Line Listing Report Time run: 30/11/2022 15:16:33

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)		Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10011152157	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved -), Swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[CREATINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10011152211	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011152561	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011152564		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011152593		Spontaneous Spontaneous	Healthcare Professional	Non European Economic Area	Not available Not	12-17 Years	Not Specified	Female Female	No No	Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Hypotonia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY	Not reported Not reported	ICSR ICSR
10011152672			Healthcare Professional	European Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10011152679	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011152750	04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011152757	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	· · · · ·		
EU-EC- 10011152827	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Pain in extremity (n/a - Recovered/Resolved -)			
EU-EC- 10011152927	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011152974	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CYANOCOBALAMIN, VITAMIN B12] (C - Vitamin B12 deficiency - n/a - [n/a - n/a - n/a])	ICSR
										Lymphadenopathy (n/a - Unknown - Other Medically Important Condition),	· , - · , - , ,		
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011153064	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -		ICSR
										- Unknown - Other Medically Important Condition)	n/a - n/a])	[MESALAZINE] (C - Colitis ulcerative - n/a - [n/a - n/a - n/a])	
EU-EC- 10011153094	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Unknown - Other			

										Medically Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10011153123	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature fluctuation (n/a - Unknown - Other Medically Important Condition), Pallor (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown - Other Medically Important Condition),			
										Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Seizure anoxic (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011153521	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011153711	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Neck pain (n/a - Not Recovered/Not Resolved -),			
EU-EC-	04/01/2022	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -) Blood pressure	COMIRNATY	Not reported	ICSR
10011153771	0 1/01/2022	Sportaricous	Professional	Economic Area	available	Years	Specified	Cindic		systolic decreased (0d - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	riot reported	ICSIX
										Dizziness (0d - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011154032	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a -	ICSR
				Area						Musculoskeletal stiffness (n/a - Unknown -),	immunisation - Not applicable - [n/a - n/a - n/a])	n/a])	
										Pain (2d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (2d -			

		I	I	I	I	l				Recovered/Resolved	I	I	ı
EU-EC- 10011154153	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10011154176	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Allergy to arthropod bite (n/a - Recovering/Resolving - Other Medically Important	n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Condition), Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10011154191	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011154196	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Thrombosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011154240	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										-), Migraine (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Recovered/Resolved -)			
EU-EC- 10011154396	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Condition), Pallor (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011154410	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Medically Important Condition)			
EU-EC- 10011154551	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotonic- hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (30s - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Medically Important Condition), Seizure (30s - Unknown - Other Medically Important			
EU-EC-	04/01/2022	Spontaneous	Healthcare	European	Not	12-17	Not	Not	No	Condition) SARS-CoV-2 test	COMIRNATY	Not reported	ICSR

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10011154602			Professional	Economic Area	available	Years	Specified	Specified		positive (n/a - Unknown -)	CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10011154818	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain lower (0d - Recovering/Resolving -), Chills (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011154836	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blood pressure decreased (0d - Recovered/Resolved -), Dizziness (0d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Influenza like illness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011154897	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Troponin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011154940	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Hypokinesia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	IRON [IRON] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-	04/01/2022	Spontonoous	Non	Europoan	Not	12-17	Not	Female	No	Muscle spasms (n/a - Recovering/Resolving -), Premenstrual pain (n/a - Unknown -)	COMIRNATY	Not reported	ICCD
10011155061	07/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Specified	i enlate	INU	Amenorrhoea (n/a - Not Recovered/Not Resolved - Disabling)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011155482	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011155540	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Other Medically Important Condition) Herpes zoster (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a -	Not reported	ICSR
EU-EC- 10011155702	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a	Not reported	ICSR

