complications | | 2 | | 2 | | |
| Intentional product misuses | | 1 | | 1 | | |
| Limb fractures and dislocations | 2 | 3 | | | 2 | 3 |
| Medication errors, product use errors and issues NEC | 161 | 537 | 156 | 529 | 5 | 8 |
| Muscle, tendon and ligament injuries | 4 | 12 | 2 | 10 | 2 | 2 |
| Nerve injuries NEC | 4 | 6 | 2 | 4 | 2 | 2 |
| Non-site specific injuries NEC | 43 | 76 | 28 | 53 | 15 | 23 |
| Non-site specific procedural complications | 1 | 7 | | 2 | 1 | 5 |
| Occupational exposures | 3 | 10 | 2 | 8 | 1 | 2 |
| Off label uses | 129 | 386 | 125 | 381 | 4 | 5 |
| Overdoses NEC | 26 | 68 | 25 | 66 | 1 | 2 |
| Pathways and sources of exposure | 12 | 27 | 12 | 26 | | 1 |
| Peripheral nerve injuries | 2 | 2 | | | 2 | 2 |
| Product administration errors and issues | 245 | 921 | 241 | 911 | 4 | 10 |
| Product confusion errors and issues | | 1 | | 1 | | |
| Product preparation errors and issues | 29 | 168 | 28 | 165 | 1 | 3 |
| Product prescribing errors and issues | 2 | 7 | 2 | 7 | | |
| Product storage errors and issues in the product use system | 3 | 3 | 3 | 3 | | |

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System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Product transcribing errors and communication issues | 1 | 1 | 1 | 1 | | |
| Radiation injuries | | 2 | | 2 | | |
| Site specific injuries NEC | 12 | 31 | 9 | 24 | 3 | 7 |
| Skin injuries NEC | 32 | 64 | 28 | 57 | 4 | 7 |
| Stoma complications | 2 | 2 | 1 | 1 | 1 | 1 |
| Thermal burns | | 2 | | 1 | | 1 |
| Underdoses NEC | 49 | 156 | 49 | 156 | | |
| Vaccination related complications | 3 | 6 | | 2 | 3 | 4 |
| | 826 | 2,796 | 769 | 2685 | 57 | 111 |

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System Organ Class

Investigations

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| | 1 | | |
| 1 | 2 | | |
| 2 | 3 | | |
| 8 | 19 | 14 | 21 |
| 14 | 31 | 7 | 11 |
| | 1 | 2 | 2 |
| | | 1 | 1 |
| | | | 1 |
| 2 | 2 | | |
| 2 | 7 | 2 | 4 |
| 2 | 5 | 2 | 3 |
| 1 | 1 | 1 | 1 |
| | 1 | | |
| 1 | 3 | 1 | 1 |
| 103 | 328 | 33 | 89 |
| 1 | 1 | | |
| 1 | 4 | | |
| 4 | 7 | | |
| 2 | 2 | | 1 |
| | 1 | | |
| 7 | 9 | 2 | 4 |
| | | 1 | 1 |
| | 1 | | |
| 3 | 13 | 3 | 4 |
| 1 | 1 | | |
| | | 1 | 1 |
| | 1 | | |
| 2 | 3 | | |
| 65 | 165 | | |
| | | 5 | 14 |
| | 3 | | 1 |
| 4 | 8 | 9 | 13 |

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System Organ Class

Investigations

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|-----|
| Nonserious | | Serious | |
| I | C | I | C |
| 1 | 8 | 1 | 2 |
| 1 | 10 | 3 | 4 |
| 2 | 5 | | |
| | 1 | | |
| 1 | 1 | | |
| | | 1 | 1 |
| | | 3 | 7 |
| | | | 1 |
| 4 | 12 | 2 | 2 |
| 1 | 2 | | |
| 52 | 132 | 35 | 84 |
| 30 | 74 | 32 | 235 |
| 1 | 1 | 1 | 1 |
| 12 | 17 | 5 | 12 |
| 324 | 868 | 169 | 524 |

| | | |
|--|-----|-------|
| Protein analyses NEC | 2 | 10 |
| Red blood cell analyses | 4 | 14 |
| Renal function analyses | 2 | 5 |
| Reproductive hormone analyses | | 1 |
| Respiratory and pulmonary function diagnostic procedures | 1 | 1 |
| Respiratory tract and thoracic imaging procedures | 1 | 1 |
| Skeletal and cardiac muscle analyses | 3 | 7 |
| Triglyceride analyses | | 1 |
| Urinalysis NEC | 6 | 14 |
| Urinary tract function analyses NEC | 1 | 2 |
| Vascular tests NEC (incl blood pressure) | 87 | 216 |
| Virus identification and serology | 62 | 309 |
| Vitamin analyses | 2 | 2 |
| White blood cell analyses | 17 | 29 |
| | 493 | 1,392 |

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System Organ Class

Metabolism and nutrition disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Appetite disorders | 61 | 165 | 59 | 154 | 2 | 11 |
| Calcium metabolism disorders | | 3 | | | | 3 |
| Diabetes mellitus (incl subtypes) | 10 | 15 | | | 10 | 15 |
| Disorders of purine metabolism | 4 | 9 | 3 | 8 | 1 | 1 |
| Electrolyte imbalance NEC | | 1 | | | | 1 |
| Fluid intake decreased | | 2 | | 1 | | 1 |
| Fluid intake increased | | 2 | | 2 | | |
| General nutritional disorders NEC | 11 | 26 | 11 | 24 | | 2 |
| Hyperglycaemic conditions NEC | 1 | 4 | 1 | 2 | | 2 |
| Hyperlipidaemias NEC | 1 | 1 | | | 1 | 1 |
| Hypoglycaemic conditions NEC | 2 | 6 | 2 | 6 | | |
| Magnesium metabolism disorders | | 1 | | | | 1 |
| Metabolic acidoses (excl diabetic acidoses) | | 1 | | 1 | | |
| Potassium imbalance | 1 | 2 | | | 1 | 2 |
| Total fluid volume decreased | 15 | 41 | 11 | 32 | 4 | 9 |
| Total fluid volume increased | 2 | 2 | 1 | 1 | 1 | 1 |
| | 108 | 281 | 88 | 231 | 20 | 50 |

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System Organ Class

Musculoskeletal and connective tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Arthropathies NEC | 20 | 47 | 18 | 43 | 2 | 4 |
| Bone disorders NEC | 3 | 4 | 3 | 4 | | |
| Bone related signs and symptoms | 39 | 126 | 34 | 113 | 5 | 13 |
| Bursal disorders | | 1 | | 1 | | |
| Cartilage disorders | 3 | 5 | 2 | 3 | 1 | 2 |
| Connective tissue disorders NEC | 3 | 7 | | | 3 | 7 |
| Extremity deformities | 2 | 2 | 2 | 2 | | |
| Intervertebral disc disorders NEC | 1 | 2 | | 1 | 1 | 1 |
| Joint related disorders NEC | 1 | 7 | 1 | 4 | | 3 |
| Joint related signs and symptoms | 371 | 1,091 | 360 | 1045 | 11 | 46 |
| Ligament disorders | | 1 | | 1 | | |
| Lupus erythematosus (incl subtypes) | | 1 | | | | 1 |
| Muscle infections and inflammations | 1 | 3 | 1 | 1 | | 2 |
| Muscle pains | 325 | 1,140 | 310 | 1088 | 15 | 52 |
| Muscle related signs and symptoms NEC | 75 | 226 | 67 | 207 | 8 | 19 |
| Muscle tone abnormalities | 3 | 8 | | 5 | 3 | 3 |
| Muscle weakness conditions | 49 | 116 | 35 | 89 | 14 | 27 |
| Musculoskeletal and connective tissue conditions NEC | 83 | 193 | 72 | 172 | 11 | 21 |
| Musculoskeletal and connective tissue deformities of skull, face and buccal cavity | | 1 | | 1 | | |
| Musculoskeletal and connective tissue infections and inflammations NEC | 2 | 2 | | | 2 | 2 |
| Musculoskeletal and connective tissue pain and discomfort | 761 | 2,216 | 708 | 2110 | 53 | 106 |
| Osteoarthropathies | 2 | 3 | 2 | 3 | | |
| Psoriatic arthropathies | | 1 | | | | 1 |
| Rheumatoid arthropathies | 5 | 7 | | | 5 | 7 |
| Soft tissue disorders NEC | 9 | 27 | 8 | 24 | 1 | 3 |
| Spine and neck deformities | 1 | 1 | 1 | 1 | | |
| Synovial disorders | 2 | 2 | 2 | 2 | | |
| Tendon disorders | 2 | 8 | 2 | 7 | | 1 |
| | 1,763 | 5,248 | 1628 | 4927 | 135 | 321 |

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Aural neoplasms malignant and unspecified | | 1 | | 1 | | |
| Breast and nipple neoplasms malignant | 1 | 1 | | | 1 | 1 |
| Cardiovascular neoplasms malignant and unspecified | | 1 | | | | 1 |
| Colorectal neoplasms malignant | 1 | 1 | | | 1 | 1 |
| Endocrine neoplasms malignant and unspecified NEC | 1 | 1 | | | 1 | 1 |
| Leukaemias acute myeloid | 2 | 2 | | | 2 | 2 |
| Leukaemias chronic myeloid | 1 | 1 | | | 1 | 1 |
| Leukaemias NEC | 1 | 1 | | | 1 | 1 |
| Lymphomas unspecified NEC | 2 | 2 | | | 2 | 2 |
| Mediastinal neoplasms malignancy unspecified NEC | 1 | 1 | | | 1 | 1 |
| Metastases to specified sites | | 1 | | | | 1 |
| Neoplasms malignant site unspecified NEC | 1 | 1 | | | 1 | 1 |
| Respiratory tract and pleural neoplasms malignant cell type unspecified NEC | 1 | 2 | | | 1 | 2 |
| Skin neoplasms malignant and unspecified (excl melanoma) | 1 | 2 | 1 | 2 | | |
| Thyroid neoplasms malignant | 1 | 1 | | | 1 | 1 |
| | 14 | 19 | 1 | 3 | 13 | 16 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abnormal reflexes | 3 | 3 | 1 | 1 | 2 | 2 |
| Abnormal sleep-related events | 1 | 2 | 1 | 2 | | |
| Acute polyneuropathies | 9 | 12 | | | 9 | 12 |
| Auditory nerve disorders | | 1 | | | | 1 |
| Autonomic nervous system disorders | 1 | 2 | 1 | 1 | | 1 |
| Central nervous system aneurysms and dissections | 1 | 1 | | | 1 | 1 |
| Central nervous system haemorrhages and cerebrovascular accidents | 51 | 75 | | | 51 | 75 |
| Chronic polyneuropathies | | 1 | | | | 1 |
| Coma states | 2 | 3 | | | 2 | 3 |
| Coordination and balance disturbances | 41 | 89 | 32 | 68 | 9 | 21 |
| Cortical dysfunction NEC | 5 | 14 | 2 | 8 | 3 | 6 |
| Cranial nerve disorders NEC | 1 | 1 | | | 1 | 1 |
| Dementia (excl Alzheimer's type) | 8 | 8 | | | 8 | 8 |
| Demyelinating disorders NEC | | 1 | | | | 1 |
| Disturbances in consciousness NEC | 211 | 462 | 79 | 238 | 132 | 224 |
| Disturbances in sleep phase rhythm | 1 | 2 | 1 | 2 | | |
| Dyskinesias and movement disorders NEC | 27 | 72 | 21 | 60 | 6 | 12 |
| Dystonias | | 1 | | | | 1 |
| Encephalitis NEC | 3 | 4 | | | 3 | 4 |
| Encephalopathies NEC | | 1 | | | | 1 |
| Eye movement disorders | 3 | 3 | | | 3 | 3 |
| Facial cranial nerve disorders | 72 | 145 | 1 | 4 | 71 | 141 |
| Generalised tonic-clonic seizures | 2 | 2 | | | 2 | 2 |
| Headaches NEC | 900 | 3,026 | 840 | 2869 | 60 | 157 |
| Increased intracranial pressure disorders | | 3 | | | | 3 |
| Lumbar spinal cord and nerve root disorders | 5 | 7 | 3 | 5 | 2 | 2 |
| Memory loss (excl dementia) | 16 | 36 | 11 | 25 | 5 | 11 |
| Meningitis NEC | 1 | 1 | | | 1 | 1 |
| Mental impairment (excl dementia and memory loss) | 38 | 81 | 14 | 37 | 24 | 44 |

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System Organ Class

Nervous system disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|------|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Migraine headaches | 57 | 164 | 53 | 153 | 4 | 11 |
| Mononeuropathies | 4 | 13 | 3 | 10 | 1 | 3 |
| Muscle tone abnormal | 1 | 5 | | 3 | 1 | 2 |
| Myelitis (incl infective) | 1 | 2 | | | 1 | 2 |
| Narcolepsy and hypersomnia | 16 | 46 | 14 | 42 | 2 | 4 |
| Nervous system disorders NEC | 9 | 14 | 5 | 8 | 4 | 6 |
| Neurological signs and symptoms NEC | 485 | 1,364 | 413 | 1180 | 72 | 184 |
| Neurologic visual problems NEC | 7 | 12 | 3 | 4 | 4 | 8 |
| Neuromuscular disorders NEC | 2 | 4 | 2 | 2 | | 2 |
| Olfactory nerve disorders | 39 | 133 | 35 | 117 | 4 | 16 |
| Optic nerve disorders NEC | | 1 | | | | 1 |
| Paraesthesias and dysaesthesias | 338 | 1,017 | 286 | 867 | 52 | 150 |
| Paralysis and paresis (excl cranial nerve) | 14 | 23 | | | 14 | 23 |
| Parkinson's disease and parkinsonism | 2 | 4 | | 2 | 2 | 2 |
| Peripheral neuropathies NEC | 11 | 28 | 2 | 4 | 9 | 24 |
| Seizures and seizure disorders NEC | 20 | 34 | | | 20 | 34 |
| Sensory abnormalities NEC | 124 | 384 | 111 | 353 | 13 | 31 |
| Sleep disturbances NEC | 9 | 29 | 9 | 29 | | |
| Speech and language abnormalities | 35 | 66 | 19 | 42 | 16 | 24 |
| Spinal cord and nerve root disorders NEC | 2 | 3 | | | 2 | 3 |
| Structural brain disorders NEC | 1 | 3 | | | 1 | 3 |
| Transient cerebrovascular events | 4 | 8 | | | 4 | 8 |
| Tremor (excl congenital) | 69 | 203 | 55 | 166 | 14 | 37 |
| Trigeminal disorders | 6 | 10 | 3 | 6 | 3 | 4 |
| Vagus nerve disorders | | 1 | | 1 | | |
| | 2,658 | 7,630 | 2020 | 6309 | 638 | 1321 |

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System Organ Class

Pregnancy, puerperium and perinatal conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---------------------------------------|------------------------------------|--------------------------------------|-------------|---|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Abortions spontaneous | 7 | 12 | | | 7 | 12 |
| Labour onset and length abnormalities | | 1 | | | | 1 |
| Normal pregnancy, labour and delivery | | 1 | | 1 | | |
| Stillbirth and foetal death | 1 | 1 | | | 1 | 1 |
| | 8 | 15 | | 1 | 8 | 14 |

System Organ Class

Product issues

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Device physical property and chemical issues | 2 | 10 | 2 | 9 | | 1 |
| Product distribution and storage issues | 24 | 129 | 24 | 129 | | |
| Product label issues | 1 | 1 | 1 | 1 | | |
| Product packaging issues | 2 | 6 | 2 | 6 | | |
| Product physical issues | 7 | 21 | 7 | 21 | | |
| Product quality issues NEC | 2 | 7 | 2 | 6 | | 1 |
| Product supply and availability issues | 1 | 2 | 1 | 2 | | |
| | 39 | 176 | 39 | 174 | | 2 |

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* I=Interval, C=Cumulative
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System Organ Class

Psychiatric disorders

High Level Term

Interval Total #
Spontaneous AE

Cumulative Total #
Spontaneous AE

| Spontaneous | | | |
|-------------|-----|---------|----|
| Nonserious | | Serious | |
| I | C | I | C |
| 4 | 4 | 2 | 4 |
| 81 | 199 | 9 | 16 |
| | 4 | 2 | 2 |
| 2 | 3 | | |
| | 1 | | 1 |
| 28 | 56 | 14 | 20 |
| | | 7 | 11 |
| 2 | 5 | 1 | 3 |
| 2 | 4 | | 1 |
| 74 | 202 | 3 | 8 |
| 5 | 14 | 1 | 3 |
| 9 | 30 | 1 | 3 |
| 5 | 17 | | 1 |
| 1 | 1 | | |
| | | 18 | 24 |
| | 1 | | |
| 7 | 18 | 1 | 4 |
| 4 | 10 | | 2 |
| 4 | 13 | 1 | 2 |
| 1 | 1 | | 1 |
| 3 | 5 | | |
| 8 | 17 | | 3 |
| 17 | 35 | 1 | 1 |
| 1 | 3 | 4 | 5 |
| | 2 | | |
| 12 | 42 | | 2 |
| | 2 | | |
| 2 | 3 | 1 | 2 |
| 1 | 1 | | 1 |
| | 2 | | |

| | | |
|---|----|-----|
| Abnormal behaviour NEC | 6 | 8 |
| Anxiety symptoms | 90 | 215 |
| Behaviour and socialisation disturbances | 2 | 6 |
| Cognitive and attention disorders and disturbances NEC | 2 | 3 |
| Communications disorders | | 2 |
| Confusion and disorientation | 42 | 76 |
| Deliria | 7 | 11 |
| Depressive disorders | 3 | 8 |
| Dissociative states | 2 | 5 |
| Disturbances in initiating and maintaining sleep | 77 | 210 |
| Eating disorders NEC | 6 | 17 |
| Emotional and mood disturbances NEC | 10 | 33 |
| Fear symptoms and phobic disorders (incl social phobia) | 5 | 18 |
| Fluctuating mood symptoms | 1 | 1 |
| Hallucinations (excl sleep-related) | 18 | 24 |
| Impulse control disorders | | 1 |
| Increased physical activity levels | 8 | 22 |
| Mental disorders NEC | 4 | 12 |
| Mood alterations with depressive symptoms | 5 | 15 |
| Mood alterations with manic symptoms | 1 | 2 |
| Mood disorders NEC | 3 | 5 |
| Panic attacks and disorders | 8 | 20 |
| Parasomnias | 18 | 36 |
| Perception disturbances NEC | 5 | 8 |
| Psychiatric symptoms NEC | | 2 |
| Sleep disorders NEC | 12 | 44 |
| Somatic symptom disorders | | 2 |
| Speech articulation and rhythm disturbances | 3 | 5 |
| Stereotypies and automatisms | 1 | 2 |
| Stress disorders | | 2 |