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										Important Condition), Myocarditis (n/a -	- [n/a - 1{DF} - Intramuscular])		
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
EU-EC-	04/04/2022					12.17		5	N	Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMPANY		TOOD
10011155838	04/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (3d - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Myocarditis (3d - Recovering/Resolving - Other Medically Important Condition),			
										Troponin increased (3d - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011156273	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Unknown - Other Medically Important Condition), Facial pain (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Unknown - Other Medically Important Condition), Myalgia (n/a -			
										Unknown - Other Medically Important Condition), Oropharyngeal pain			
										(n/a - Unknown - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011156596	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Dyspnoea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Echocardiogram abnormal (n/a - Unknown -), Pericardial effusion	n/a - n/a])		
										(n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011156600	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Prolactin-producing pituitary tumour (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011156647	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -), Thrombosis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	04/01/2022	Spontaneous	Non	European	Not	12-17	Not	Male	No	Unknown - Other Medically Important Condition) Myocarditis (n/a -	COMIRNATY	Not reported	ICSR
10011157145			Healthcare Professional	Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10011157220	04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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										Condition)	[n/a - n/a - n/a])		
EU-EC- 10011157266	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSE
										Vaccination failure (n/a - Unknown - Other Medically	Intramuscular])		
EU-EC- 10011157318	04/01/2022	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Economic Area						Loss of consciousness (30s - Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011157577	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Lethargy (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				Alca						Unknown -), Syncope (n/a -	applicable - [n/a - n/a - n/a])		
EU EC	04/04/2022	Constant	11	Nor	Note	12.17	Note	Na-L-	NI-	Unknown - Other Medically Important Condition)	COMIDNATI	Network	TOOD
EU-EC- 10011157580	04/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - n/a - n/a])		
										Pain (n/a - Not Recovered/Not Resolved -),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011158107	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a -	Not reported	ICSR
										Condition), Vaccination failure (n/a - Unknown -	[n/a - n/a - Intramuscular])		
	24/24/2022					10.15				Other Medically Important Condition)			
EU-EC- 10011158325	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[CICLESONIDE] (C - Asthma - n/a - [n/a - n/a - Oral]), [SALBUTAMOL,	ICSR
										Dyspnoea at rest (n/a - Not Recovered/Not Resolved - Other	n/a - Intramuscular])	SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Oral])	
										Medically Important Condition),		ilya - Oraij)	
										Dyspnoea exertional (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pulmonary function test decreased (n/a - Not Recovered/Not Resolved -),			
										Wheezing (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011158462	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy (6d - Recovered/Resolved - Other Medically Important Condition),			
										Mastication disorder (7d -			

EU-EC- 10011158468		Spontaneous eu/analytic	Professional	Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Unknown - Life Threatening, Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR 8/24
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										Oropharyngeal pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) Sinus tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10011158538	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011158783	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011158808	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Myocarditis (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011159080	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10011159089	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2h - Recovered/Resolved -), Eye pain (2h - Recovered/Resolved -), Hypoaesthesia (2h - Recovered/Resolved -), Neck pain (2h - Recovered/Resolved -), Pain (2h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	04/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	-) Tachycardia (n/a -	COMIRNATY	Not reported	ICSR
10011159103			Healthcare Professional	Economic	available	Years				Recovering/Resolving -), Tremor (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	·	
EU-EC-	04/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	-) Asthenia (n/a -	COMIRNATY	Not reported	ICSR
10011159121			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -), Cough (n/a - Recovering/Resolving -), Decreased appetite (n/a - Recovering/Resolving -), Dehydration (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Paronychia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving -), Tracheitis (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving	(S - COVID-19 immunisation - Not applicable - [1d -		
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10011159221	04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10011159222	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011159223	04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent		No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-		Spontaneous		European	Not	12-17	Not	Female	No	Asthenia (1d -	COMIRNATY	Not reported	ICSR 10/24

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10011159224			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10011159227	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Chest pain (n/a - Not Recovered/Not Resolved -), Vaccination site reaction (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011159427	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Migraine (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011159802	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011159924	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Eye swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Hypersensitivity (n/a - Recovered/Resolved - Other Medically Important Condition), Hypersomnia (n/a - Recovered/Resolved - Other Medically Important Condition), Lymph node pain (n/a - Recovered/Resolved - Other Medically Important Condition), Lymph node pain (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved -), Oropharyngeal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Pharyngeal swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Pharyngeal swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Pharyngeal swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Pharyngitis (n/a - Pharyn	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FLUDROCORTISONE ACETATE] (C - Hypotension - n/a - [124d - n/a - n/a])	ICSR

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										Recovered/Resolved -), Pyrexia (n/a -			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011160206	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving -), Fatique (n/a - Not			
										Recovered/Not Resolved -), Headache (n/a - Not			
										Recovered/Not Resolved -),			
EU-EC-	04/01/2022	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Recovered/Resolved -) Myocarditis (9d -	COMIRNATY	Not reported	ICSR
10011160393			Professional	Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10011160498	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011160507	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[IBUPROFEN] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved -),	applicable - [1d - n/a - n/a])	[MENINGOCOCCAL VACCINE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011160707	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	,,	(S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Urticaria (2d - Recovering/Resolving -)	n/a])		
EU-EC- 10011160718	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011160724	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a -	Not reported	ICSR
										Hypoaesthesia (1d - Recovered/Resolved -)	1{DF} - n/a])		
EU-EC- 10011160752	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (n/a - Recovered/Resolved	[ind ind ind]		
										-), Injection site			
										paraesthesia (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -),			
										Somnolence (n/a - Recovered/Resolved -)			
EU-EC- 10011160821	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved -)	n/a])		