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* I=Interval, C=Cumulative
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System Organ Class

Psychiatric disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Substance related and addictive disorders | | 1 | | | | 1 |
| Suicidal and self-injurious behaviour | 2 | 2 | | | 2 | 2 |
| Thinking disturbances | 10 | 22 | 9 | 20 | 1 | 2 |
| Tic disorders | | 1 | | 1 | | |
| | 351 | 841 | 282 | 716 | 69 | 125 |

System Organ Class

Renal and urinary disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Bladder and urethral symptoms | 23 | 45 | 18 | 38 | 5 | 7 |
| Bladder disorders NEC | 1 | 1 | 1 | 1 | | |
| Genital and urinary tract disorders NEC | 1 | 1 | 1 | 1 | | |
| Nephropathies and tubular disorders NEC | 1 | 1 | 1 | 1 | | |
| Renal disorders NEC | 6 | 8 | 2 | 4 | 4 | 4 |
| Renal failure and impairment | 3 | 8 | | | 3 | 8 |
| Renal lithiasis | 2 | 3 | | | 2 | 3 |
| Renal structural abnormalities and trauma | 1 | 1 | | | 1 | 1 |
| Urethral disorders NEC | 2 | 2 | 1 | 1 | 1 | 1 |
| Urinary abnormalities | 8 | 15 | 7 | 13 | 1 | 2 |
| Urinary tract signs and symptoms NEC | 9 | 24 | 7 | 22 | 2 | 2 |
| | 57 | 109 | 38 | 81 | 19 | 28 |

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* I=Interval, C=Cumulative
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 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Reproductive system and breast disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breast disorders NEC | 1 | 2 | 1 | 2 | | |
| Breast signs and symptoms | 18 | 40 | 18 | 39 | | 1 |
| Erection and ejaculation conditions and disorders | 4 | 4 | | | 4 | 4 |
| Lactation disorders | | 2 | | 2 | | |
| Menopausal effects NEC | 1 | 1 | 1 | 1 | | |
| Menstruation and uterine bleeding NEC | 12 | 38 | 12 | 38 | | |
| Menstruation with decreased bleeding | 2 | 2 | 1 | 1 | 1 | 1 |
| Menstruation with increased bleeding | 6 | 9 | 6 | 9 | | |
| Pelvis and broad ligament disorders NEC | | 1 | | 1 | | |
| Penile and scrotal infections and inflammations | 1 | 1 | 1 | 1 | | |
| Penile disorders NEC (excl erection and ejaculation) | | 1 | | | | 1 |
| Reproductive tract disorders NEC (excl neoplasms) | 2 | 2 | 2 | 2 | | |
| Reproductive tract signs and symptoms NEC | 1 | 4 | 1 | 3 | | 1 |
| Scrotal disorders NEC | 3 | 3 | 3 | 3 | | |
| Sexual function and fertility disorders NEC | 1 | 1 | 1 | 1 | | |
| Testicular and epididymal disorders NEC | 2 | 3 | 2 | 3 | | |
| Uterine disorders NEC | | 1 | | | | 1 |
| Uterine infections and inflammations (excl cervix) | 1 | 1 | 1 | 1 | | |
| Vulvovaginal disorders NEC | 2 | 9 | 2 | 5 | | 4 |
| Vulvovaginal signs and symptoms | 2 | 5 | 2 | 2 | | 3 |
| | 59 | 130 | 54 | 114 | 5 | 16 |

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

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Breathing abnormalities | 199 | 545 | 128 | 345 | 71 | 200 |
| Bronchial conditions NEC | 1 | 1 | | | 1 | 1 |
| Bronchospasm and obstruction | 28 | 81 | 19 | 53 | 9 | 28 |
| Conditions associated with abnormal gas exchange | | 2 | | | | 2 |
| Coughing and associated symptoms | 126 | 402 | 112 | 348 | 14 | 54 |
| Diaphragmatic disorders | 1 | 1 | | | 1 | 1 |
| Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) | 3 | 3 | | | 3 | 3 |
| Laryngeal spasm, oedema and obstruction | 2 | 11 | | | 2 | 11 |
| Lower respiratory tract inflammatory and immunologic conditions | 2 | 3 | | 1 | 2 | 2 |
| Lower respiratory tract signs and symptoms | 9 | 19 | 8 | 17 | 1 | 2 |
| Nasal congestion and inflammations | 42 | 174 | 40 | 162 | 2 | 12 |
| Nasal disorders NEC | 27 | 64 | 19 | 52 | 8 | 12 |
| Paranasal sinus disorders (excl infections and neoplasms) | 17 | 45 | 16 | 43 | 1 | 2 |
| Parenchymal lung disorders NEC | 2 | 5 | | 1 | 2 | 4 |
| Pharyngeal disorders (excl infections and neoplasms) | 52 | 164 | 35 | 103 | 17 | 61 |
| Pleural infections and inflammations | 2 | 3 | 1 | 1 | 1 | 2 |
| Pneumothorax and pleural effusions NEC | | 2 | | | | 2 |
| Pulmonary oedemas | 5 | 11 | | | 5 | 11 |
| Pulmonary thrombotic and embolic conditions | 3 | 6 | | | 3 | 6 |
| Respiratory failures (excl neonatal) | 2 | 5 | | 1 | 2 | 4 |
| Respiratory signs and symptoms NEC | 7 | 12 | 5 | 9 | 2 | 3 |
| Respiratory tract disorders NEC | 15 | 31 | 9 | 23 | 6 | 8 |
| Tracheal disorders (excl infections and neoplasms) | | 1 | | | | 1 |
| Upper respiratory tract signs and symptoms | 273 | 948 | 235 | 790 | 38 | 158 |
| | 818 | 2,539 | 627 | 1949 | 191 | 590 |

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System Organ Class

Skin and subcutaneous tissue disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|---|------------------------------------|--------------------------------------|-------------|------|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Acnes | 5 | 10 | 5 | 10 | | |
| Alopecias | 2 | 5 | 2 | 5 | | |
| Angioedemas | 6 | 19 | | 1 | 6 | 18 |
| Apocrine and eccrine gland disorders | 147 | 417 | 139 | 384 | 8 | 33 |
| Bullous conditions | 12 | 32 | 6 | 25 | 6 | 7 |
| Dermal and epidermal conditions NEC | 71 | 161 | 63 | 146 | 8 | 15 |
| Dermatitis and eczema | 9 | 32 | 8 | 30 | 1 | 2 |
| Dermatitis ascribed to specific agent | | 2 | | 2 | | |
| Erythemas | 94 | 258 | 81 | 221 | 13 | 37 |
| Exfoliative conditions | 6 | 11 | 6 | 9 | | 2 |
| Hypopigmentation disorders | 1 | 1 | 1 | 1 | | |
| Photosensitivity and photodermatosis conditions | 3 | 11 | 3 | 11 | | |
| Pigmentation changes NEC | 1 | 1 | | | 1 | 1 |
| Pilar disorders NEC | | 5 | | 4 | | 1 |
| Pruritus NEC | 156 | 481 | 136 | 429 | 20 | 52 |
| Psoriatic conditions | 2 | 3 | 2 | 3 | | |
| Purpura and related conditions | 9 | 21 | 6 | 16 | 3 | 5 |
| Rashes, eruptions and exanthems NEC | 262 | 745 | 220 | 643 | 42 | 102 |
| Rosaceas | 1 | 2 | 1 | 2 | | |
| Scaly conditions | 1 | 1 | 1 | 1 | | |
| Skin and subcutaneous conditions NEC | 1 | 2 | 1 | 2 | | |
| Skin and subcutaneous tissue ulcerations | 2 | 2 | 1 | 1 | 1 | 1 |
| Skin haemorrhages | 1 | 1 | 1 | 1 | | |
| Skin vascular conditions NEC | 1 | 1 | 1 | 1 | | |
| Skin vasculitides | 2 | 2 | 2 | 2 | | |
| Skin vasomotor conditions | 1 | 4 | | 1 | 1 | 3 |
| Urticarias | 78 | 334 | 61 | 267 | 17 | 67 |
| | 874 | 2,564 | 747 | 2218 | 127 | 346 |

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System Organ Class

Social circumstances

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|-------------------|------------------------------------|--------------------------------------|-------------|----|---------|----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Disability issues | 26 | 71 | 20 | 61 | 6 | 10 |
| Social issues NEC | 1 | 3 | 1 | 3 | | |
| | 27 | 74 | 21 | 64 | 6 | 10 |

System Organ Class

Surgical and medical procedures

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|---|---------|---|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Dental and gingival therapeutic procedures | 1 | 1 | 1 | 1 | | |
| Immunisations | | 1 | | 1 | | |
| Spine and spinal cord therapeutic procedures | | 1 | | | | 1 |
| Therapeutic procedures NEC | 1 | 1 | 1 | 1 | | |
| | 2 | 4 | 2 | 3 | | 1 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Vascular disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | | | |
|--|------------------------------------|--------------------------------------|-------------|-----|---------|-----|
| | | | Nonserious | | Serious | |
| | | | I | C | I | C |
| Accelerated and malignant hypertension | 2 | 7 | | | 2 | 7 |
| Aneurysms and dissections non-site specific | 2 | 2 | | | 2 | 2 |
| Arterial infections and inflammations | | 1 | | 1 | | |
| Blood pressure disorders NEC | 5 | 8 | 5 | 7 | | 1 |
| Circulatory collapse and shock | 4 | 9 | | | 4 | 9 |
| Haemorrhages NEC | 14 | 20 | | 1 | 14 | 19 |
| Lymphoedemas | 2 | 11 | 2 | 11 | | |
| Non-site specific embolism and thrombosis | 14 | 19 | | | 14 | 19 |
| Non-site specific vascular disorders NEC | 5 | 10 | 5 | 10 | | |
| Peripheral embolism and thrombosis | 4 | 10 | | | 4 | 10 |
| Peripheral vascular disorders NEC | 71 | 305 | 59 | 244 | 12 | 61 |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | 16 | 49 | 14 | 45 | 2 | 4 |
| Phlebitis NEC | | 1 | | 1 | | |
| Site specific vascular disorders NEC | 18 | 37 | 11 | 26 | 7 | 11 |
| Varicose veins NEC | | 1 | | 1 | | |
| Vascular hypertensive disorders NEC | 65 | 142 | 39 | 88 | 26 | 54 |
| Vascular hypotensive disorders | 19 | 39 | 11 | 22 | 8 | 17 |
| | 241 | 671 | 146 | 457 | 95 | 214 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

UNITED STATES MINOR OUTLYING ISLANDS

System Organ Class

General disorders and administration site conditions

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|----------------------------|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Vaccination site reactions | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Injury, poisoning and procedural complications

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|--|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Product administration errors and issues | | 1 | | 1 |
| | | 1 | | 1 |

System Organ Class

Respiratory, thoracic and mediastinal disorders

| High Level Term | Interval Total # Spontaneous AE | Cumulative Total # Spontaneous AE | Spontaneous | |
|---|------------------------------------|--------------------------------------|-------------|---|
| | | | Nonserious | |
| | | | I | C |
| Coughing and associated symptoms | 1 | 1 | 1 | 1 |
| Paranasal sinus disorders (excl infections and neoplasms) | 1 | 1 | 1 | 1 |
| Upper respiratory tract signs and symptoms | 1 | 1 | 1 | 1 |
| | 3 | 3 | 3 | 3 |

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* I=Interval, C=Cumulative
 * AE=Adverse Event
 * Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Appendix 3 (Referred in Section 9.2 Overview of Signals)

Tabular summary of safety topics and signals evaluated during the reporting interval

Product name: PF-07302048 (BNT162b2)

Reporting interval: 01 February 2021 – 28 February 2021

Eye swelling and Eye pain were signals that were closed (determined not to be risks) on 03 February 2021. Vomiting and Diarrhoea were signals that were closed (determined to be adverse reactions) on 10 February 2021. This is noted in the SMSR (01 Jan 2021 – 31 Jan 2021), therefore these events are not included in this table.

| Signal Term | Date Detected | Status (ongoing, or closed) | Date Closed (for closed signals) | Source or trigger of signal | Reason for evaluation and summary of key data | Method of signal evaluation | Action(s) taken or planned |
|---|---------------|-----------------------------|----------------------------------|--|--|---|---|
| Signals Determined not to be Risks | | | | | | | |
| Hearing Loss and Tinnitus | 08 Feb 2021 | Closed | 17 Feb 2021 | Post-authorization spontaneous reports and clinical safety data review. Note: Following internal review of hearing loss, the Jan 2021 SMSR EMA/PRAC final assessment requested review of hearing loss and tinnitus (Competent authority [EMA] request for assessment) | Cases of hearing loss were noted in clinical study C4591001 and in post-authorization reports. | Clinical study and safety database case series review Epidemiology observed vs expected analyses Note: Following receipt of PRAC Jan 2021 SMSR Final assessment report, Hearing loss was re-evaluated, and Tinnitus was evaluated | Following evaluation of reports and vaccine literature, it was determined that the available data did not support a causal association with vaccine. The topic will continue to be monitored. |

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| Signal Term | Date Detected | Status (ongoing, or closed) | Date Closed (for closed signals) | Source or trigger of signal | Reason for evaluation and summary of key data | Method of signal evaluation | Action(s) taken or planned |
|--|--|-----------------------------|----------------------------------|---|---|--|--|
| Delayed Syncope | 04 Feb 2021 | Closed | 24 Feb 2021 | Competent authority (US-FDA) request for assessment | To determine if delayed syncope is a risk following the US-FDA request to provide an assessment of syncope occurring at least 1 day after vaccination | Clinical study and safety database case review | Delayed syncope and loss of consciousness were evaluated, and it was determined that there is insufficient evidence to support a causal relationship to vaccine. The topic will continue to be monitored |
| Immune Thrombocytopenia | 21 Jan 2021 Re-opened 25 Feb 2021 | Closed | 08 Mar 2021 | Inquiry from multiple competent authorities Signal re-opened following receipt of EMA/PRAC final assessment report of Jan 2021 SMSR requesting a review of immune thrombocytopenia | To determine if thrombocytopenia is a risk of vaccination | Review of clinical and non-clinical study data and review of post-authorization and epidemiological safety data. | Following evaluation, it was determined that that the available data did not support a causal association with vaccine. The topic will continue to be closely monitored. |
| Topics Determined not to be Validated Signals | | | | | | | |
| Myocarditis and Pericarditis | 15 Feb 2021 | Closed | 17 Feb 2021 | Competent authority (MHRA) request for assessment | To determine if reports of myocarditis or pericarditis are a safety signal | Safety database case review | Post-authorization cases and O/E analyses reviewed, and safety topic was determined not to be a validated signal |

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| Signal Term | Date Detected | Status (ongoing, or closed) | Date Closed (for closed signals) | Source or trigger of signal | Reason for evaluation and summary of key data | Method of signal evaluation | Action(s) taken or planned |
|---|---------------|-----------------------------|----------------------------------|--|---|---|---|
| Guillain-Barre syndrome | 26 Feb 2021 | Closed | 03 Mar 2021 | Competent authority (EMA) request for assessment | To determine if reports of GBS are a safety signal | Safety database case review | Post-authorization cases and O/E analyses reviewed, and safety topic was determined not to be a validated signal |
| Severe cutaneous adverse reactions (SCAR) | 21 Feb 2021 | Closed | 03 Mar 2021 | Post-authorization spontaneous reports | To determine if reports of Erythema multiforme, Stevens Johnson syndrome or Toxic epidermal necrolysis are a safety signal | Safety database case review | Post-authorization cases and O/E analyses reviewed, and safety topic was determined not to be a validated signal |
| Ongoing Signals | | | | | | | |
| Tachycardia | 28 Jan 2021 | Ongoing | NA | Board of Health PV report | PV Report from France (Marseille PV Regional Centre) for period 17 Dec 2020 to 15 Jan noted 4 cases of serious tachycardia and considered it a potential signal | Clinical study and safety database case series review | An evaluation of tachycardia has been subsumed in an evaluation of vaccine stress-related responses that is ongoing |

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| Signal Term | Date Detected | Status (ongoing, or closed) | Date Closed (for closed signals) | Source or trigger of signal | Reason for evaluation and summary of key data | Method of signal evaluation | Action(s) taken or planned |
|--------------|---------------|-----------------------------|----------------------------------|---|--|---|--|
| Dizziness | 18 Jan 2021 | Ongoing | NA | Post-authorization spontaneous reports and inquiry from a competent authority | Post authorization data shows dizziness to be among most frequently reported AEs. Additionally, the MHRA noted to Pfizer/BNT in routine PV discussions that they have noted frequently reported events of dizziness and the EMA PRAC final assessment report for the Jan 2021 SMSR contained a request to provide a safety evaluation of Dizziness | Clinical study and safety database case series review | An evaluation of dizziness has been subsumed in an evaluation of vaccine stress-related responses that is ongoing |
| Paraesthesia | 29 Dec 2020 | Ongoing | NA | Post authorization spontaneous reports and inquiry from a competent authority | Inquiries regarding paraesthesia from Israel MOH and PRAC request for review of paraesthesia and dysaesthesia prompted evaluation | Clinical study and safety database case series review | An evaluation of these reports occurred and on 10 Feb 2021 and it was determined that there is insufficient evidence to support a causal relationship to vaccine. However, a further evaluation of paraesthesia has been subsumed in an evaluation of vaccine stress-related responses that is ongoing |

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| Signal Term | Date Detected | Status (ongoing, or closed) | Date Closed (for closed signals) | Source or trigger of signal | Reason for evaluation and summary of key data | Method of signal evaluation | Action(s) taken or planned |
|----------------------------------|--|-----------------------------|----------------------------------|---|--|---|---|
| Vaccine stress-related responses | 10 Feb 2021 | Ongoing | NA | Post authorization spontaneous reports | To determine if data is supportive of including the concept in the CDS and local labels | Clinical study and safety database case series review | An evaluation of this signal is ongoing |
| Herpes Zoster | 05 Oct 2020 as safety topic. Reopened 21 Feb 2021 | Ongoing | NA | 05 Oct 2020: Clinical study safety data review 21 Feb 2021: Post-authorization spontaneous reports | Initially opened as safety topic and closed following review of clinical study data (C4591001). Re-opened: Cases noted on internal non-statistical line listing review. | Review of clinical study data. Review of post-authorization safety data Epidemiology O/E analysis | An evaluation of this signal is ongoing |

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| | | | | | | | |
|------------------|--|---------|----|---|---|---|---|
| Facial paralysis | 03 Dec 2020 opened as safety signal. 19 Dec 2020 reopened | Ongoing | NA | Clinical Trial Data Enquiry from competent authority Post-authorization reports | Initially opened and closed following review of unblinded clinical study data (C4591001) (DLP 14 Nov 2020) Re-opened due to EMA request to include as adverse reaction in EU SmPC at time of conditional approval Signal has remained open and is closely monitored | Review of unblinded clinical study data; review of post-authorization and epidemiological safety data (Observed vs Expected analyses) | At the time of conditional approval by the EMA, facial paralysis was added as an adverse reaction to Section 4.8 of the EU SmPC per EMA request. Core position: Based on the results of the evaluation to date, a causal association with BNT162b2 has not been established. However, causality assessment will be further informed by the evaluation of safety data from the final analysis of clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorization safety studies are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy after vaccination through formal |
|------------------|--|---------|----|---|---|---|---|

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| | | | | | | | |
|--|--|--|--|--|--|--|-----------------------|
| | | | | | | | comparative analyses. |
|--|--|--|--|--|--|--|-----------------------|

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Appendix 3.1 (Referred to in Section 9.2 Overview of Signals)

Summary of Safety Topics and Signal Evaluations

Table 1 presents signal evaluation summaries for PF-07302048 (BNT162b2) during the current reporting period.

Eye swelling and Eye pain were signals that were closed (determined not to be risks) on 03 February 2021 and Vomiting and Diarrhoea were signals that were closed (determined to be adverse reactions) on 10 February 2021. This is noted in the SMSR (01 Jan 2021 – 31 Jan 2021) and therefore they are not included in this table

Table 1. Summary of Signal Evaluations During the Reporting Interval

| Signal | Summary of Evaluation |
|--|---|
| Signals Determined not to be Risks | |
| Hearing loss and tinnitus | Hearing loss was evaluated in early Feb 2021 following reports received from participants in Study C4591001 and reported in the post-authorization safety database. Following evaluation and presentation to the internal joint safety management team, it was determined that the available data did not support a causal association with vaccine. Following this, the EMA PRAC final assessment report for the Jan 2021 SMSR was received and noted to contain a request to review hearing loss/deafness and tinnitus (see Appendix 3.3). A re-evaluation of hearing loss was conducted as was an evaluation of tinnitus. It was determined that there was no change in the previous conclusion on hearing loss and tinnitus was also determined not to be a causally associated risk of BNT162b2 use. This topic will continue to be monitored |
| Delayed syncope | Following a request for assessment of the topic by the US-FDA, Pfizer evaluated post-authorization reports of syncope and loss of consciousness occurring at least 1 day after vaccination. Reports were complicated by the presence of other factors such as hypersensitivity events, reactogenicity events and the presence of baseline medical conditions, including COVID-19, that were potentially contributory to the occurrence of syncope. It was determined that there was insufficient evidence to support a causal association of the specific event of delayed syncope to BNT162b2. This topic will continue to be monitored. |
| Immune Thrombocytopenia | The EMA PRAC final assessment report for the Jan 2021 SMSR contained a request to provide a safety evaluation of Immune thrombocytopenia. This evaluation is included in the Feb 2021 SMSR (See Appendix 3.2). The MAH has closely monitored reports of thrombocytopenia, including reviewing case series of post-authorization cases, non-clinical data, clinical data and epidemiological analyses (O/E). At this time, there is insufficient evidence to conclude that immune thrombocytopenia/thrombocytopenia is caused by BNT162b2. Close monitoring of this event continues. |
| Topics Determined not to be Validated Signals | |
| Myocarditis and Pericarditis | During a routine PV meeting with UK MHRA, the MHRA notified Pfizer of reports of pericarditis and myocarditis being reported to the national Yellow Card scheme. An evaluation of reports in the post-authorization safety database was conducted and the topic was determined not to be a validated signal. This topic will continue to be monitored. |
| Guillain-Barré syndrome | The EMA PRAC final assessment report for the Jan 2021 SMSR contained a request to provide a safety evaluation of Guillain-Barré syndrome. This evaluation is included in the Feb 2021 SMSR (See Appendix 3.6). The outcome of the |

| | |
|---|---|
| | evaluation of reports in the post-authorization safety database is that GBS was determined not to be a validated signal. This topic will continue to be monitored. |
| Severe Cutaneous Adverse Reactions (SCAR) | Reports of Erythema multiforme, Stevens Johnson syndrome and Toxic epidermal necrolysis were noted to be reported in the post-authorization spontaneous safety database and were thus evaluated. The outcome of the evaluation of reports in the post-authorization safety database is that SCAR was determined not to be a validated signal. This topic will continue to be monitored. |
| Ongoing Signals | |
| Tachycardia | Following review of the France Marseille PV Regional Centre PV report (17 Dec 2020 to 15 Jan 2021), in which 4 cases of serious tachycardia were noted as a potential risk, Pfizer has reviewed reports of tachycardia from the post-authorization safety database and the topic has been subsumed in an evaluation of vaccine stress-related responses that is currently ongoing |
| Dizziness | Dizziness has been noted as a frequently reported post-authorization AE in routine pharmacovigilance surveillance. Additionally, <ul style="list-style-type: none"> • In a routine PV meeting, MHRA noted cases of dizziness being reported to the national Yellow Card system, and • The EMA PRAC final assessment report for the Jan 2021 SMSR contained a request to provide a safety evaluation of Dizziness Pfizer has reviewed reports of dizziness from the post-authorization safety database and the evaluation is included in the Feb 2021 SMSR (See Appendix 3.5). The topic was subsequently subsumed in an evaluation of vaccine stress-related responses that is currently ongoing |
| Paraesthesia and Dysaesthesia | Following a query by the Israeli BOH regarding paraesthesia and a request by the PRAC to review paraesthesia and dysaesthesia, an evaluation of events reported in the clinical study and post-authorization setting was conducted on 10 Feb 2021. There was not evidence to support paraesthesia as a neurological causally associated reaction to the vaccine, however a further evaluation of paraesthesia has been subsumed in an evaluation of vaccine stress-related responses that is ongoing. |
| Vaccine stress-related responses | Based on post-authorization report and competent authority comments about events such as tachycardia, paraesthesia and dizziness, the topic of vaccine stress-related responses is ongoing. |
| Herpes zoster | This topic has been monitored in the clinical study (C4591001) and following authorization of the vaccine, cases have been reported to the post-authorization safety database. An evaluation of the signal is ongoing at this time and progress will be updated in the next SMSR. |
| Facial Paralysis | At the time of conditional approval in the EU, “Acute peripheral facial paralysis” was included as an adverse reaction in the EU SmPC at the request of the EMA. The MAH did not include this event in the CDS as a causally associated adverse reaction due to the lack of evidence for a causal association. Monitoring of the event has continued, and it has been determined by the internal joint safety management team, that causality assessment will be further informed by additional data from the remaining clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorization safety studies C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell’s palsy after vaccination through formal comparative analyses. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June 2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk. |

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APPENDIX 3.2 - SAFETY EVALUATION OF IMMUNE THROMBOCYTOPENIA

1. INTRODUCTION

This is an updated evaluation of the spontaneous cases of thrombocytopenia reported to the safety database for BNT/Pfizer COVID-19 vaccine, to be included in the February 2021 Summary Monthly Safety Report (SMSR).

2. METHODOLOGY

The Pfizer safety database was searched for spontaneously reported BNT/Pfizer COVID-19 vaccine post-authorization adverse event reports using MedDRA v 23.1 search strategy HLT Thrombocytopenias and SMQ Haematopoietic thrombocytopenia (narrow and broad) that have been reported to through 25 February 2021 (as of date 26 February 2021).

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

Cases were assessed using the Brighton Collaboration diagnostic criteria for thrombocytopenia.ⁱ The case definition of thrombocytopenia (TP) as an adverse event following immunization proposed by this working group is summarized below:

Level 1 of diagnostic certainty (confirmed TP):

Platelet count less than $150 \times 10^9 /L$

And confirmed by blood smear examination or the presence of clinical signs and symptoms of spontaneous bleeding.

Level 2 of diagnostic certainty (unconfirmed TP):

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Platelet count less than $150 \times 10^9/L$

Level 3 of diagnostic certainty:

Not applicable

3. RESULTS

Using this broad search strategy, 83 cases were retrieved from the safety database. This included the following number of events coded to relevant PTs: Thrombocytopenia (36 events), Immune thrombocytopenia (22 events), Thrombocytopenic purpura and Thrombotic thrombocytopenic purpura (2 events each), Pancytopenia and Platelet disorder (1 event each).

The 83 cases were individually reviewed to ensure focus on the safety event of interest. Eleven reports were eliminated from further review because they contained insufficient information to determine key factors including whether and when thrombocytopenia had occurred in relation to vaccination. A further 5 reports were eliminated because they were not relevant to the topic (1 case of hemoglobin decrease, not platelet decrease; 1 case did not meet BC case definition of thrombocytopenia; 3 cases described a patient inquiring about the appropriateness of vaccination for her husband with history of thrombocytopenia and relaying she heard about cases of thrombocytopenia and death post-vaccination).

The remaining 67 spontaneous reports of thrombocytopenia were reported between 21 Dec 2020 and 24 Feb 2021. They were all serious cases and included 38 women and 26 men between the ages of 21 and 97 years of age (mean 60.1). Country of case origin: US (25), UK (16), Germany and France (6 each), Belgium, Italy and Spain (2 each) and 1 each from Austria, Czech Republic, Ireland, Israel, Mexico, Portugal, Slovenia and Switzerland. There were 8 deaths.

3.1. Brighton Collaboration Criteria Level 1

There were 19 cases meeting criteria for BC Level 1 (platelet count of less than $150 \times 10^9 /L$ and signs or symptoms of bleeding). These cases included 2 patients with a medical history of thrombocytopenia or immune thrombocytopenia, one of which was diagnosed with COVID-19 at the time of their reported AE of thrombocytopenia.

Thirteen cases occurred following dose 1 of the vaccine, 2 followed dose 2 and 4 cases did not specify dose. The latency from vaccination to thrombocytopenia or evidence of bleeding ranged from 1 day following vaccination to 30 days; most cases (15) occurred within 12 days following vaccination. Reported platelet nadirs ranged from 0 to $114 \times 10^9/L$. Treatment was noted in 14 reports and included modalities such as IVIg, platelet transfusions and corticosteroids.

Outcome was provided in 15 cases: Recovered/Recovered with sequelae/Recovering (9), Fatal (3), Not recovered (3). The fatal cases were:

1. AER (b) (6) A 56-year-old male physician in the US with a medical history of hypertension (on no medications), social alcohol use and no history of COVID-19, received his first vaccination on 18 Dec 2020. On 21 Dec, he presented to the ED

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with petechiae on his hands, feet and body. He had no other symptoms. He was found to have a platelet count of <1 . He was admitted and received treatment for 2 weeks including platelet transfusions, IVIG, steroids, rituximab and eltrombopag. His platelet count remained low and on 03 Jan, he was reported to have had an emergency splenectomy. On the same day, he had an intracranial bleed and a craniectomy but died. An autopsy was performed on 05 Jan however results were not provided.

2. AER (b) (6) An 82-year-old man in the UK with a medical history of cardiac bypass on an unspecified anticoagulant and gabapentin, presumably for back pain, received his first vaccination on 07 Jan 2021. He had epistaxis 28 days later and the following morning he collapsed and was found to have a platelet count of 0 and a cerebral haemorrhage. He died that day and it was not reported if an autopsy was performed.
3. AER (b) (6) An 88 year old frail woman in the UK with a medical history of aortic stenosis, atrial fibrillation, colon cancer, chronic renal disease, hip fracture and hypoparathyroidism, on anticoagulants among other medications was admitted to the hospital with symptoms related to an intracranial hemorrhage 30 days following vaccination; her platelet count was $12 \times 10^9/L$. A head CT confirmed the bleed. She was treated for immune thrombocytopenia and was reported to have a modest rise in platelets without extension of the bleeding, however she contracted pneumonia and died.

3.2. Brighton Collaboration Criteria Level 2

There were 32 cases meeting criteria for BC Level 2 (platelet count of less than $150 \times 10^9/L$). These cases included 11 patients with a medical history of thrombocytopenia or immune thrombocytopenia and 1 patient who was diagnosed with COVID-19 at the time of their reported AE of thrombocytopenia.

Twelve cases occurred following dose 1 of the vaccine, 5 followed dose 2 and 14 cases did not specify dose. An additional case (AER (b) (6)) was the only case of rechallenge in the total 67 reports.

- AER (b) (6) A 77 year old man in the US who was receiving unspecified treatment for a low platelet count prior to vaccination, received his first dose of vaccine on 09 Jan 2021 and with routine blood work at an unspecified time later noted that his platelet count had dropped “17 points.” Following his 2nd dose on 30 Jan 2021, blood work at an unspecified time after dose 2 showed that his platelet count had dropped even further (value not provided).

The latency from vaccination to thrombocytopenia or evidence of bleeding ranged from the same day of vaccination to 17 days; most cases (24) occurred within 12 days following vaccination. Reported platelet nadirs ranged from 0 to $138 \times 10^9/L$. Treatment was noted in 18 reports and included modalities such as platelet transfusions and corticosteroids.

Outcome was provided in 18 cases: Recovered/Recovering (8), Not recovered (6), Fatal (4). The fatal cases were:

1. AER (b) (6) 72-year-old man in France with a medical history of neurofibromatosis, kyphosis and chronic anxiety on multiple medications was brought to the hospital by his wife 9 days following vaccination for worsening of his general condition including cognitive and psychiatric states. Since the day after vaccination he had been having trouble breathing, fatigue, diffuse pain and asthenia that had limited his ability to go on walks. In the hospital, he was found to have thrombocytopenia (platelets 125 G/L), lymphopenia (0.8 G/L) and anemia (12.5 g/dl). The platelet nadir while in hospital was 73. Following an extensive workup, he was thought to have a rapidly progressive neurological disorder such as progressive Parkinson-like syndrome. After 1 week in the hospital he developed aspiration pneumonia; he died due to adult respiratory distress syndrome after 20 days in the hospital.
2. AER (b) (6) A 73-year-old man in Belgium with a history of end-stage renal disease (on hemodialysis), heart failure, atrial fibrillation, pneumonia and malnutrition received his 2nd vaccination on 06 Feb 2021. He developed a headache 30 minutes later then had decreased oxygen saturation and became comatose. In the hospital he had an elevated CRP, dimers, lactate and troponin (107 ng/l) and platelets of 61,000. He died that night; doctors did not think there was a causal relationship to the vaccine.
3. AER (b) (6) A 96-year-old woman in France with a medical history of osteoporosis, tetraparesis from cervical stenosis, severe kyphoscoliosis, hypothyroidism and supraventricular tachycardia on multiple medications received vaccination on 07 Jan 2021. The following day she was noted to have worsening cognitive function, falling out of bed, etc. Over the course of the next 10 days her oxygen requirements increased, and heart rate alternated between bradycardia and tachycardia (150 bpm) including atrial fibrillation. She was not febrile. Platelet count 8 days following vaccination was 96,000. Her other labs showed hyponatremia, hyperkalemia and elevated CRP. She died on 17 Jan 2021; an autopsy was not performed.
4. AER (b) (6) The wife of a man of unspecified age in the US reported that her husband died 2 weeks following vaccination of thrombocytopenia. His medical history and medications were not provided. She reported only the following: BP 159/106, bilirubin 1.50, osmolarity 297, urea 22.3, monocytes 12.1%, platelets 0. It was not known if an autopsy was performed.

3.3. Brighton Collaboration Criteria Level 3

There were 16 cases meeting criteria for BC Level 3. These cases included 1 patient with a medical history of immune thrombocytopenia.

Seven cases occurred following dose 1 of the vaccine, 2 followed dose 2 and 7 cases did not specify dose. When specified, latency from vaccination to thrombocytopenia or evidence of bleeding ranged from the same day as vaccination to 32 days following vaccination; half of the cases (8) occurred within 12 days following vaccination. Two cases specified platelet counts (5 and 70 x 10⁹/L). Treatment was noted in 5 reports.

Outcome was provided in 9 cases: Recovered/Recovering (4), Not recovered (4), Fatal (1).
 The fatal case was:

1. AER (b) (6) A consumer in the US reported that a patient of unspecified age and gender experienced thrombocytopenia, neutropenic fever and a pulmonary embolism at an unspecified date in relation to vaccination. Medical history and medications were not reported. The patient died on an unspecified date and it was not known if an autopsy was performed.

4. EPIDEMIOLOGY ANALYSIS

The MAH has conducted unadjusted observed to expected ratio (O/E) analyses for the 67 spontaneous reports of thrombocytopenia as of 26 February 2021. Expected case counts were derived using respective background incidence rates of 3.82/100,000 PYⁱⁱ.

An estimated 64,572,821.9 doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 21 February 2021ⁱ. This estimate was derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized.ⁱⁱⁱ For periods when more than one vaccine was authorized for use in each country, the doses administered were assumed to be divided equally by the number of vaccines approved. This estimate does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios are reported with a 21-day risk window and without any risk window for the cumulative period with exposure through 21 February 2021. The O/E for both risk windows includes all cases in the numerator regardless of the duration between vaccination and the date of event onset.

Table 1. Observed to Expected Ratio of Spontaneously Reported Thrombocytopenia through 21 Feb 2021, Background Rate = 3.82/100,000PY^a

| | 21 Days (2,875,622 PY) | No risk window (4,396,086 PY) |
|-----------------------------|-----------------------------------|--|
| Observed cases ^b | 67 | 67 |
| Expected cases | 110 | 168 |
| O/E | 0.610 | 0.399 |
| (95% CI) | 0.473, 0.775 | 0.309, 0.507 |

a. Willame, 2020

b. Subsequent to review

The ratios of observed to expected cases do not exceed 1 over either risk window.

¹ Thrombocytopenia cases are reported through 26 February. Pfizer generates person years of exposure on weekly basis. Expected number of cases is based on 21 February 2021 to provide a conservative estimate for signal detection.

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There are several limitations to observed to expected analyses for signal detection. The observed case counts are likely to be underestimated due to underreporting that occurs with spontaneous report surveillance. Additional reasons for underestimations include incomplete reporting and lags in reporting. Spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are more likely to be reported even if they do not meet the clinical definition. Conversely, events that have not been previously associated with a vaccine are more likely to be underreported due to lack of recognition of a potential association.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Additionally, with multiple vaccines becoming available globally, the assumption that the vaccines are distributed in equal proportions may lead to over or underestimates.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. The population from which the background rates used in this analysis were derived may differ from the vaccinated population with respect to delivery of health care, population demographics, and underlying health status of the populations. To date, the majority of exposure derives from the US.