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EU-EC- 10011160918	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown -), Fibrin D dimer increased (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Troponin (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	04/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Unknown -) Chills (n/a -	COMIRNATY	Not reported	ICSR
10011160995	0 1/01/2022	Sportaneous	Healthcare	Economic Area	available	Years	Acoeseen	ridic		Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	not reported	1001
										Injection site swelling (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving			
EU-EC- 100111161050	04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10011161059	04/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Nausea (1d - Recovered/Resolved	n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011101035				Area	uvulubic	reurs				-), Vomiting (1d - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011161096	04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										segment depression (n/a - Not Recovered/Not Resolved -),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Rhinorrhoea (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011161162	04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011161253	04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash macular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011161335	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011161569	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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									Fatigue (n/a - Recovered/Resolved -),			
									Headache (n/a - Recovered/Resolved			
									Lymphadenopathy			
									(n/a - Recovered/Resolved -),			
									Myalgia (n/a - Recovered/Resolved -),			
									Pyrexia (n/a - Recovered/Resolved -)			
04/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
									Generalised tonic- clonic seizure (n/a - Recovered/Resolved - Other Medically Important Condition),			
									Presyncope (0d - Recovered/Resolved			
04/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-)	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn -	Not reported	ICSR
04/01/2022	Spontaneous		Non	Not	12-17	Not	Female	No	Drug ineffective (n/a	COMIRNATY	Not reported	ICSR
		Professional	Economic Area	avallable	rears	Specified			Recovered/Resolved With Sequelae - Other Medically Important Condition),			
									Dysmenorrhoea (60d			
									-),			
									Heavy menstrual bleeding (n/a - Recovering/Resolving -),			
									Polymenorrhoea (n/a			
									Recovering/Resolving -),			
									Suspected COVID-19 (n/a -			
									Recovered/Resolved With Sequelae - Other Medically Important Condition)			
04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	(S - n/a - n/a -	Not reported	ICSR
03/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -).	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
									,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	immunisation - Not		
03/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
									Fatigue (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - n/a - n/a])		
									Headache (n/a - Not Recovered/Not Resolved -),			
									Insomnia (n/a - Not Recovered/Not Resolved -),			
									Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -)			
	04/01/2022 04/01/2022 04/01/2022	04/01/2022 Spontaneous 04/01/2022 Spontaneous 04/01/2022 Spontaneous 03/01/2022 Spontaneous	04/01/2022 Spontaneous Professional 03/01/2022 Spontaneous Professional 03/01/2022 Spontaneous Professional	04/01/2022 Spontaneous Healthcare Professional Buropean Economic Area 04/01/2022 Spontaneous Non Healthcare Professional European Economic Area 04/01/2022 Spontaneous Professional Non Healthcare Professional European Economic Area 04/01/2022 Spontaneous Professional Non Healthcare Professional European Economic Area 03/01/2022 Spontaneous Professional Non Healthcare Professional European Economic Area 03/01/2022 Spontaneous Professional Non Healthcare Professional European Economic Area 03/01/2022 Spontaneous Professional Non Healthcare Professional European Economic Area	04/01/2022 Spontaneous Healthcare Professional European Economic Area 04/01/2022 Spontaneous Non Healthcare Professional Area 04/01/2022 Spontaneous Non Healthcare Professional Area 04/01/2022 Spontaneous Non Healthcare Professional Area 03/01/2022 Spontaneous Non Healthcare Economic Area	04/01/2022 Spontaneous Healthcare Professional European Reconomic Area Professional European Professional European Professional European Professional European Reconomic Area Professional European Professional European Reconomic Area Professional Reconomic Reconomic Area Professional Reconomic Reconom	04/01/2022 Spontaneous Healthcare Professional Area Non Professional European Not available Professional Area Non Healthcare Economic Area Non Healthcare Economic Area Non Healthcare Economic Area Non Healthcare Economic Area 04/01/2022 Spontaneous Non Healthcare Economic Area 03/01/2022 Spontaneous Non Healthcare Economic Professional Area 03/01/2022 Spontaneous Non Healthcare Economic Area Not 12-17 Not Specified Not available Professional Area Not available Professional Area	04/01/2022 Spontaneous Non Healthcare Professional European Economic Area Not Wallable Professional European Economic Area Not Healthcare Professional Economic Area Not Healthcare Professional Economic Area Not Healthcare Professional Economic Rarea Not Specified Professional Rarea Not Wallable Professional Economic Rarea Not Wallable Professional Economic Rarea Not Wallable Professional Rarea Specified Male Wallable Professional Rarea Not Wa	04/01/2022 Spontaneous Professional European Professional Economic Area Not Professional Area Not Not Professional Economic Not Professional Area Not Not Professional Economic Not Professional Economic Not Professional Economic Not Professional Economic Not	Professional Professional Security Professional Security Professional Profess	Professional Pro	PA-BI-7/2022 Sportbrooks Participation Participation

EU-EC- 10011141425		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified		No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011141495	03/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Unknown -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hypersomnia (n/a - Unknown -),			
										Illness (n/a - Unknown -),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Migraine (n/a - Not Recovered/Not Resolved -),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved -)			
EU-EC- 10011141507	03/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011142081	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Menstruation irregular (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011143013	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Menstrual disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011143345	03/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Illness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011143435	03/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Recovering/Resolving - Other Medically Important Condition)	immunisation - Not	Not reported	ICSR
EU-EC- 10011143542	03/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -), Inappropriate	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										schedule of product administration (n/a - Unknown -),	n/a - n/a])		
										Lymphadenopathy (n/a - Recovered/Resolved			

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										Pain (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10011143580	03/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011143585	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
										Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10011143592	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011143834	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a -	Not reported	ICSR
										Diarrhoea (n/a - Not Recovered/Not Resolved -),	n/a - Intramuscular])		
										Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not			
										Recovered/Not Resolved -), Nausea (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10011143976	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Agitation (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Altered state of consciousness (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Confusional state (1d			
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dysarthria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Encephalitis (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important			