A final limitation concerns the risk windows, the time it is assumed that one is at risk for a given event if there is a causal association to the vaccine. Expected cases counts were determined under two assumptions: a 21 day window and an unlimited risk window. Observed to expected analyses were completed using the same number of observed cases compared to expected under both assumptions, regardless of proximity of the reported event to the date of vaccination. This may lead to an overestimation of the O/E ratio if the observed cases occurred outside of the 21-day risk period. On the other hand, the ratio may be underestimated using the unlimited risk window if the risk period is finite.

5. SUMMARY AND CONCLUSION

The safety database contains 67 spontaneous reports of thrombocytopenia following the Pfizer/BNT COVID-19 vaccine as of 26 Feb 2021. Due to the diversity of case details, for example, variable time to onset to thrombocytopenia or bleeding, variable patient age and co-morbidities, variable outcomes from recovered to fatal and occurrence at either dose 1 or dose 2, it seems unlikely that a similar mechanism for thrombocytopenia is at play in these cases. Further, thrombocytopenia occurring on the same day or within a few days of vaccination seem inconsistent with a vaccine-mediated immune mechanism of platelet destruction. Currently, there is insufficient data to confirm a causal association. This topic will be followed closely in the upcoming PSURs.

ⁱ Thrombocytopenia: Case definition and guidelines for collection, analysis, and presentation of immunization safety data. Wise, RP et al. The Brighton Collaboration Thrombocytopenia Working Group. *Vaccine* 25 (2007) 5717-5724.

ⁱⁱ Willame C, Dodd C, van der Aa L, Picelli G, Emborg HD, Kahlert J, Gini R, Huerta C, Martín-Merino E, McGee C, de Lusignan S, Roberto G, Villa M, Weibel D, Titievsky L, Sturkenboom MCJM. Incidence Rates of Autoimmune Diseases in European Healthcare Databases: A Contribution of the ADVANCE Project. *Drug Saf.* 2021 Mar;44(3):383-395. doi: 10.1007/s40264-020-01031-1. Epub 2021 Jan 19. PMID: 33462778; PMCID: PMC7892524.

ⁱⁱⁱ <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates> (accessed 21 February 2021).

APPENDIX 3.3 – SAFETY EVALUATION OF HEARING LOSS AND TINNITUS

1. INTRODUCTION

This is an evaluation of cases of deafness, sudden hearing loss and tinnitus spontaneously reported to the Pfizer safety database for BNT/Pfizer COVID-19 vaccine; this evaluation will be included in the February 2021 Summary Monthly Safety Report (SMSR).

2. METHODOLOGY

The Pfizer safety database was searched for spontaneously reported BNT/Pfizer COVID-19 vaccine post-authorization adverse event reports using MedDRA v 23.1 search strategy SMQ Hearing impairment (**narrow**) that were reported through 25 February 2021 (as of date 26 February 2021).

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an adverse event, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an adverse event is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.
- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports does not necessarily indicate that a particular adverse event was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

3. RESULTS

Using this wide search strategy, 463 cases were retrieved from the safety database. This included the following number of events coded to relevant PTs: Deafness (57 events), Deafness bilateral (3 events), Deafness neurosensory (12 events), Deafness transitory (2 events), Deafness unilateral (22 events), Sudden hearing loss (17 events) and Tinnitus (290 events).

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3.1. Hearing Loss

Cases coded with any PT containing the term “deafness” or with the PT Sudden hearing loss were individually reviewed to ensure focus on the safety event of interest. From a total of 109 cases, 15 were eliminated from further review:

- 2 cases did not describe hearing loss following vaccination,
- 9 cases contained evidence of a more likely explanation of hearing loss (5 cases described brief hearing loss in association with fainting/vasovagal event, 2 cases described the presence of an ear/external ear infection, 1 case described brief hearing loss associated with a diabetic coma, and 1 case described a HBV vaccination with a closer temporal association with the hearing loss than the COVID-19 vaccination), and
- 4 cases contained insufficient information to determine whether and when hearing loss had occurred in relation to vaccination.

The remaining 94 reports of deafness or sudden hearing loss were reported between 17 Dec 2020 and 19 Feb 2021. They were all serious cases and included 58 women and 34 men between the ages of 19 and 93 years of age (mean 56.3). Country of case origins were: US (40), UK (21), Germany (9), Netherlands (5), Italy (3), Spain, Poland, Greece and France (2 each), Belgium, Canada, Croatia, Czech Republic, Mexico, Portugal, Serbia and Sweden (1 each). There were no deaths.

Of the 94 reports, time from vaccination to onset of hearing loss was noted in 84:

- On the same day of vaccination (16); from 30 minutes to 6 hours,
- One day following vaccination (25),
- 2-3 days following vaccination (16),
- 4-7 days following vaccination (16),
- 9-14 days following vaccination (7),
- 16-21 days following vaccination (4).

Fifty-three (53) patients reported experiencing hearing loss after dose 1, 12 were reported following dose 2 and 29 reports did not specify dose. One report described a patient with hearing loss after dose 1 that worsened after dose 2 (AER (b) (6)). Tinnitus was co-reported with a minority of the cases (28/94, 29.8%).

Some of the patients (23) had medical histories potentially contributory to hearing loss. These histories included patients with:

- Previous hearing loss with or without tinnitus (5),
- Tinnitus alone (1),
- Acoustic neuroma (1),
- Meniere’s disease (1),
- Autoimmune disease (3),
- Diabetes mellitus (5),
- Migraine with vestibular symptoms (1),
- History of COVID-19 (5),
- Stroke (1).

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Outcome information showed 36 (38.3%) patients recovered, recovered with sequelae or were recovering; and 42 (44.7%) had not recovered at the time of reporting. Of the 36 patients who recovered or were recovering their hearing, ages ranged from 25 to 90 years (mean 54.8), 80.6% of the cases had a time to onset of less than 7 days and the duration of hearing loss, when provided, ranged from 10 minutes to 4 weeks; in the majority of cases (12/16, 75%), the duration was ≤ 7 days. Tinnitus was concurrent with 10 of the cases.

3.2. Tinnitus

There were 285 reports coded with the PT Tinnitus between 14 Dec 2020 and 23 Feb 2021. Of these 285 reports, 168 were serious and 117 were non-serious. The reports included 216 women and 65 men between the ages of 19 and 85 years of age (mean 50.8). Country of case origins were: US (108), UK (111), Italy (11), Mexico (8), Greece (7), France (5), Poland and Hungary (4 each), Finland, Spain, Denmark and Croatia (3 each), Canada and Germany (2 each) and singular cases from Sweden, Slovakia, Serbia, Romania, Portugal, Netherlands, Israel, Ireland, Czech Republic, Bulgaria and Austria. There were no deaths.

Focusing on the 168 serious reports containing the event Tinnitus, 2 of the reports were not relevant to the topic because they did not describe tinnitus. The remaining 166 reports included 129 women and 35 men between the ages of 22 and 85 years of age (mean 50.6). Latency from vaccination to tinnitus was provided in 133 reports and ranged from the same day (2 minutes after vaccination) to 30 days:

- Same day of vaccination (37)
- 1 day following vaccination (39)
- 2 days following vaccination (21)
- 3-6 days following vaccination (23)
- 7-9 days following vaccination (4)
- 10-20 days following vaccination (6)
- 21-30 days following vaccination (3)

When specified, 58 of the tinnitus events occurred after dose 1 and 16 occurred after dose 2. Two reports (AER (b) (6) and AER (b) (6)) described tinnitus after both dose 1 and dose 2. Duration of tinnitus was reported in 27 (16.3%) reports and ranged from 1 minute to “weeks”; 14 cases lasted from 1 to 9 days. Outcome for the 166 reports was as follows: 33 recovered/recovered with sequelae, 18 recovering, 81 not recovered and 34 outcomes were not known. Some patients had medical histories contributing to the possibility of experiencing tinnitus. Twenty-four (24) patients had medical histories of tinnitus and 5 described worsening of the tinnitus following vaccination. Seven (7) patients had medical histories of deafness, Meniere’s disease or mastoid disorders. Seven (7) patients had medical histories of COVID-19, one of these patients has also experienced tinnitus at the time of COVID-19. Two (2) patients were diagnosed with COVID-19 at the time they were having tinnitus. Three (3) of the patients had tinnitus associated with syncope occurring following vaccination.

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4. EPIDEMIOLOGY ANALYSIS

The MAH has conducted unadjusted observed to expected ratio (O/E) analyses for the 168 serious tinnitus cases and the 94 reports of deafness or sudden hearing loss. Expected case counts were derived using respective background incidence rates of 54.0/100,000 PYⁱ and 27.0/100000 PYⁱⁱ.

An estimated 64,572,821.9 doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 21 February 2021. This estimate was derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized. ⁱⁱⁱ For periods when more than one vaccine was authorized for use in each country, the doses administered were assumed to be divided equally by the number of vaccines approved. This estimate does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios are reported with a 21-day risk window and without any risk window for the cumulative period with exposure through 21 February 2021. The O/E for both risk windows included all cases in the numerator regardless of the duration between vaccination and the date of event onset.

Table 1. Observed to Expected Ratio of Spontaneously Reported Tinnitus through 21 Feb 2021, Background Rate = 54.0/100,000PY^a

| | 21 Days (2875621.9 PY) | No risk window (4396086.1 PY) |
|-----------------------------|---------------------------|----------------------------------|
| Observed cases ^b | 168 | 168 |
| Expected cases | 1552 | 2373 |
| O/E | 0.108 | 0.071 |
| (95% CI) | 0.092, 0.126 | 0.061, 0.082 |

a. [Martinez, 2015](#)

b. Subsequent to review

Table 2. Observed to Expected Ratio of Spontaneously Reported Hearing Loss through 21 Feb 2021, Background Rate = 27.0/100,000PY^a

| | 21 Days (2875621.9 PY) | No risk window (4396086.1 PY) |
|-----------------------------|---------------------------|----------------------------------|
| Observed cases ^b | 94 | 94 |
| Expected cases | 776 | 1187 |
| O/E | 0.121 | 0.079 |
| (95% CI) | 0.098, 0.148 | 0.064, 0.097 |

b. [Alexander, 2013](#)

b. Subsequent to review

The ratio of observed to expected cases does not exceed 1 over either risk window for either endpoint.

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There are several limitations to observed to expected analyses for signal detection. The observed case counts are likely to be underestimated due to underreporting that occurs with spontaneous report surveillance. Additional reasons for underestimations include incomplete reporting and lags in reporting. Spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are more likely to be reported even if they do not meet the clinical definition. Conversely, events that have not been previously associated with a vaccine are more likely to be underreported due to lack of recognition of a potential association.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Additionally, with multiple vaccines becoming available globally, the assumption that the vaccines are distributed in equal proportions may lead to over or underestimates.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. The population from which the background rates used in this analysis were derived may differ from the vaccinated population with respect to delivery of health care, population demographics, and underlying health status of the populations. To date, the majority of exposure derives from the US.

A final limitation concerns the risk windows, the time it is assumed that one is at risk for a given event if there is a causal association to the vaccine. Expected cases counts were determined under two assumptions: a 21-day window and an unlimited risk window. Observed to expected analyses were completed using the same number of observed cases compared to expected under both assumptions, regardless of proximity of the reported event to the date of vaccination. This may lead to an overestimation of the O/E ratio if the observed cases occurred outside of the 21-day risk period. On the other hand, the ratio may be underestimated using the unlimited risk window if the risk period is finite.

5. SUMMARY AND CONCLUSION

Hearing loss, including deafness and sudden hearing loss, have been spontaneously reported following vaccination with Pfizer/BNT B162b2 vaccine. Most reports are in adult and elderly patients, consistent with age populations targeted for vaccination in most regions. Most of the reports are in women, also consistent with the overall AE reporting profile. Most of the hearing loss reported occurs within one week after vaccination and has a duration of less than 1 week. There is one “rechallenge” report of a patient who experienced hearing loss following the first dose of vaccination which worsened after the second dose (AER (b) (6)). Outcomes have been variable, and follow-up is occurring.

At this time, statistical signal detection using EB05 >2 against a background of all other Pfizer products has not shown disproportionate reporting for events of hearing loss. Likewise, the observed to expected analyses for hearing loss does not indicate a signal.

Currently, there is insufficient data to conclude there is a causal association of hearing loss with the vaccine. This topic will be followed closely in the upcoming PSURs.

Tinnitus has also been reported in association with vaccination. Some reports are associated with hearing loss, but most are not. When reported in serious cases, tinnitus has mostly occurred soon after vaccination (within 1 week). Duration data is only available in a minority of cases; duration ranges from days to weeks. Two “rechallenge” reports describe tinnitus occurring after both dose 1 and dose 2 (AER (b) (6) and AER (b) (6)). Most of the events of tinnitus in the serious cases have not resolved at the time of reporting and follow-up is occurring. At this time there has been no statistical signal of disproportionate reporting for tinnitus in the Pfizer safety database, nor has it signaled in the observed to expected analyses. The review of this data does not suggest a causal association of tinnitus with the vaccine.

i Martinez C, Wallenhorst C, McFerran D, Hall DA Incidence rates of clinically significant tinnitus: 10-year trend from a cohort study in England Ear Hear 2015 May-Jun;36(3):e69-75 doi: 10.1097/AUD.0000000000000121 PMID: 25470370; PMCID: PMC4415963

ii Alexander TH, Harris JP Incidence of sudden sensorineural hearing loss Otol Neurotol 2013 Dec;34(9):1586-9 doi: 10.1097/MAO.0000000000000222 PMID: 24232060

iii <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates> (accessed 21 February 2021).

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APPENDIX 3.4 SAFETY EVALUATION OF INSOMNIA

1. METHOD

The Pfizer safety database Argus was searched for all BNT162b2 vaccine spontaneous and literature reports and serious clinical trial reports received through 25th February 2021 using the following MedDRA version 23.1 search criteria: PT: Insomnia.

These PTs were also used to search adverse events in subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the clinical trial Phase 2/3 safety population of ~38,000 participants (with a data cut-off date of 14 November 2020). This included a total of 18,801 subjects receiving BNT162b2 and 18,785 subjects receiving placebo.

2. RESULTS

Insomnia

Overall a total of 647 cases reporting PT insomnia were retrieved in the database. Among them 309 cases were assessed as non-serious and 338 as serious. A total of 462 (71.4%) subjects were female, 164 (25.3%) males and 21 (3.2%) subjects did not report the gender. Most reports are from US (280) followed by UK (231).

The age group was reported ranging from 0.8 to 90 years (reported for 579 cases, mean 50.6). Age distribution is reported below in Table 1.

Table 1. Age Breakdown of Subjects Reporting Insomnia

| Age range | Number of cases | Percentage (%) |
|-----------------------------------|-----------------|----------------|
| Less than or equal to 17 years | 1 | 0.2 % |
| 18 - 30 years | 73 | 11.3 % |
| 31 - 50 years | 235 | 36.3 % |
| 51 - 64 years | 135 | 20.9 % |
| 65 - 74 years | 65 | 10.0 % |
| Greater than or equal to 75 years | 71 | 11.0 % |
| Unknown | 67 | 10.4 % |

Most cases reported insomnia associated to reactogenicity events as pyrexia, vaccination site pain/pain, pain in extremity, headache, nausea as shown in Table 2.

Table 2. Most common co-reported PT with Insomnia

| Preferred term | Number of cases |
|----------------|-----------------|
| Pain | 276 |
| Headache | 254 |
| Pyrexia | 187 |
| Nausea | 149 |

Table 2. Most common co-reported PT with Insomnia

| Preferred term | Number of cases |
|-----------------------|------------------------|
| Vaccination site pain | 112 |
| Pain in extremity | 17 |

When reported, the most commonly reported time from the administration of vaccine to the onset of the event of insomnia, was as follows: within the same day in 218 cases, the next day in 152 cases, between 2-7 days in 67 cases and between 8-30 days in 22 cases.

Time to onset, when reported, was as follows: the same day in 221 cases, the day after in 153 subjects, between 2-7 days after vaccination in 68 cases and between 8-30 days in 23 cases.

The duration of Insomnia was reported in 74 cases and was as follows: within 1 day (29 cases), from 1-2 days (26), 3-5 days (11), from longer than 5 days to 7 days (3), and from almost 13 days to 20 days (3).

The outcome per the event of Insomnia was reported as recovered/recovering (for 253 events), recovered with sequelae (for 5 events), not recovered (for 131 events), and unknown (for 257 events).

Clinical Trial data

In the Phase 2/3 safety population, insomnia was reported in 23 subjects (0.1%) in the BNT162b2 group compared with 6 subjects (0.0%) in the placebo group.

3. CONCLUSION

A total of 647 spontaneous cases reported PT Insomnia cumulatively through 25th February 2021. Most cases reported time to the onset ranging from within the same vaccination day to the day after, and most of the cases reported associated reactogenicity events such as Pain, Headache, Pyrexia, Nausea, Vaccination site pain, and Pain in extremity which could contribute to difficulty to fall asleep. When reported (in 74 out of 647 cases), the most commonly reported duration of Insomnia was short in duration (from one to two days; 55 cases). Overall, given the totality of the available information, changes in the risk minimization measures or updates to the product information label are not warranted at this time.

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APPENDIX 3.5 - SAFETY EVALUATION OF DIZZINESS

1. METHOD

The Pfizer safety database was searched for all BNT162b2 vaccine reports of dizziness received through 26 February 2021 using the following MedDRA version 23.1 search criteria: PT: Dizziness.

PT Dizziness was also searched in Clinical study C4591001 subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the clinical trial Phase 2/3 safety population of ~38,000 participants (with a data cut-off date of 14 November 2020). This included a total of 18,801 subjects receiving BNT162b2 and 18,785 subjects receiving placebo.

2. RESULTS

2.1. Safety Database

A total of 4637 cases were retrieved using the criteria mentioned above. There were 3751 females (80.9%), 762 males (16.4%) and gender was not reported for 124 cases (2.7%). A total of 2486 cases containing the PT Dizziness were assessed as serious and 2151 as non-serious. A total of 4579 cases were spontaneous, and one was a solicited report. Fifty-seven reports were from clinical studies and were blinded so they are not further considered in this evaluation. One case was a solicited report.

Age ranged between 0.1 to 107 years (mean of 48 years, N = 4248), age stratification is reported in Table 1.

Table 1. Age Stratification

| Age stratification | Number of cases | Percentage (%) |
|-----------------------------------|-----------------|----------------|
| Less than or equal to 17 years | 13 | 0.3 % |
| 18 - 30 years | 721 | 15.5 % |
| 31 - 50 years | 1847 | 39.8 % |
| 51 - 64 years | 864 | 18.6 % |
| 65 - 74 years | 412 | 8.9 % |
| Greater than or equal to 75 years | 404 | 8.7 % |
| Unknown | 376 | 8.1 % |

Most cases were reported from UK (1571) follow by US (1471). The list of the top 10 reporting countries are listed in [Table 2](#).

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Table 2. Top 10 Reporting Countries

| Countries | Number of cases | Percentage (%) |
|----------------|-----------------|----------------|
| UNITED KINGDOM | 1571 | 33.9 % |
| UNITED STATES | 1471 | 31.7 % |
| MEXICO | 441 | 9.5 % |
| GERMANY | 210 | 4.5 % |
| ITALY | 128 | 2.8 % |
| DENMARK | 115 | 2.5 % |
| SPAIN | 70 | 1.5 % |
| GREECE | 61 | 1.3 % |
| PORTUGAL | 59 | 1.3 % |
| SWEDEN | 53 | 1.1 % |

Time to onset, when provided, was reported as the same day for 1809 cases, the day after vaccination for 1334 subjects, day 2-7 days after vaccination in 601 cases and from 8-14 days after vaccination in 78 cases.

Many cases were associated with reactogenicity events such as nausea, vomiting, pyrexia, pain, headache and with events such as tachycardia, hypotension and anxiety. PTs most commonly co-reported with dizziness are in Table 3. A total of 201 cases out of 4637 reported dizziness as the only adverse event in the case.

Table 3. Most Commonly Co-Reported PTs

| PT | Number of Cases |
|--|-----------------|
| Headache | 1793 |
| Pain, Vaccination site pain, Pain in extremity | 1790 |
| Nausea, Vomiting | 1658 |
| Pyrexia, Chills | 1343 |
| Tachycardia, Palpitations | 548 |
| Dyspnoea | 496 |
| Syncope, Presyncope, Loss of consciousness | 415 |
| Hypotension, Blood pressure decrease | 141 |
| Allergy, Anaphylaxis | 128 |
| Anxiety, Fear | 96 |
| Dizziness is the only PT reported in case | 201 |

Outcome at case level was reported as follows: resolved/resolving/resolved with sequel for 2447 subjects, not recovered at time of reporting for 1425 cases, fatal for 8 patients and unknown for 757 cases. The 8 cases reporting a fatal outcome are presented in Table 4 and none was directly due to the event dizziness.

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Table 4. Fatal Reports

| AER Number | Age (years) | Gender | Medical History | Conmed | Events Reported | Country |
|------------|-------------|--------|--|---|--|----------------|
| (b) (6) | | MALE | Asthma / Vitamin D deficiency | COLECALCIFEROL / SALBUTAMOL SULFATE | Death, Epistaxis, Headache, Dizziness, Haemoptysis, Haematemesis | UNITED KINGDOM |
| (b) (6) | 27.00 | MALE | | | Haematemesis, Loss of consciousness, Dizziness, Pyrexia. The events presented 2 days after vaccination. No additional information were available | UNITED KINGDOM |
| (b) (6) | 63.00 | MALE | Angioplasty / Anticoagulant therapy / Bone marrow transplant / Cardiac disorder / Leukaemia / Liver disorder / Myocardial infarction / Osteonecrosis / Stent placement | | Acute myocardial infarction, Cardiac arrest, Dizziness, Fall | GREECE |
| (b) (6) | 80.00 | MALE | Arteriosclerosis / Atrial fibrillation / Chronic obstructive pulmonary disease / Renal disorder | | Arteriosclerosis, Cardiovascular disorder, Dizziness, Nausea, Headache | UNITED STATES |
| (b) (6) | 91.00 | MALE | Atrial fibrillation / Cardiac failure chronic / Chronic respiratory failure / Deep vein thrombosis / Dependence on oxygen therapy / Fall / Hypertension / Implantable | APIXABAN / BUMETANIDE / MORPHINE / TRAMADOL | Cardiac failure, Hallucination, Oedema peripheral, Confusional state, Dizziness | NORWAY |

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Table 4. Fatal Reports

| AER Number | Age (years) | Gender | Medical History | Conmed | Events Reported | Country |
|------------|-------------|--------|---|--|---|---------|
| | | | defibrillator insertion / Intermittent claudication / Living in residential institution / Non-tobacco user / Pleural effusion / Polymyalgia rheumatica / Prostate cancer / Walking aid user | | | |
| (b) (6) | 95.00 | FEMALE | Cardiac failure / Dementia / Living in residential institution / Multimorbidity / Treatment noncompliance | | Syncope, General physical health deterioration, Dyspnoea, Muscular weakness, Dizziness, Bedridden, Apnoea | NORWAY |
| (b) (6) | 66.00 | FEMALE | Coeliac disease / Crohn's disease | ALENDRONIC ACID / BUDESONIDE / CALCIUM CARBONATE | Death, Restless legs syndrome, Dizziness, Dyspnoea | SWEDEN |
| (b) (6) | 94.00 | MALE | Dementia Alzheimer's type / Osteoporosis / Prostatic adenoma / Prostatitis | | Death, Chest discomfort, Vomiting, Vertigo, Dizziness, Neuralgia, Fall | FRANCE |

Among the cases reporting only dizziness as symptom, age ranged between 18 to 90 years (mean: 53.8 years, median: 53 years, N: 171), were mostly females (136 Females, 54 Males and 11 of unknown gender). Medical history was reported for 66 out of 201 cases and blood pressure abnormal/hypertension was reported for 20 cases, 11 reported asthma, previous Covid-19 diseases was reported in 7 patients, anxiety/mental disorder/depression and diabetes/glucose intolerance in 4 patients each. None of these cases reported a fatal outcome.

Duration of the event dizziness was reported by 761 cases and it ranges from minutes to 20 days as shown in [Table 5](#).

Table 5. Duration of Dizziness

| Duration of the event Dizziness | Number of cases |
|--|------------------------|
| Minutes to 2 hours | 118 |
| Between 2 to 24 hours | 396 |
| Between 2-10 days | 124 |
| Between 11-20 days | 123 |
| Total: | 761 |

2.2. Clinical Trial Data

Only unblinded cases will be discussed in this report. In the Phase 2/3 safety population, insomnia was reported in 56 subjects (0.3%) in the BNT162b2 group compared with 48 subjects (0.3%) in the placebo group. No differences in frequency of dizziness reports occurred in participants vaccinated with BNT162b2 and participants receiving placebo.

3. CONCLUSION

Overall, 4637 cases of dizziness were retrieved in the Pfizer safety database. Most cases of dizziness were reported in the context of reactogenicity events or events consistent with stress or anxiety. The majority of cases reported dizziness occurring within minutes of vaccination or the same day and with a limited duration. Considering this presentation of the event and the clinical data which does not support dizziness as a reaction to the vaccine itself, dizziness appears to be most consistent with an immunization stress related reaction rather than a unique vaccine adverse reaction. It will be considered within the review of vaccine stress-related responses that is ongoing and no change to the CDS is warranted at this time, prior to the completion of the vaccine stress-related responses review.

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Pfizer-BioNTech COVID-19 Vaccine (BNT162, PF-07302048)

Guillain-Barré Syndrome

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LIST OF ABBREVIATIONS

| Abbreviation | Definition |
|---------------------|---|
| COVID-19 | Coronavirus Disease 2019 |
| CSF | cerebrospinal fluid |
| GBS | Guillain-Barré Syndrome |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MFS | Miller Fisher syndrome |
| MMR | measles, mumps, and rubella |
| SARS | Severe Acute Respiratory Syndrome |
| SARS-CoV-2 | Coronavirus-2; virus causing the disease COVID-19 |
| SMQ | standardized MedDRA query |

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1. INTRODUCTION

Guillain–Barré syndrome (GBS) is currently the most frequent cause of acute flaccid paralysis in developed countries and constitutes one of the serious emergencies in neurology.^{1,2} GBS is an acute inflammatory polyneuropathy, characterized by a rapidly progressive, symmetric, ascending flaccid paresis, weakness, with areflexia and albuminocytologic dissociation (ie, high levels of protein in the cerebrospinal fluid and normal cell counts). Based on clinical features, etiology, pathologic and electrophysiological studies, GBS may be sub classified into several forms. These are: acute inflammatory demyelinating polyradiculoneuropathy; axonal forms of GBS, which include acute motor-sensory axonal neuropathy and acute motor axonal neuropathy; and Miller Fisher syndrome (MFS).³ MFS syndrome is characterized by ophthalmoplegia, ataxia, areflexia and albuminocytologic dissociation.^{1,2} The diagnosis is made through clinical findings, cerebrospinal fluid analysis (CSF) and nerve conduction studies. Treatment involves the administration of intravenous immunoglobulins, plasma exchange, continuous monitoring and supportive care.² Though the syndrome is rare, early diagnosis and treatment can significantly improve outcomes and avoid the need for ventilatory support.¹

Although the underlying etiology and pathophysiology of GBS are not completely understood, it is considered to be a post-infectious autoimmune disease. Auto-antibodies develop in response to variety bacterial or viral antigens that cross react with epitopes on peripheral nerves, leading to demyelination, axonal damage or both.^{4,5} About Two thirds of cases are preceded by symptoms of upper respiratory tract infection or diarrhea within the previous 6 weeks from symptoms onset.^{2,6} The interval between the prodromal infection and the onset of GBS symptoms varies between 1 week and 3 weeks (averaged 11 days), occasionally longer.⁷ *Campylobacter jejuni* (*C. jejuni*) is the most frequent antecedent infection. A recent meta-analysis showed that 30% of GBS cases are attributable to *C. jejuni* infection.⁸ Cytomegalovirus has been found as second common antecedent infection which was identified in up to 13% of cases.⁹ The incidence of GBS following *C. jejuni* infection and primary CMV infection were estimated to be between 0.25 -0.65 and 0.6 - 2.2 cases per 1000 cases.¹⁰ Other infectious agents related to GBS are Epstein–Barr virus, varicella–zoster virus, and *Mycoplasma pneumoniae*.⁹

The overall incidence of GBS ranges from 0.81 to 1.89 (median 1.11) cases per 100,000 person-years. GBS incidence increases by 20% for every 10-year increase in age. The age-specific GBS rate increased from 0.62 cases per 100,000 person-years among 0 to 9 years old to 2.66 cases per 100,000 person-years among 80 to 89 years old population. Some studies showed a slight peak in late adolescence and young adulthood, coinciding with an increased risk of infections with cytomegalovirus and *C. jejuni*, and a second peak in the elderly.^{7,11} Males are more commonly affected (relative risk 1.78) than females.⁴

GBS is associated with increased hospitalization rate, length of hospital stay and mortality rate among older population. The overall case-fatality ratio of GBS ranges from 4.4% to 10%. The case-fatality ratio ranged from 0.7% among persons <15 years old to 8.6% among persons >65 years old. Overall, 12% of patients required hospitalization and intensive care unit treatment.^{1,12} Follow up after one year reported that 62% of the patients had complete functional recovery with no or minimal residual symptoms, whereas, remaining 38% patients

had made a poor functional recovery, 18% being unable to run, 9% being unable to walk unaided, 4% being bedbound or ventilated.¹³

2. GUILLAIN-BARRÉ SYNDROME AND VACCINATION

Several case reports and small case series have raised the concern about linkage of GBS to vaccinations on the grounds of a mere temporal association, but no secure causal relationship has been established until now.^{7,14} The estimated attributable risk of vaccine-related GBS in the adult population is one case per 100,000 vaccinations.¹⁵ Among the vaccines, evidence for causal relationship between vaccination and GBS have been published for influenza vaccine used in swine flu immunization campaign in 1976 and rabies vaccines prepared from either suckling mouse brain or mature sheep brain (Semple vaccine).^{16,17}

However, the results of studies investigating association between influenza vaccination and GBS following influenza immunization campaign in 1976 are conflicting. No temporally related increase in Guillain-Barré syndrome was found in members of the US Army who received the A/New Jersey (swine) influenza vaccine in 1976–1977.¹⁸ Another study found a non-significant increase in the risk of vaccine-associated Guillain–Barré syndrome in 1992–1993 and 1993–1994 influenza seasons.¹⁹

Other studies showed an increase risk of GBS among vaccinees who received influenza vaccines. Following suspension of National Influenza Immunization Program with A/New Jersey influenza vaccine in 1976, nationwide surveillance for GBS found significantly elevated attack rate in adult vaccinated population. The study also showed that the period of increased risk was concentrated primarily within the 5-week period after vaccination, although it lasted for approximately 9 or 10 weeks.¹⁵ Some years later, Vaccine Adverse Event Reporting System data from 1991 through 1999 showed an increased risk of acute GBS and severe GBS in comparison to an adult tetanus-diphtheria vaccine control group, although in 2002-2003, a 4-fold reduction in the annual reporting rate of GBS from 0.17 to 0.04 per 100, 000 vaccinees was observed compared to 1993-1994.²⁰

Since then, many articles have been published reporting small increased risk of GBS after influenza vaccination or following receipt of monovalent inactivated (H1N1), but also a number of studies reported that the relative and attributable risks of Guillain-Barré syndrome after seasonal influenza vaccination are lower than those after influenza illness.²¹⁻²³

3. GULLAIN-BARRÉ SYNDROME AND COVID-19

There is growing evidence that COVID-19 can also affect the nervous system. There are essentially two principal routes for viruses to gain entry into the central nervous system (CNS): hematogenous or neuronal retrograde dissemination.²⁴⁻²⁶ In hematogenous entry, a virus can infect endothelial cells of the blood brain barrier to gain access or infect leukocytes for dissemination into the CNS.²⁴⁻²⁶ As a second major route of entry to the CNS, some viruses infect neurons in the periphery and use the axonal transport machinery to enter the CNS.²⁴⁻²⁷ This could represent another potential route of entry to the CNS for SARS-CoV-2, that is via the cranial nerve. Moreover, the olfactory nerve serves as a shortcut for many viruses into the CNS.²⁸

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Examples of COVID-19 CNS disease include encephalopathy, encephalitis, acute disseminated encephalomyelitis, meningitis, ischemic and hemorrhagic stroke, venous sinus thrombosis and endothelialitis. In the peripheral nervous system COVID-19 is associated with dysfunction of smell and taste, muscle injury, the Guillain-Barre syndrome and its variants.²⁹

A number of case reports describing GBS in temporal association with COVID-19 infection have been reported.³⁰⁻³⁷ A subsequent systematic review from Abu-Rumeileh et al³⁸ analyzed the literature published on GBS until July 2020 and the analysis included 73 patients reported in 52 publications. They concluded that a broad age range was affected (mean 55, min 11–max 94 years) with male predominance (68.5%). Most patients showed respiratory and/or systemic symptoms, and developed GBS manifestations after COVID-19. However, asymptomatic cases for COVID-19 were also described. The distributions of clinical variants and electrophysiological subtypes resemble those of classic GBS, with a higher prevalence of the classic sensorimotor form and the acute inflammatory demyelinating polyneuropathy, although rare variants like MFS were also reported. The duration from onset of viral illness to neurologic manifestations have ranged from 3 to 33 days. CSF albumin cytological dissociation was present in about 71% cases, and CSF SARS-CoV-2 RNA was absent in all tested cases. More than 70% of patients showed a good prognosis, mostly after treatment with intravenous immunoglobulin. Patients with less favorable outcome were associated with a significantly older age in accordance with previous findings regarding both classic GBS and COVID-19. COVID-19-associated GBS seems to share most features of classic post-infectious GBS and possibly the same immune-mediated pathogenetic mechanisms.

In a pooled global analysis of three studies, Guillain-Barre syndrome was reported as a complication in 0.2% (0.2% to 0.9% range; 8/4,299) of PCR-confirmed COVID-positive hospitalized cases.³⁹⁻⁴¹

In conclusion, a causal association between GBS and COVID-19 remains speculative. Nevertheless, given that GBS has been already described as postinfectious complications of other coronavirus (Middle East respiratory syndrome) sharing similarities with SARS-CoV-2, the occurrence of GBS needs to be closely monitored and evaluated during the pandemic.⁴²

4. METHODOLOGY

The clinical trial database related to study C4591001 (COVID-19 vaccine study) was searched for cases of anaphylaxis using the following Standardized MedDRA Query: “Guillain-Barré Syndrome”, narrow search.

Cases will be adjudicated according to Brighton Collaboration (BC)⁴³ case definition and level of diagnostic certainty.

BC levels 1-3 of diagnostic certainty are defined as GBS or MFS with a different level of diagnostic certainty. Level 1 provides the highest level of diagnostic certainty, whereas the diagnostic certainty is lowest for level 3. Level 4 is defined as “reported event of GBS or FS, with insufficient evidence to meet the case definition” and level 5 as not a case of GBS or FS”.⁴³ Brighton collaboration details are reported below:

Level 1 of diagnostic certainty

- Bilateral AND flaccid weakness of the limbs
- AND
- Decreased or absent deep tendon reflexes in weak limbs
- AND
- Monophasic illness pattern AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau
- AND
- Electrophysiologic findings consistent with GBS
- AND
- Cytoalbuminologic dissociation (ie, elevation of CSF protein level above laboratory normal value AND CSF total white cell count <50 cells/ μ L)
- AND
- Absence of an identified alternative diagnosis for weakness
 -

Level 2 of diagnostic certainty

- Bilateral AND flaccid weakness of the limbs
- AND
- Decreased or absent deep tendon reflexes in weak limbs
- AND
- Monophasic illness pattern AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau
- AND
- CSF total white cell count <50 cells/ μ L (with or without CSF protein elevation above laboratory normal value)
- OR
- IF CSF not collected or results not available, electrophysiologic studies consistent with GBS
- AND
- Absence of identified alternative diagnosis for weakness
 -

Level 3 of diagnostic certainty

- Bilateral AND flaccid weakness of the limbs
- AND
- Decreased or absent deep tendon reflexes in weak limbs
- AND
- Monophasic illness pattern AND interval between onset and nadir of weakness between 12 h and 28 days AND subsequent clinical plateau
- AND
- Absence of identified alternative diagnosis for weakness

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5. RESULTS

A total of 32 cases were identified using the search criteria described above. There were 22 female, 8 males and in 2 cases gender was not reported. The age range between 18 to 88 years of age (50.6 mean) aside of an additional case of 1-month of age. The age distribution was as follows: 20 (62.5%) adults (age ≥ 18 to < 65), 5 (15.6%) elderly (age ≥ 65), and for 6 (18.7%) cases the age was not reported, in addition a patient was reported as 1-month old. Most of the cases were reported from US (13, 40.6%), United Kingdom (5, 15.6%) followed by Mexico, Israel, Germany, Greece (2, 9.5% each), Italy, Chile, Sweden, Spain and Cyprus (1 each). The outcome of the event was reported as not recovered at time of reporting in 11 cases (34.4%), as recovering/resolving in 6 cases (18.7%), and as unknown in 14 cases (43.7%). One case had a fatal outcome (summary reported below).