									Condition),			
									Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
									Muscle contractions involuntary (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
									Seizure (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
									Vomiting (n/a - Unknown - Other Medically Important Condition)			
03/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -), Rash papular (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
03/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving -), Pain in extremity	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
									Peripheral swelling			
03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (6d - Recovered/Resolved -), Fatigue (6d -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
									Headache (2d - Recovered/Resolved -),			
									Somnolence (6d - Recovered/Resolved -)			
03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
									Recovering/Resolving -), Skin haemorrhage	meanascalary)		
									Skin injury (n/a - Recovering/Resolving			
03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR
									Vaccination failure (n/a - Unknown - Other Medically Important Condition)	The amascalar j)		
03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
									(n/a - Unknown - Other Medically Important Condition)			
03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Caused/Prolonged Hospitalisation), Dehydration (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
	03/01/2022	03/01/2022 Spontaneous 03/01/2022 Spontaneous 03/01/2022 Spontaneous 03/01/2022 Spontaneous	D3/01/2022 Spontaneous Non Healthcare Professional D3/01/2022 Spontaneous Healthcare Professional D3/01/2022 Spontaneous Non Healthcare Professional D3/01/2022 Spontaneous Healthcare Professional D3/01/2022 Spontaneous Healthcare Professional D3/01/2022 Spontaneous Healthcare Professional D3/01/2022 Spontaneous Healthcare Professional	Healthcare Professional Spontaneous Non Healthcare Professional Suropean Healthcare Economic Area	Healthcare Professional Ruropean Healthcare Professional Professional Ruropean Ruropean Professional Ruropean	Healthcare Professional Reconomic Area Not Professional Solution (Area) 33/01/2022 Spontaneous Healthcare Professional Reconomic Area Not Professional Reconomic Area 33/01/2022 Spontaneous Non Healthcare Professional Reconomic Area Not Professional Reconomic Reconomic Area Not Professional Reconomic Reconomic Area Not Professional Reconomic Area	Healthcare Professional Reconomic Area Specified 33/01/2022 Spontaneous Healthcare Professional Reconomic Area Specified Area Specified 33/01/2022 Spontaneous Healthcare Professional Reconomic Area Specified Specif	Healthcare Professional Area European Area Not Professional Professional Area Not Not Professional Area Not Not Not Not Professional Area Not	Healthcare Professional Area	- Caused Prickongo - Countries and Committee - Caused Prickongo - Caused - Cau	Caused Processoral Control Caused Proceso	Contact Cont

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										Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation),			
										Pancreatitis acute (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011145230	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Administration site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011145469	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011145491	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011145724	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (0d - Recovered/Resolved - Life Threatening), Skin reaction (0d -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	03/01/2022	Chantanaous	Haalthaara	Europoan	Not	12-17	Adolescent	Malo	No	Recovered/Resolved - Life Threatening) COVID-19 (n/a -	COMIRNATY	Not reported	ICCD
10011145776	03/01/2022	Spontaneous	Professional	European Economic Area	available	Years	Adolescent	Male	NO	Unknown - Other	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011145931	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011146099	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011146137	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Condition), Headache (1wk - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011146180	03/01/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Important Condition) COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		

										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011146268	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (2d - Recovered/Resolved - Disabling), Fatigue (2d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Headache (2d - Recovered/Resolved - Disabling),			
										Injection site reaction (2d - Recovered/Resolved - Disabling),			
										Malaise (2d - Recovered/Resolved - Disabling),			
										Myalgia (2d - Recovered/Resolved - Disabling),			
										Polymenorrhoea (2d - Recovered/Resolved - Disabling)			
EU-EC- 10011146438	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
FIL F0	02/04/2022					12.17		-		Vaccination failure (n/a - Unknown - Other Medically Important Condition)			1000
EU-EC- 10011146611	03/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSF</u>
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 100111146760	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011146837	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstrual disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[FLUOXETINE] (C - Depression - n/a - [n/a - 20mg - n/a])	ICSR
										(n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011147006	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
										Headache (3d - Recovered/Resolved -), Injection site pain	n/a])		
										(3d - Recovered/Resolved -)			
EU-EC- 10011147026	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angina pectoris (6d - Not Recovered/Not Resolved -), Arrhythmia (6d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC-	02/01/2022	Spontaneous	Hoalthcaro	European	Not	12-17	Adolescent	Malo	No	Recovered/Not Resolved -) COVID-19 (n/a -	COMIRNATY	Not raparted	ICSR
10011147128	03/01/2022	Sportaneous	Professional	Economic Area	available	Years	AGOIGSCEIL	i iul	140	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	1008
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011147431	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