All cases have been assessed according to BC criteria as follows:

- 1 case (3.1%) met level 1
- 2 cases (6.3%) met level 2
- 26 cases (81.3%) met level 4
- 3 cases (9.4%) met level 5

Two cases reported a medical history of polyneuropathy (chronic inflammatory demyelinating polyradiculoneuropathy/Peripheral sensory neuropathy). All other cases did not report a medical history of auto-immune diseases/previous GBS/other polyneuropathy or provided a medical history of recent infections. In 18 cases (56.2%), time to onset was reported ranging between 2 to 20 days post vaccination, in 4 cases (12.5%) it was reported as the same vaccination day or the day after and in 10 cases (31.2%) time to onset was not reported. The duration of the event was unknown or not reported in 27 cases (84.3%), in 2 cases (6.25%) it was reported as 1-2 days and in 3 cases (9.4%) it was reported as 11 or more days.

Case meeting BC Level 1

AER# (b) (6) : this case refers to a 49-year-old female patient that 4 days after vaccination experienced symptoms initially of sensory disturbances followed by motor disturbances. The diagnosis was confirmed by cyto-albuminologic dissociation and electroneurography with findings consistent with a demyelinating sensorimotor polyneuropathy. The medical history was not provided with respect to recent infections (respiratory and/or gastrointestinal) or previous auto-immune disorders. Outcome was reported as not yet recovered at time of reporting.

Cases meeting BC Level 2

AER# (b) (6) : this case refers to a 52-year-old male patient that 18 days after vaccine administration experienced acute paresthesia in the limbs. Symptoms worsened over the next

days (greater intensity of paresthesia, tactile hypoesthesia, walk instability and global areflexia). A neurophysiological study confirmed that those alterations were compatible with a sensitive-motor polyradiculoneuropathy of the demyelinating type. The patient did not have a medical history of previous polyneuropathies or recent infections.

AER# (b) (6) : this case refers to a 65-year-old male patient that 2 days after vaccination experienced bilateral lower extremity weakness, pain and paresthesia in bilateral hands and legs. Symptoms worsened in the next couple of weeks. The neurological exam showed areflexia throughout. All findings were consistent with acute inflammatory demyelinating polyneuropathy (AIDP or Guillain Barre Syndrome). The diagnosis was confirmed by cyto-albuminologic dissociation.

Case (AER# (b) (6)) reporting a fatal outcome:

The case reporting the fatal outcome met level 4 of BC and refers to an 81-year-old patient with a reported time to onset of 54 days. No medical history was reported for the patient. The reported event referred to a worsening in the weakness in both legs, without any further detail regarding his medical history and the pre-existing weakness in the limb (reported as worsening). The patient's health conditions deteriorated in couple of days (numbness in abdomen, progressive breathing problems) until he was admitted to the hospital and died. Overall, the information available at this time are not sufficient to perform an assessment of the causal relationship with the vaccine.

6. OBSERVED ANALYSIS OF BLINDED CLINICAL TRIAL DATA

We conducted unadjusted observed to expected ratio (O/E) analyses for the 32 Guillain-Barre cases reported. Expected case counts were derived using a background incidence rate of 2.06/100 000 PY from a meta-analysis of EU health records.⁴⁴

An estimated 75,397,549 doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 28 February 2021. This estimate was derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized.⁴⁵ For periods when more than one vaccine was authorized for use in each country, the doses administered were assumed to be divided equally by the number of vaccines approved. This estimate does not reflect exposure in persons vaccinated in countries that did not publicly report.

O/E ratios are reported assuming a 21-day risk window and without any risk window for the cumulative period through 28 February 2021. The O/E for both risk windows included all 32 cases in the numerator regardless of the duration between vaccination and the date of event onset.

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Table 1. Observed to Expected Ratio of Spontaneously Reported Guillain-Barre through 28 Feb 2021

| Cumulative (N=32) | | |
|------------------------------|---------------------------|----------------------------------|
| Background rate | Risk Period | |
| | 21 Days (3,489,001 PY) | No risk window (5,777,558 PY) |
| 2.06/100,000 PY ^a | | |
| Expected cases | 71.9 | 119 |
| O/E | 0.45 | 0.27 |
| (95% CI) | 0.305, 0.629 | 0.184, 0.380 |

a. Willame, et al 2021⁴⁴

The ratio of observed to expected cases does not exceed 1 over either risk window.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are more likely to be reported and potentially reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, the population from which the background rates used in this analysis were derived may differ from the vaccinated population with respect to delivery of health care, population demographics, and underlying health status of the populations. However, to date, the majority of exposure derives from the US.

A final limitation concerns the time at risk for a given event during which an excess of risk occurs in the case of causal association. 21 days and no risk window were selected to provide a range of evaluation for the number of expected cases, however, observed cases were included regardless of proximity to vaccination which may lead to overestimate if the observed cases occurred outside of the 21-day risk period.

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7. CONCLUSION

In summary the majority of the cases reported (26, 81.3%) met level 4 of BC and among them, 3 cases reported a time to onset that, even though plausible does not have a biological plausibility to trigger the reported demyelination (range from 30 minutes-same day as vaccination).

One case met level 1 of the BC criteria: medical history did not report recent infections or previous auto-immune disorders but time to onset (4 days) is plausible with the clinical manifestation of GBS. Two additional cases (AER# (b) (6), AER# (b) (6)) met level 2 of BC: although the medical history did not include mentioning of recent infections or previous auto-immune disorders, the reported time to onset (2 days with a progression of the symptoms over the next 20 days after vaccination; 18 days; 11 days, respectively) is plausible with the clinical manifestation of the syndrome.

An estimated 75,397,549 doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 28 February 2021.

The ratio of observed to expected cases does not exceed 1 over either risk window.

Overall, given the totality of the available information, changes in the risk minimization measures or updates to the product information label are not warranted at this time. The benefit risk profile of the vaccine remains favorable. The topic will continue to be closely monitored.

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8. APPENDIX

Appendix 1. Summary of the reported cases

| Table 2. Summary of Reported Cases | | | | | | | | | | | |
|---|------------|-----------------|---------------|--------------------|---|---|----------------|--------------------------------|-----------------|-----------------|----------------|
| AER Number | Age | Age Unit | Gender | Med History | Conc Meds | Events | Country | Latency (time to onset) | Duration | BC Level | Outcome |
| (b) (6) | 39 | YEARS | MALE | | | Hypoaesthesia, Hypoaesthesia, Hypoaesthesia, Burning sensation, Burning sensation, Musculoskeletal pain, Paraesthesia, Guillain-Barre syndrome, Cerebrovascular accident, Back pain | UNITED STATES | 6 days | 1-2 days | 5 | Not recovered |
| (b) (6) | 36 | YEARS | FEMALE | | DROSPIRENONE, ETHINYLESTRADIOL, BETADEX CLATHRATE | Guillain-Barre syndrome, Paraesthesia | UNITED STATES | 9 days | | 4 | Not recovered |
| (b) (6) | 37 | YEARS | FEMALE | | | Demyelinating polyneuropathy | UNITED STATES | 5 days | | 4 | Not recovered |

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| | | | | | | | | | | | |
|---------|----|-------|--------|------------------------------|--------------------------|---|----------------|---------|--------------------|---|---------------|
| (b) (6) | 88 | YEARS | MALE | | | Guillain-Barre syndrome | UNITED KINGDOM | 30 min | | 4 | Not recovered |
| (b) (6) | 40 | YEARS | FEMALE | | | Guillain-Barre syndrome, Hypoaesthesia oral | UNITED STATES | Unknown | | 4 | Unknown |
| (b) (6) | 37 | YEARS | FEMALE | | | Guillain-Barre syndrome, Muscular weakness, Facial paresis, Fatigue, Gait inability | UNITED STATES | 4 hours | | 4 | Recovering |
| (b) (6) | | | FEMALE | | | Guillain-Barre syndrome | UNITED STATES | Unknown | | 4 | Unknown |
| (b) (6) | 70 | YEARS | MALE | Benign prostatic hyperplasia | TAMSULOSIN HYDROCHLORIDE | Peroneal nerve palsy, Guillain-Barre syndrome | UNITED STATES | Unknown | | 4 | Not recovered |
| (b) (6) | 40 | YEARS | MALE | | | Guillain-Barre syndrome | UNITED STATES | 2 days | 11 days and beyond | 4 | Unknown |
| (b) (6) | 38 | YEARS | FEMALE | | COLECALCIFEROL / ZINC | Palpitations, Paraesthesia, Guillain-Barre syndrome | IRELAND | 3 days | | 5 | Not recovered |

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| | | | | | | | | | | | |
|---------|----|-------|--------|---|--|--|---------------|---------|---------|---|---------------|
| (b) (6) | | | FEMALE | Anxiety / Myalgia | | Guillain-Barre syndrome, Headache, Paraesthesia, Pain in extremity, Back pain, Myalgia, Nausea | UNITED STATES | 1 day | | 5 | Unknown |
| (b) (6) | 41 | YEARS | FEMALE | Breast cancer / Gastroesophageal reflux disease / Hyperlipidaemia | | Guillain-Barre syndrome | UNITED STATES | 5 days | | 4 | Not recovered |
| (b) (6) | 31 | YEARS | FEMALE | | | Demyelinating polyneuropathy | ITALY | Unknown | 20 days | 4 | Recovering |
| (b) (6) | 64 | YEARS | MALE | | | Guillain-Barre syndrome | UNITED STATES | Unknown | | 4 | Unknown |
| (b) (6) | 61 | YEARS | MALE | | | Guillain-Barre syndrome | GERMANY | 13 days | | 4 | Not recovered |

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| | | | | | | | | | | | |
|---------|----|-------|------|--|--|--|---------------|---------------------------------|--|---|---------------|
| (b) (6) | 65 | YEARS | MALE | Coronary artery disease / Cryptogenic cirrhosis / Drug hypersensitivity / Factor V Leiden mutation / Hyperlipidemia / Stent placement / Type 2 diabetes mellitus | ACETYLSALICYLIC ACID / AMLODIPINE / BUPROPION / HYDROCHLORIDE / CARVEDILOL / CITALOPRAM / ERGOCALCIFEROL / INSULIN GLARGINE / MELATONIN / METFORMIN / OMEPRAZOLE / SENNA / ALEXANDRINA | Guillain-Barre syndrome, CSF protein increased, Muscular weakness, Pain in extremity, Paraesthesia, Areflexia, Facial paresis, Hypoaesthesia, Lumbar puncture abnormal | UNITED STATES | 2 days, progress over 2.5 weeks | | 2 | Not recovered |
|---------|----|-------|------|--|--|--|---------------|---------------------------------|--|---|---------------|

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| | | | | | | | | | | | |
|---------|----|-------|--------|----------------------------|--|--|--------|-------------------------------|-----------------------------|---|---------------|
| (b) (6) | 49 | YEARS | FEMALE | | | Guillain-Barre syndrome, Respiratory distress, Paraesthesia, Sensory disturbance, Back pain, Asthenia, Gait disturbance, Dysarthria, Dysphagia, Areflexia | SWEDEN | 4 days, progressing on day 10 | ICU admission after 20 days | 1 | Not recovered |
| (b) (6) | 18 | YEARS | FEMALE | Hypersensitivity / Illness | | Pyrexia, Headache, Asthenia, Fatigue, Dizziness, Rash, Decreased appetite, Nausea, Vomiting, Diarrhoea, Tachycardia, Rhinorrhoea, Oropharyngeal pain, Myalgia, Arthralgia, Eye injury, Paralysis, Guillain-Barre syndrome, Hypotension, Pain, Paraesthesia | MEXICO | 2-4 days | | 4 | Not recovered |
| (b) (6) | 53 | YEARS | FEMALE | Hypersensitivity | | Guillain-Barre syndrome, Muscular weakness, Diarrhoea, Paraesthesia | MEXICO | 5 days | | 4 | Unknown |
| (b) (6) | | | FEMALE | | | Guillain-Barre syndrome | CHILE | unknown | | 4 | Unknown |

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| | | | | | | | | | | | |
|---------|----|-------|---------|---|--|---|---------------|------------------------------|----------|-----------------------------------|-----------|
| (b) (6) | | | FEMALE | | | Guillain-Barre syndrome | ISRAEL | unknown | | 4 | Unknown |
| (b) (6) | | | NO DATA | Chronic inflammatory demyelinating polyradiculoneuropathy | | Chronic inflammatory demyelinating polyradiculoneuropathy, Condition aggravated, Off label use, Product use issue | ISRAEL | 7 days after the second dose | Unknown | 5 (flare up of a underlying CDIP) | Unknown |
| (b) (6) | 42 | YEARS | FEMALE | | | Guillain-Barre syndrome | GREECE | Unknown | Unknown | 4 | Unknown |
| (b) (6) | 40 | YEARS | FEMALE | | | Guillain-Barre syndrome, Fatigue, Paralysis, Pain, Pyrexia, Chills | GREECE | 4-5 days | 1-2 days | 4 | Resolving |
| (b) (6) | | | NO DATA | | | Guillain-Barre syndrome | UNITED STATES | Unknown | Unknown | 4 | Unknown |
| (b) (6) | 52 | YEARS | MALE | Haemorrhoids / Lithiasis / Rectal haemorrhage / Renal colic | | Guillain-Barre syndrome, Gastroenteritis, Pyrexia | SPAIN | 18 days | Unknown | 2 | Unknown |

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| | | | | | | | | | | | |
|---------|----|--------|--------|--|------------|--|----------------|--|---------|---|---------------|
| (b) (6) | 39 | YEARS | FEMALE | | | Guillain-Barre syndrome, Myalgia, Arthralgia | GERMANY | 9 days from covid vaccine and 52 days from influenza vaccine | Unknown | 4 | Not recovered |
| (b) (6) | 80 | YEARS | FEMALE | | | Myelitis, Gait inability, Gait disturbance, Sluggishness, Asthenia, Hyponatraemia, Guillain-Barre syndrome, Fibrin D dimer increased | CYPRUS | 1 day | Unknown | 4 | Resolving |
| (b) (6) | 1 | MONTHS | FEMALE | | | Guillain-Barre syndrome | UNITED KINGDOM | 18 days | Unknown | 4 | Recovering |
| (b) (6) | 57 | YEARS | FEMALE | Asthma / Dyspnoea | SALBUTAMOL | Paralysis, Dyspnoea, Cough, Guillain-Barre syndrome, Suspected COVID-19 | UNITED KINGDOM | 10 days | Unknown | 4 | Not recovered |
| (b) (6) | 47 | YEARS | FEMALE | Dyspnoea / Peripheral sensory neuropathy | | Dyspnoea, Guillain-Barre syndrome | UNITED KINGDOM | 15 days | Unknown | 4 | Recovering |
| (b) (6) | 81 | YEARS | FEMALE | | | Guillain-Barre syndrome, Aponia | UNITED KINGDOM | 54 days | Unknown | 4 | Fatal |

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| | | | | | | | | | | | |
|---------|----|-------|--------|--|--|---|-----------------------|---------|---------|---|---------|
| (b) (6) | 57 | YEARS | FEMALE | Cough / Dyspnoea / Fall / Suspected COVID-19 | | Dyspnoea, Cough, Respiratory failure, Guillain-Barre syndrome, Suspected COVID- 19, COVID-19 | UNITED KINGDO M | 11 days | Unknown | 2 | Unknown |
|---------|----|-------|--------|--|--|---|-----------------------|---------|---------|---|---------|

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APPENDIX 4. CUMULATIVE APPROVAL/AUTHORISATION STATUS

| Product Detail Set Name | Marketing Authorization Holder | Country | Approval Date | Authorization Type |
|---------------------------------------|--------------------------------|----------------------|---------------|--|
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer/BioNTech | United Kingdom | 1-Dec-20 | Temporary authorization under regulation 174 |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Bahrain | 3-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Israel | 6-Dec-20 | Special import approval Clause 29 |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Canada | 9-Dec-20 | Interim Order |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Qatar | 10-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Saudi Arabia | 10-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Mexico | 11-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | United States | 11-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Kuwait | 13-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Oman | 13-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Lebanon | 14-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Singapore | 14-Dec-20 | Pandemic Special Access Route |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Costa Rica | 15-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Ecuador | 15-Dec-20 | Importation Authorization |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | United Arab Emirates | 15-Dec-20 | EUA |

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| | | | | |
|---------------------------------------|----------|----------------|-----------|--|
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Chile | 16-Dec-20 | Special import for emergency use article 99 |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Panama | 16-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Jordan | 17-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Serbia | 17-Dec-20 | Import License |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Switzerland | 19-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Austria | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Belgium | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Bulgaria | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Croatia | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Cyprus | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Czech Republic | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Denmark | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Estonia | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Finland | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | France | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Germany | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Greece | 21-Dec-20 | Conditional marketing authorization approval |

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| | | | | |
|---------------------------------------|----------|---------------|-----------|--|
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Hungary | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Iceland | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Ireland | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Italy | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Latvia | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Liechtenstein | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Lithuania | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Luxembourg | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Malta | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Netherlands | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Norway | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Poland | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Portugal | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Romania | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Slovakia | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Slovenia | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Spain | 21-Dec-20 | Conditional marketing authorization approval |

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|---------------------------------------|----------|--------------------|-----------|--|
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Sweden | 21-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Argentina | 22-Dec-20 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Iraq | 27-Dec-20 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Colombia | 6-Jan-21 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Malaysia | 8-Jan-21 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Tunisia | 11-Jan-21 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Philippines | 14-Jan-21 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Uruguay | 21-Jan-21 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Australia | 24-Jan-21 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Hong Kong | 25-Jan-21 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Peru | 1-Feb-21 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | New Zealand | 3-Feb-21 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Dominican Republic | 8-Feb-21 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Japan | 14-Feb-21 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Ukraine | 22-Feb-21 | EUA |
| Pfizer-BioNTech COVID-19 mRNA vaccine | Pfizer | Brazil | 23-Feb-21 | Conditional marketing authorization approval |
| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Macau | 23-Feb-21 | Special import permit |

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| Pfizer-BioNTech COVID-19 mRNA vaccine | BioNTech | Albania | 24-Feb-21 | Conditional marketing authorization approval |
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APPENDIX 5. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Anti-acetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

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coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

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tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

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fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

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infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothermia hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lamb's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

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increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

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neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

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brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

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neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

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APPENDIX 5.1 OBSERVED VERSUS EXPECTED ANALYSIS FOR ADVERSE EVENTS OF SPECIAL INTEREST

2.5. INTRODUCTION

As part of ongoing signal detection activities, MAH is conducting observed to expected analyses to determine whether the reported counts of spontaneously reported AESI are higher than expected based on the “natural” background rates of the AESI in the absence of exposure, as outlined in the “Considerations on core requirements for RMP’s of COVID-19 vaccines: coreRMP19 guidance”¹ and by Mahaux et al.² Analyses are reported cumulatively for the period since the vaccine was first granted emergency use authorization (9 December 2020) as well as for the monthly reporting interval (1 February 2021 – 28 February 2021).

2.6. METHODS

2.6.1. Variables

The AESI list included in this report is informed by recommendations from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (VAERS surveillance) and MHRA. For SMSR 3, MAH has added several events to the unadjusted observed to expected ratio (O/E) analyses compared with SMSR2: Acute liver injury, Anosmia/ageusia, Arrhythmia, Chillblains, Coronary artery disease, Cutaneous vasculitis, Haemorrhage, Heart failure, Herpes zoster, Limb ischemia, Meningitis, Multisystem inflammatory syndrome (MIS), Myasthenia Gravis, Peripheral neuropathy, Vasculitis

2.6.2. Data Sources and Analysis

2.6.2.1. Observed cases

Spontaneously reported case counts are processed from the safety database via the pre-defined MedDRA search criteria provided in the results tables (Section 2.7). Unless otherwise noted in each table, events have not undergone adjudication, which is considered appropriate in a setting where the goal of the O/E analysis is signal detection.²

2.6.2.2. Expected cases

Expected case counts were determined cumulatively and for the monthly interval by multiplying estimated background incidence rates by the duration of post-vaccination exposure time (ENCePP, 2010). Duration of exposure time was estimated for the cumulative and interval period overall and using a 21-day risk window, the estimated period after vaccination during which acute vaccine-associated events are expected to occur.³

- Background incidence rates: Sources of background incidence rate estimates are noted in footnotes to the tables and include the literature as well as analyses conducted within electronic health records database and include, where available data from ACCESS project.¹¹ If a plausible range of background rates was identified across multiple data sources, a single rate from the low end of the range was selected.

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This conservative approach is more likely to identifying a signal than an approach using a higher background rate⁴

- **Post vaccination exposure time:** Estimated exposure time was derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized.⁵ For periods when more than one vaccine was authorized for use in each country, the doses administered were assumed to be divided equally by the number of brands of vaccines authorized. The estimate of administered doses does not reflect exposure in persons vaccinated in countries that did not publicly report. Exposure time was calculated assuming both a 21-day risk window and without assuming a risk window for both the interval and cumulative period.
 - Of note, the 21-day risk window is not applied to the observed case count. All cases observed during the interval or cumulative period are included regardless of proximity of event to date of vaccination. This is a conservative approach for the purpose of signal detection.

2.7. RESULTS: OBSERVED VS EXPECTED ANALYSES

An estimated 75,397,549 doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 28 February 2021.

Table 1. Observed^a to Expected Ratio of Spontaneously Reported Acute Disseminated Encephalomyelitis (ADEM) through 28 Feb 2021, (Background rate 5.25/100,000 PY^b)

| | Cumulative (N=22) | | Interval (N=19) | |
|------------------|--------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 183.2 | 303.3 | 80.1 | 85.9 |
| O/E ratio | 0.12 | 0.073 | 0.237 | 0.221 |
| (95% CI) | 0.075, 0.182 | 0.045, 0.110 | 0.143, 0.370 | 0.133, 0.345 |

a. PT codes: Acute disseminated encephalomyelitis, Encephalitis, Encephalopathy, Encephalomyelitis
 b. Willame, et al 2021⁶

Table 2. Observed^a to Expected Ratio of Spontaneously Reported Acute kidney injury/Renal failure through 28 Feb 2021, Background Rate = 1,344.13/100,000 PY^b

| | Cumulative (N=69) | | Interval (N=45) | |
|------------------|--------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 46896.7 | 77657.9 | 20518.9 | 21989.5 |
| O/E ratio | 0.001 | 0.001 | 0.002 | 0.002 |
| (95% CI) | 0.001, 0.002 | 0.001, 0.001 | 0.002, 0.003 | 0.001, 0.003 |

a. PT Codes: Acute kidney injury, Renal failure
 b. Study C4591004

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Table 3. Observed^a to Expected Ratio of Spontaneously Reported Acute Liver Injury/Liver injury through 28 Feb 2021, Background Rate = 3.60/100,000 PY^b

| | Cumulative (N=5) | | Interval (N=2) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 125.6 | 208 | 55 | 58.9 |
| O/E ratio | 0.04 | 0.024 | 0.036 | 0.034 |
| (95% CI) | 0.013, 0.093 | 0.008, 0.056 | 0.004, 0.131 | 0.004, 0.123 |

a. PT Codes: Liver injury
 b. PFE_SE_PNG

Table 4. Observed^a to Expected Ratio of Spontaneously Reported Acute Myocardial Infarction/Myocardial infarction through 28 Feb 2021, Background Rate = 201.80/100,000 PY^b

| | Cumulative (N=130) | | Interval (N=74) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 7040.8 | 11659.1 | 3080.6 | 3301.4 |
| O/E ratio | 0.018 | 0.011 | 0.024 | 0.022 |
| (95% CI) | 0.015, 0.022 | 0.009, 0.013 | 0.019, 0.030 | 0.018, 0.028 |

a. PT Codes: Acute myocardial infarction, Myocardial infarction
 b. PFE_SE_PNG

Table 5. Observed^a to Expected Ratio of Spontaneously Reported Acute respiratory distress syndrome (ARDS) through 28 Feb 2021, Background Rate = 746.65/100,000 PY^b

| | Cumulative (N=10) | | Interval (N=7) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 26050.6 | 43138.1 | 11398.1 | 12214.9 |
| O/E ratio | 0 | 0 | 0.001 | 0.001 |
| (95% CI) | 0.000, 0.001 | 0.000, 0.000 | 0.000, 0.001 | 0.000, 0.001 |

a. PT Codes: Acute respiratory distress syndrome
 b. Study C4591004

Table 6. Observed^a to Expected Ratio of Spontaneously Reported Anosmia/Ageusia through 28 Feb 2021, Background Rate = 4.77/100,000 PY^b

| | Cumulative (N=291) | | Interval (N=148) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 166.4 | 275.6 | 72.8 | 78 |
| O/E ratio | 1.749 | 1.056 | 2.032 | 1.897 |
| (95% CI) | 1.553, 1.961 | 0.938, 1.184 | 1.718, 2.388 | 1.603, 2.228 |

a. PT Codes: Anosmia, Ageusia

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b. ACCESS narrow⁷ (FISABIO, 2019)

Table 7. Observed^a to Expected Ratio of Spontaneously Reported Arrhythmia through 28 Feb 2021, Background Rate = 772.90/100,000 PY^b

| | Cumulative (N=102) | | Interval (N=83) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 26966.5 | 44654.7 | 11798.8 | 12644.4 |
| O/E ratio | 0.004 | 0.002 | 0.007 | 0.007 |
| (95% CI) | 0.003, 0.005 | 0.002, 0.003 | 0.006, 0.009 | 0.005, 0.008 |

a. PT Codes: Arrhythmia

b. PFE_SE_PNG

Table 8. Observed^a to Expected Ratio of Spontaneously Reported Autoimmune thyroiditis through 28 Feb 2021, Background Rate = 6.20/100,000 PY^b

| | Cumulative (N=6) | | Interval (N=5) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 216.3 | 358.2 | 94.6 | 101.4 |
| O/E ratio | 0.028 | 0.017 | 0.053 | 0.049 |
| (95% CI) | 0.010, 0.060 | 0.006, 0.036 | 0.017, 0.123 | 0.016, 0.115 |

a. PT Codes: Autoimmune thyroiditis

b. PFE_SE_PNG

Table 9. Observed^a to Expected Ratio of Spontaneously Reported Bell's Palsy through 28 Feb 2021, Background Rate = 23.84/100,000 PY^b

| | (N=449) | | Interval (N=323) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 831.78 | 1377.37 | 363.93 | 390.01 |
| O/E ratio | 0.540 | 0.326 | 0.888 | 0.828 |
| (95% CI) | 0.491, 0.592 | 0.297, 0.358 | 0.793, 0.990 | 0.740, 0.924 |

a. PT Codes: Facial paresis, Facial paralysis

b. Willame, et al 2021⁶

Table 10. Observed^a to Expected Ratio of Spontaneously Reported Chillblains through 28 Feb 2021, Background Rate = 10.21/100,000 PY^b

| | Cumulative (N=7) | | Interval (N=4) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 356.2 | 589.9 | 155.9 | 167 |
| O/E ratio | 0.02 | 0.012 | 0.026 | 0.024 |
| (95% CI) | 0.008, 0.040 | 0.005, 0.024 | 0.007, 0.066 | 0.007, 0.061 |

a. PT Codes: Chillblains

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b. ACCESS narrow⁷ (CPRD, 2019)

Table 11. Observed^a to Expected Ratio of Spontaneously Reported Chronic Fatigue Syndrome/ME/PVFS through 28 Feb 2021, Background Rate = 13.16/100,000 PY^b

| | Cumulative (N=8) | | Interval (N=4) | |
|-----------------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 459.2 | 760.3 | 200.9 | 215.3 |
| O/E ratio (95% CI) | 0.017 0.008, 0.034 | 0.011 0.005, 0.021 | 0.02 0.005, 0.051 | 0.019 0.005, 0.048 |

a. PT Codes: Chronic fatigue syndrome, Post viral fatigue syndrome

b. Vincent, et al 2012⁸

Table 12. Observed^a to Expected Ratio of Spontaneously Reported Coronary Artery Disease through 28 Feb 2021, Background Rate = 179.29/100,000 PY^b

| | Cumulative (N=6) | | Interval (N=3) | |
|-----------------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 6255.4 | 10358.6 | 2737 | 2933.1 |
| O/E ratio (95% CI) | 0.001 0.000, 0.002 | 0.001 0.000, 0.001 | 0.001 0.000, 0.003 | 0.001 0.000, 0.003 |

a. PT Codes: Coronary artery disease

b. ACCESS narrow⁷ (FISABIO. 2019)

Table 13. Observed^a to Expected Ratio of Spontaneously Reported Cutaneous Vasculitis through 28 Feb 2021, Background Rate = 14.10/100,000 PY^b

| | Cumulative (N=9) | | Interval (N=8) | |
|-----------------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 491.9 | 814.6 | 215.2 | 230.7 |
| O/E ratio (95% CI) | 0.018 0.008, 0.035 | 0.011 0.005, 0.021 | 0.037 0.016, 0.073 | 0.035 0.015, 0.068 |

a. PT Codes: Cutaneous vasculitis, Vasculitic rash, Urticarial vasculitis

b. ACCESS narrow⁷ (Solid Organ Cutaneous vasculitis BIFAP, 2019)

Table 14. Observed^a to Expected Ratio of Spontaneously Reported Death (any causes)/Death through 28 Feb 2021, Background Rate = 1,116.40/100,000 PY^b

| | Cumulative (N=1219) | | Interval (N=794) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 38951.2 | 64500.7 | 17042.5 | 18263.9 |
| O/E ratio | 0.031 | 0.019 | 0.047 | 0.043 |

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| | | | | |
|----------|--------------|--------------|--------------|--------------|
| (95% CI) | 0.030, 0.033 | 0.018, 0.020 | 0.043, 0.050 | 0.041, 0.047 |
|----------|--------------|--------------|--------------|--------------|

- a. Cases with fatal outcome
- b. <https://wonder.cdc.gov>

Table 15. Observed^a to Expected Ratio of Spontaneously Reported Deep Vein Thrombosis through 28 Feb 2021, Background Rate = 50.00/100,000 PY^b

| | Cumulative (N=35) | | Interval (N=23) | |
|----------------|--------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 1744.5 | 2888.8 | 763.3 | 818 |
| O/E ratio | 0.02 | 0.012 | 0.03 | 0.028 |
| (95% CI) | 0.014, 0.028 | 0.008, 0.017 | 0.019, 0.045 | 0.018, 0.042 |

- a. PT Code: Deep vein thrombosis
- b. Heit, 2015⁹

Table 16. Observed^a to Expected Ratio of Spontaneously Reported Erythema Multiforme through 28 Feb 2021, Background Rate = 86.20/100,000 PY^b

| | Cumulative (N=13) | | Interval (N=11) | |
|----------------|--------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 3007.5 | 4980.3 | 1315.9 | 1410.2 |
| O/E ratio | 0.004 | 0.003 | 0.008 | 0.008 |
| (95% CI) | 0.002, 0.007 | 0.001, 0.004 | 0.004, 0.015 | 0.004, 0.014 |

- a. PT Code: Erythema multiforme
- b. Study C4591004

Table 17. Observed^a to Expected Ratio of Spontaneously Reported Fibromyalgia through 28 Feb 2021, Background Rate = 430.00/100,000 PY^b

| | Cumulative (N=17) | | Interval (N=12) | |
|----------------|--------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 15002.7 | 24843.5 | 6564.2 | 7034.7 |
| O/E ratio | 0.001 | 0.001 | 0.002 | 0.002 |
| (95% CI) | 0.001, 0.002 | 0.000, 0.001 | 0.001, 0.003 | 0.001, 0.003 |

- a. PT Code: Fibromyalgia
- b. Creed, 2020¹⁰

Table 18. Observed^a to Expected Ratio of Spontaneously Reported Guillain-Barré syndrome (GBS) through 28 Feb 2021, Background Rate = 2.06/100,000 PY

| | Cumulative (N=24) | | Interval (N=20) | |
|----------------|--------------------------------------|----------------------------------|--------------------------------------|----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected Cases | 71.9 | 119 | 31.4 | 33.7 |
| O/E Ratio | 0.334 | 0.202 | 0.636 | 0.593 |

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| | | | | |
|--------|--------------|--------------|--------------|--------------|
| 95% CI | 0.214, 0.497 | 0.129, 0.300 | 0.388, 0.982 | 0.362, 0.917 |
|--------|--------------|--------------|--------------|--------------|

- a. PT Codes: Guillain-Barre syndrome
- b. Willame, et al 2021⁶

Table 19. Observed^a to Expected Ratio of Spontaneously Reported Haemorrhage through 28 Feb 2021, Background Rate = 22.30/100,000 PY^b

| | Cumulative (N=42) | | Interval (N=34) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 778 | 1288.4 | 340.4 | 364.8 |
| O/E ratio | 0.054 | 0.033 | 0.1 | 0.093 |
| (95% CI) | 0.039, 0.073 | 0.023, 0.044 | 0.069, 0.140 | 0.065, 0.130 |

- a. PT Codes: Haemorrhage
- b. PFE_SE_PNG

Table 20. Observed^a to Expected Ratio of Spontaneously Reported Heart Failure through 28 Feb 2021, Background Rate = 335.01/100,000 PY^b

| | Cumulative (N=91) | | Interval (N=71) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 11688.5 | 19355.4 | 5114.1 | 5480.7 |
| O/E ratio | 0.008 | 0.005 | 0.014 | 0.013 |
| (95% CI) | 0.006, 0.010 | 0.004, 0.006 | 0.011, 0.018 | 0.010, 0.016 |

- a. PT Codes: Cardiac failure, Cardiac failure acute
- b. ACCESS narrow⁷ (BIFAP, 2019)

Table 21. Observed^a to Expected Ratio of Spontaneously Reported Herpes Zoster through 28 Feb 2021, Background Rate = 414.21/100,000 PY^b

| | Cumulative (N=282) | | Interval (N=199) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 14451.9 | 23931.4 | 6323.2 | 6776.4 |
| O/E ratio | 0.02 | 0.012 | 0.031 | 0.029 |
| (95% CI) | 0.017, 0.022 | 0.010, 0.013 | 0.027, 0.036 | 0.025, 0.034 |

- a. PT Codes: Herpes zoster, Ophthalmic herpes zoster, Herpes zoster reactivation, Herpes zoster infection, neurological, Herpes zoster oticus, Herpes zoster cutaneous disseminated, Varicella zoster virus infection
- b. C4591004

Table 22. Observed^c to Expected Ratio of Spontaneously Reported Hypertension through 28 Feb 2021, Background Rate = 926/100,000 PY^d

| | Cumulative (N=611) | | Interval (N=433) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 32315.1 | 53511.7 | 14139.0 | 15152.33 |

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| | | | | |
|-----------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| O/E ratio (95% CI) | 0.019 0.017, 0.020 | 0.011 0.011, 0.012 | 0.031 0.028, 0.034 | 0.029 0.026, 0.031 |
|-----------------------|------------------------------|------------------------------|------------------------------|------------------------------|

- a. Cases without MH of Diastolic hypertension;Essential hypertension;Hypertension;Hypertensive crisis;Hypertensive emergency;Hypertensive heart disease;Systolic hypertension, Blood pressure abnormal, Blood pressure increased
- b. ACCESS narrow⁷ (CPRD, 2019)

Table 23. Observed^c to Expected Ratio of Spontaneously Reported Thrombocytopenia through 28 Feb 2021, Background Rate = 3.82/100,000 PY^d

| | Cumulative (N=52) | | Interval (N=41) | |
|-----------------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 133.3 | 220.7 | 58.3 | 62.5 |
| O/E ratio (95% CI) | 0.39 0.291, 0.512 | 0.236 0.176, 0.309 | 0.703 0.505, 0.954 | 0.656 0.471, 0.890 |

- c. PT Codes: Immune thrombocytopenia, Thrombocytopenia
- d. Willame, et al 2021⁶

Table 24. Observed^a to Expected Ratio of Spontaneously Reported Limb Ischemia through 28 Feb 2021, Background Rate = 260.00/100,000 PY^b

| | Cumulative (N=3) | | Interval (N=1) | |
|-----------------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 9071.4 | 15021.6 | 3969.1 | 4253.5 |
| O/E ratio (95% CI) | <0.001 0.000, 0.001 | <0.001 0.000, 0.001 | <0.001 0.000, 0.001 | <0.001 0.000, 0.001 |