											1{DF} - Intramuscular])		
EU-EC- 10011147440	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Asthmatic crisis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC- 10011147774		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Headache (3d - Recovered/Resolved -), Hypoacusis (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -), Presyncope (30min - Recovered/Resolved -), Tinnitus (3d - Recovered/Resolved -), Vision blurred (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10011147783	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011147882	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Polymenorrhoea (n/a - Recovering/Resolving -)	immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011147884	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011147898	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Tachycardia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 100111148050	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC- 10011148081	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011148398		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Life Threatening), Histamine intolerance (n/a - Not Recovered/Not Resolved - Life Threatening), Mast cell activation syndrome (n/a - Not Recovered/Not Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011148535		Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Unknown -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF

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			Professional	Area							(S - n/a - n/a - [n/a - n/a - n/a])		
										Genital ulceration			
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011150004	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011140305	02/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -),	(S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - n/a - n/a - n/a),	ICSR
										Chills (1d - Recovered/Resolved -), Fatigue (n/a -	applicable - [n/a - 1{DF} - n/a])	[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Recovering/Resolving -), Headache (1d -		[SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a -	
										Recovered/Resolved -), Malaise (n/a -		n/a])	
										Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving			
										-), Pyrexia (2d - Recovered/Resolved			
EU-EC- 10011140490	02/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cellulitis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Feeling hot (n/a - Unknown -),	applicable - [1d - n/a - n/a])		
	00 (04 (0000					12.17				Swelling face (n/a - Not Recovered/Not Resolved -)			1000
EU-EC- 10011140522	02/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lip swelling (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Vision blurred (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	n/a - n/a])		
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011140612	02/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Dizziness (n/a - Unknown - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Pallor (n/a - Unknown - Other Medically Important Condition),			
J										Syncope (n/a -			

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										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011140625	02/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immunisation (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011140682	02/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site mass (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Medically Important Condition)			
EU-EC- 10011140691	02/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC- 10011140702	02/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011137537	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Conjunctivitis (n/a - Recovering/Resolving -), Periorbital swelling (n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10011137769	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011137815	01/01/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Eye oedema (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 300ug - n/a])	Not reported	ICSR
EU-EC- 10011137853	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138007	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Not Recovered/Not Resolved -)	(S - COVID-19	[ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

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EU-EC- 10011138042	01/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving	(S - COVID-19 immunisation - Not applicable - [n/a -	[ETHOSUXIMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	- ICSR
EU-EC- 10011138055	01/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138061	01/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hyperpyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138087	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138261	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (55d - Recovered/Resolved -), Chills (n/a - Recovering/Resolving -), Ear infection (n/a - Recovering/Resolving -), Eye infection (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Haemoptysis (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Respiratory tract infection (n/a - Rescovering/Resolving -), Respiratory tract infection (n/a - Recovering/Resolving Resolving -), Respiratory tract infection (n/a - Recovering/Resolving Resolving Resolving Resolving Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138268	01/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138277	01/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Polymenorrhoea (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138316	01/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	01/01/2022	Spontaneous	Non	European	Not	12-17	Not	Female	No	Lymphadenopathy	COMIRNATY	Not reported	ICSR

10011138318			Healthcare Professional		available	Years	Specified			(n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10011138505	01/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
10011138520		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vertigo (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011138819	01/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011139005	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Extensive swelling of vaccinated limb (4d - Recovered/Resolved -), Injection site swelling (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011139090	01/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR



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