- a. PT Codes: Peripheral ischaemia
- b. Duff, et al. 2019¹¹

Table 25. Observed^a to Expected Ratio of Spontaneously Reported Meningitis through 28 Feb 2021, Background Rate = 0.10/100,000 PY^b

| | Cumulative (N=5) | | Interval (N=4) | |
|-----------------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 3.49 | 5.78 | 1.53 | 1.64 |
| O/E ratio (95% CI) | 1.43 0.465, 3.344 | 0.865 0.281, 2.020 | 2.62 0.714, 6.709 | 2.45 0.666, 6.260 |

- a. PT Codes: Meningitis, Meningitis aseptic
- b.. CDC¹²

Table 26. Observed^a to Expected Ratio of Spontaneously Reported Multiple Sclerosis (MS) through 28 Feb 2021, Background Rate = 11.60/100,000 PY^b

| | Cumulative (N=23) | Interval (N=14) |
|--|-------------------|-----------------|
|--|-------------------|-----------------|

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| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
|----------------|---|---|---|---|
| Expected cases | 404.7 | 670.2 | 177.1 | 189.8 |
| O/E ratio | 0.057 | 0.034 | 0.079 | 0.074 |
| (95% CI) | 0.036, 0.085 | 0.022, 0.051 | 0.043, 0.133 | 0.040, 0.124 |

- a. PT Codes: Optic neuritis, Multiple sclerosis relapse, Multiple sclerosis
- b. PFE_SE_PNG

Table 27. Observed^a to Expected Ratio of Spontaneously Reported Multisystem Inflammatory Syndrome through 28 Feb 2021, Background Rate = 1.47/100,000 PY^b

| | Cumulative (N=23) | | Interval (N=13) | |
|----------------|---|---|---|---|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 51.3 | 84.9 | 22.4 | 24 |
| O/E ratio | 0.448 | 0.271 | 0.579 | 0.541 |
| (95% CI) | 0.284, 0.673 | 0.172, 0.406 | 0.308, 0.991 | 0.288, 0.924 |

- a. PT Codes: Systemic inflammatory response syndrome, Multiple organ dysfunction syndrome, Multisystem inflammatory syndrome in children
- b. ACCESS narrow⁷ (BIFAP, 2019)

Table 28. Observed^a to Expected Ratio of Spontaneously Reported Myasthenia Gravis through 28 Feb 2021, Background Rate = 0.17/100,000 PY^b

| | Cumulative (N=3) | | Interval (N=3) | |
|----------------|---|---|---|---|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 5.9 | 9.8 | 2.6 | 2.8 |
| O/E ratio | 0.506 | 0.305 | 1.156 | 1.079 |
| (95% CI) | 0.104, 1.478 | 0.063, 0.893 | 0.238, 3.378 | 0.222, 3.152 |

- a. PT Codes: Myasthenia gravis
- b. Carr, 2010¹³

Table 29. Observed^a to Expected Ratio of Spontaneously Reported Myocarditis through 28 Feb 2021, Background Rate = 4.40/100,000 PY^b

| | Cumulative (N=25) | | Interval (N=20) | |
|----------------|---|---|---|---|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 153.5 | 254.2 | 67.2 | 72 |
| O/E ratio | 0.163 | 0.098 | 0.298 | 0.278 |
| (95% CI) | 0.105, 0.240 | 0.064, 0.145 | 0.182, 0.460 | 0.170, 0.429 |

- a. PT Codes: Myocarditis
- b. Elfstrom, et al. 2007¹⁴

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Table 30. Observed^a to Expected Ratio of Spontaneously Reported Narcolepsy through 28 Feb 2021, Background rate 1.08/100,000 PY^b

| | Cumulative (N=5) | | Interval (N=3) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 37.7 | 62.4 | 16.5 | 17.7 |
| O/E ratio | 0.133 | 0.08 | 0.182 | 0.17 |
| (95% CI) | 0.043, 0.310 | 0.026, 0.187 | 0.038, 0.532 | 0.035, 0.496 |

- a. PT Codes: Cataplexy, Narcolepsy
 b. Willame, et al 2021⁶

Table 31. Observed^a to Expected Ratio of Spontaneously Reported Pericarditis through 28 Feb 2021, Background Rate = 18.00/100,000 PY^b

| | Cumulative (N=32) | | Interval (N=23) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 628 | 1040 | 274.8 | 294.5 |
| O/E ratio | 0.051 | 0.031 | 0.084 | 0.078 |
| (95% CI) | 0.035, 0.072 | 0.021, 0.043 | 0.053, 0.126 | 0.050, 0.117 |

- a. PT Codes: Pericarditis
 b. Elfstrom, et al. 2007¹⁴

Table 32. Observed^a to Expected Ratio of Spontaneously Reported Peripheral Neuropathy through 28 Feb 2021, Background Rate = 2.50/100,000 PY^b

| | Cumulative (N=53) | | Interval (N=37) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 87.2 | 144.4 | 38.2 | 40.9 |
| O/E ratio | 0.608 | 0.367 | 0.97 | 0.905 |
| (95% CI) | 0.455, 0.795 | 0.275, 0.480 | 0.683, 1.336 | 0.637, 1.247 |

- a. PT Codes: Neuropathy peripheral, Polyneuropathy
 b. PFE_SE_PNG

Table 33. Observed^a to Expected Ratio of Spontaneously Reported Pulmonary Embolus through 28 Feb 2021, Background Rate = 30.00/100,000 PY^b

| | Cumulative (N=60) | | Interval (N=48) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 1046.7 | 1733.3 | 458 | 490.8 |
| O/E ratio | 0.057 | 0.035 | 0.105 | 0.098 |
| (95% CI) | 0.044, 0.074 | 0.026, 0.045 | 0.077, 0.139 | 0.072, 0.130 |

- a. PT Codes: Pulmonary embolism
 b. Heit, 2015⁹

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Table 34. Observed^a to Expected Ratio of Spontaneously Reported Rheumatoid Arthritis, polyarthritis through 28 Feb 2021, Background Rate = 64.70/100,000 PY^b

| | Cumulative (N=31) | | Interval (N=25) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 2257.4 | 3738.1 | 987.7 | 1058.5 |
| O/E ratio | 0.014 | 0.008 | 0.025 | 0.024 |
| (95% CI) | 0.009, 0.019 | 0.006, 0.012 | 0.016, 0.037 | 0.015, 0.035 |

a. PT Codes: Rheumatoid arthritis, Polyarthritis
 b. PFE_SE_PNG

Table 35. Observed^a to Expected Ratio of Spontaneously Reported Seizures / convulsions/Seizure disorders (inc. febrile) through 28 Feb 2021, Background Rate = 82.90/100,000 PY^b

| | Cumulative (N=253) | | Interval (N=199) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 2892.4 | 4789.6 | 1265.5 | 1356.2 |
| O/E ratio | 0.087 | 0.053 | 0.157 | 0.147 |
| (95% CI) | 0.077, 0.099 | 0.047, 0.060 | 0.136, 0.181 | 0.127, 0.169 |

a. PT Codes: Febrile convulsion, Seizure, Generalised tonic-clonic seizure, Partial seizures
 b. PFE_SE_PNG

Table 36. Observed^a to Expected Ratio of Spontaneously Reported Stroke/Cerebrovascular stroke/Stroke and other cerebrovascular events through 28 Feb 2021, Background Rate = 198.40/100,000 PY^b

| | Cumulative (N=273) | | Interval (N=195) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 6922.18 | 11462.67 | 3028.7 | 3245.76 |
| O/E ratio | 0.039 | 0.024 | 0.064 | 0.060 |
| (95% CI) | 0.035, 0.044 | 0.021, 0.027 | 0.056, 0.074 | 0.052, 0.069 |

a. PT Codes: Cerebral haemorrhage, Haemorrhagic stroke, Cerebral haematoma, Subarachnoid haemorrhage, Brain stem haemorrhage, Haemorrhage intracranial, Intracranial haematoma, Cerebrovascular accident, Ischaemic stroke, Cerebral infarction, Basal ganglia stroke, Cerebral thrombosis, Cerebral venous sinus thrombosis, Thrombotic stroke, Basal ganglia infarction, Basilar artery thrombosis, Brain stem stroke, Lacunar infarction
 b. PFE_SE_PNG

Table 37. Observed^a to Expected Ratio of Spontaneously Reported Transverse myelitis through 28 Feb 2021, Background Rate = 0.97/100,000 PY^b

| | Cumulative (N=20) | | Interval (N=17) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 33.8 | 56 | 14.8 | 15.9 |
| O/E ratio | 0.591 | 0.357 | 1.148 | 1.071 |

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| | | | | |
|----------|--------------|--------------|--------------|--------------|
| (95% CI) | 0.361, 0.913 | 0.218, 0.551 | 0.669, 1.838 | 0.624, 1.715 |
|----------|--------------|--------------|--------------|--------------|

- a. PT Codes: Myelitis transverse, Myelitis
- b. Willame, et al 2021⁶

Table 38. Observed^c to Expected Ratio of Spontaneously Reported Type 1 Diabetes through 28 Feb 2021, Background Rate = 38.9/100,000 PY^d

| | Cumulative (N=3) | | Interval (N=3) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 1357.2 | 2247.5 | 593.8 | 636.4 |
| O/E ratio | 0.002 | 0.001 | 0.005 | 0.005 |
| (95% CI) | 0.000, 0.006 | 0.000, 0.004 | 0.001, 0.015 | 0.001, 0.014 |

- a. PT Codes: Type 1 diabetes mellitus NOTE: PT codes for SMSR2 included Diabetes mellitus without rest
- b. PFE_SE_PNG

Table 39. Observed^c to Expected Ratio of Spontaneously Reported Vasculitis through 28 Feb 2021, Background Rate = 11.43/100,000 PY^d

| | Cumulative (N=23) | | Interval (N=19) | |
|----------------|---------------------------------------|-----------------------------------|---------------------------------------|-----------------------------------|
| | 21-Day Risk Window (3,489,001 PY) | No Risk window (5,777,558 PY) | 21-Day Risk Window (1,526,560 PY) | No Risk Window (1,635,967 PY) |
| Expected cases | 398.6 | 660.1 | 174.4 | 186.9 |
| O/E ratio | 0.058 | 0.035 | 0.109 | 0.102 |
| (95% CI) | 0.037, 0.087 | 0.022, 0.052 | 0.066, 0.170 | 0.061, 0.159 |

- c. PT Codes: Vasculitis, Polymyalgia rheumatica
- d. Study C4591004

For most cumulative and interval data, the upper limit of the 95% CI is substantially less than 1.

For most events, the ratio is higher in the interval period than in the cumulative, even when restricted to the 21-day risk window. This could reflect changes in the accuracy of the person year estimate, increased reporting rate over time, an increased reporting rate with second dose as the proportion of vaccinees receiving a second dose is increasing over time, higher rates of spontaneous event reporting in countries where the vaccine was recently authorized, or a combination of these.

Anosmia/ageusia, meningitis, peripheral neuropathy, transverse myelitis, and myasthenia gravis were found to have a 95% CI is greater than 1 for at least one of the risk periods (cumulative/interval) or risk windows (21-weeks, no risk window). While typically the lower level of the 95% CI would be the criterion for evaluating a difference from expectation, in this setting, given the generally substantial gap between the lower limit and 1, an upper limit in excess of one might suggest the possibility of an excess risk in vaccinees. These events are further described in the Discussion.

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2.8. DISCUSSION

2.8.1. Cardiogenic shock and postural orthostatic tachycardia syndrome

At this time, although included as requested by regulatory authorities to be included as AESI, relevant background rates have not been identified for the analysis of cardiogenic shock and postural orthostatic tachycardia syndrome.

2.8.2. Anosmia/Ageusia

For anosmia/ageusia, the lower level of the confidence interval exceeds 1 for both the cumulative and interval (01-28 Feb 2021) risk periods and for the no risk window and 21-day risk windows, suggesting that the observed rate of this outcome is higher in vaccinees in comparison to the background rate, generated from 2019 medical records. Anosmia/ageusia is notably a symptom of COVID-19 illness. Contemporaneous background rates of this endpoint are therefore likely to be increased in the background due to COVID-19 compared to the 2019 data used for the background rate. The MAH's COVID-19 vaccine requires 2-doses spaced 21-days apart before achieving maximum effectiveness. It is possible that within the 21-day window especially that COVID-19 may occur. Alternatively, general awareness of anosmia/ageusia is currently increased as a result of COVID-19 compared with 2019. Cases of anosmia/ageusia reported in this report will be reviewed and described in the next SMSR.

2.8.3. Meningitis, Myasthenia gravis, Transverse myelitis, Peripheral neuropathy

For Meningitis, Myasthenia gravis, Transverse myelitis, and Peripheral neuropathy the upper level of the 95% confidence interval exceeds one for at least one of the cumulative or interval risk periods, suggesting the possibility that the true O/E may exceed 1. As these rates are not related to COVID, we would not expect contemporaneous rates to be higher than in the historical periods used for determining background rates. These are known potential risks of vaccines and would be likely to be reported. Cases of the events reported in this report will be reviewed and described in the next SMSR.

2.8.4. Age-Adjustment

The MAH is aware of requests for age-stratified O/E analyses for Bell's palsy and serious ear and labyrinth disorders *as per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002.1)*. At this time, the MAH is not able to provide these because accurate information about age-distribution of vaccine is unknown and challenging to estimate given the country-specific guidelines for populations to prioritize for vaccination as well as differences in population structure. The MAH will continue to try to identify relevant sources of information to allow for age-adjusted O/E estimates.

2.8.5. Limitations

There are several limitations to observed to expected analyses for signal detection. The observed case counts are likely to be underestimated due to underreporting that occurs with spontaneous report surveillance. Additional reasons for underestimations includes incomplete reporting and lags in reporting. Spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are

more likely to be reported even if they do not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are more likely to be underreported due to lack of recognition of a potential association.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus the exposure is underestimated. Additionally exposure post dose 1 and dose 2 is not differentiated such that any differences in risk of AESI between dose 1 and dose 2 is not measured.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. The background rates used in this analysis are derived from one large US electronic health records database, one large US insurance claims database, EU- health care systems, or regional studies published in the literature and the majority of exposure data derives from the US. However, it is possible that the delivery of health care, population demographics, and underlying health status of the populations used for the background rate estimates differ from those expected in the persons administered the vaccine.

A final limitation concerns the risk window, the period during which one is expected to be at risk of a given event if there is a causal association between the event and the vaccine. Two periods: 21 days and unlimited time are the risk windows selected to provide an estimate assuming a more acute onset (21-day window) and a more latent onset (unlimited window) The 21-day risk window is potentially conservative as all observed cases are included in the numerator of the O/E ratio regardless of the days since vaccination dose, which will lead to an overestimation of the ratio if observed cases occurred outside of the risk window.

2.9. OBSERVED TO EXPECTED ANALYSES FOR ANAPHYLAXIS (IDENTIFIED RISK)

Given that anaphylaxis is an identified risk, the goal of an observed to expected comparison would not be signal identification but risk estimation. Risk of anaphylaxis is reported per dose administered in comparison with rates observed for other vaccines rather than in an unexposed population.

The MAH has conducted unadjusted observed to expected ratio (O/E) analyses after reviewing the 1232 cumulative cases of anaphylaxis occurring outside of a clinical trial setting reported in the global safety database. Anaphylaxis cases were identified using the MedDRA version 23.1 SMQ Anaphylactic reaction (broad with algorithm applied) and then focusing on cases presenting any symptom on day 0 (vaccination day). Cases assessed as Brighton Collaboration Levels 1-2 are included (N=766) in the analysis. A background rate¹⁵ of vaccine anaphylaxis 1.31 per million doses was assumed.

An estimated 75,397,549.3 doses of Pfizer-BioNTech COVID 19 vaccine have been administered through 28 February 2021. This estimate is derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized.⁵ For periods when more than one vaccine was authorized for use in each country, the doses

administered were assumed to be divided equally by the number of vaccines approved. This estimate does not reflect exposure in persons vaccinated in countries that did not publicly report.

For each event, expected counts were determined by multiplying the number of doses administered by the expected rates per dose.

An O/E ratio of 7.76 (95% CI, 7.22, 8.33) was observed for BNT162b2 compared with the background rate for anaphylaxis cases observed in the US.¹⁵ This rate has declined from the 9.47 (95% CI, 8.61 – 10.40) reported in SMSR2, which included events reported through January. However, whether the decline reflects decreased reporting, changes in the accuracy of the exposure estimate, or changes in population being vaccinated is unknown.

There are several limitations to consider when interpreting these analyses. The analyses did not adjust for differences in characteristics between persons being administered the vaccine and populations from which the background rate is derived such as age and comorbidities. At this time, national/local guidelines typically recommend prioritizing vaccine administration for healthcare workers at high-risk of COVID-19 exposure and persons with underlying conditions who are at risk of serious COVID-19 illness, including the elderly and those with underlying health conditions. The spontaneous reports system likely underestimates the true number of observed events in vaccinated persons due to incomplete reporting or a lag in reporting.

On the other hand, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine, eg, due to news media reports, are more likely to be reported than other events. With respect to the expected number of events, estimates concerning both exposure to vaccine and the background rate have limitations. This exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the total doses of vaccine administration used to determine the expected count of events is potentially underestimated.

Further, the delivery of health care, population demographics, and underlying health status of the populations included in the background rate estimates differ from those expected in the persons administered the vaccine.

¹ Consideration on core requirements for RMPs of COVID19 vaccines
coreRMP19 guidance EMA/544966/2020

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APPENDIX 6. LITERATURE REVIEW IN THE REPORTING PERIOD (METHODOLOGY)

A web-based literature review service is used to review medical literature from clinical and non-clinical literature sources for significant safety information relevant to authorized Pfizer medicinal product including reviews and practice guidelines.

The following bibliographic databases are searched in this order:

1. MEDLINE®
2. Embase

Each search uses controlled vocabulary terms that are unique to each database. For each database, the search focuses on the following:

- AEs, effects and outcomes
- Generic name of the drug
- Prenatal and perinatal exposure and exposure through breast milk
- Drug interactions
- Clinical studies
- Epidemiology and meta-analyses
- Poisoning and toxicity
- Drug resistance and drug tolerance
- Toxicity tests

Searches are limited by date and by literature type. Editorials, and news reports (i.e., works consisting of an announcement or statement of recent or current events of new data and matters of interest in the field of medicine or science) are excluded because they are not peer-reviewed.