

## Line Listing Report

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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)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (D Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10013230681	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (1wk - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013230747	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (1wk - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013233619	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (2d - Recovered/Resolved - ), Menarche (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013218218	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013218681	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular use])	Not reported
EU-EC-10013219723	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013220528	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013223016	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rhinitis (n/a - Unknown - ), Sneezing (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013207353	10/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - ), Tremor (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013208224	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013209748	10/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Foreign body ingestion (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013212708	10/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthma (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-100132197232	09/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Haematemesis (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported

											Seizure (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	n/a - Intramuscular use])	
EU-EC-10013197619	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (4d - Recovered/Resolved - ), Fear of injection (4d - Recovered/Resolved - ), Hyperhidrosis (4d - Recovered/Resolved - ), Lip discoloration (4d - Recovered/Resolved - ), Nausea (4d - Recovered/Resolved - ), Night sweats (4d - Recovered/Resolved - ), Peripheral coldness (4d - Recovered/Resolved - ), Syncope (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013198418	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymph node pain (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013198801	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Status epilepticus (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013198805	09/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013199826	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bradycardia (n/a - Recovered/Resolved - ), Hypotonic-hyporesponsive episode (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013200155	09/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypoaesthesia (2h - Recovered/Resolved - ), Paralysis (2h - Recovered/Resolved - Other Medically Important Condition), Sensory loss (2h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013200188	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Decreased appetite (1d - Recovered/Resolved - ), Dry mouth (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Urine output decreased (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013201837	09/08/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Erythema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S	Not reported	

			Professional	Area													
EU-EC-10013204131	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (1530min - Recovered/Resolved - ), Tachycardia (1530min - Recovered/Resolved - Other Medically Important Condition)	- COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported				
EU-EC-10013204513	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported					
EU-EC-10013185604	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Periorbital swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Sensation of foreign body (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported					
EU-EC-10013186328	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved - ), Product administered to patient of inappropriate age (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported					
EU-EC-10013186571	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chromaturia (n/a - Recovering/Resolving - Other Medically Important Condition), Jaundice (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported					
EU-EC-10013186759	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Gaze palsy (n/a - Unknown - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported					
EU-EC-10013187039	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition), Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported					
EU-EC-10013187087	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Electroencephalogram abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular use])	Not reported					
EU-EC-10013187173	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported					

										Myelitis transverse (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013187285	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition), Thrombocytopenia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013187316	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Multisystem inflammatory syndrome in children (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013187852	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013187972	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Swelling face (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013188051	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013188078	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Chills (n/a - Recovering/Resolving - ), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - ), Swelling of eyelid (n/a - Recovering/Resolving - ), Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013188105	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Optic neuritis (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013188106	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013188128	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013188156	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dermatitis atopic (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported

											Eczema impetiginous (n/a - Recovering/Resolving - Other Medically Important Condition)	n/a - Intramuscular use)]	
EU-EC-10013188157	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Febrile convulsion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013188255	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Recovered/Resolved - ), COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Lethargy (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Tachycardia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013188355	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - ), Myoclonus (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013188504	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Febrile convulsion (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013188626	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013188788	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Partial seizures (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013188791	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Dyskinesia (n/a - Recovered/Resolved - ), Lethargy (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	

EU-EC-10013189488	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bruxism (n/a - Recovering/Resolving - Other Medically Important Condition), COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular use])	Not reported
EU-EC-10013189492	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthma (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013189547	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013189841	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypophagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral coldness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013189872	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (22d - Recovered/Resolved - Other Medically Important Condition), Headache (22d - Recovered/Resolved - Other Medically Important Condition), Nausea (22d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (22d - Recovered/Resolved - Other Medically Important Condition), Vomiting (22d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013189996	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - ), Pyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013190072	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Petit mal epilepsy (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

											Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - Intramuscular use])	
EU-EC-10013190074	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013190211	08/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013190579	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Status epilepticus (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013194658	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Partial seizures (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013194762	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013184627	07/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Contusion (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013185104	07/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diabetic ketoacidosis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypophagia (n/a - Recovered/Resolved - Other Medically Important Condition), Lethargy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013173392	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Febrile convulsion (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013174347	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013174476	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Eye swelling (n/a - Recovered/Resolved - ), Lip swelling (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	

EU-EC-10013174598	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013174689	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Febrile convulsion (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174690	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Febrile convulsion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174829	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - ), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174830	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174855	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174884	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174919	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (n/a - Recovered/Resolved - ), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Periorbital swelling (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Swelling face (n/a - Recovered/Resolved - ), Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174921	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Extrapulmonary tuberculosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174922	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Acute stress disorder (n/a - Unknown - ), Syncope (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported



EU-EC-10013174923	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Medically Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Rash (n/a - Unknown - )	n/a - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174939	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure anoxic (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174941	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013174984	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Hypophagia (n/a - Recovered/Resolved - ), Lethargy (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Urticaria (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013175226	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013175256	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	B precursor type acute leukaemia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013175306	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Disseminated tuberculosis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013175473	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013175538	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cough (n/a - Recovered/Resolved - ), Fatigue (n/a - Recovered/Resolved - ), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013175676	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013175731	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphangitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Overdose (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported

										Unknown - ), Product administered to patient of inappropriate age (n/a - Unknown - )	n/a - Intramuscular use])	
EU-EC-10013175903	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013176002	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pneumonia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013176518	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Psychogenic seizure (n/a - Recovering/Resolving - ), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013176543	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013176567	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013176570	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Autoimmune disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Bursitis (n/a - Not Recovered/Not Resolved - ), Periarthritis (n/a - Not Recovered/Not Resolved - ), Product administered to patient of inappropriate age (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013176669	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013176756	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - ), Appendicitis (n/a - Recovering/Resolving - Other Medically Important Condition), Ultrasound abdomen abnormal (n/a - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013177440	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013177905	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown - ), Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

										Off label use (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10013179091	05/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Body temperature increased (6wk - Recovered/Resolved - ), Cough (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Guillain-Barre syndrome (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving - ), Overdose (n/a - Unknown - ), Overweight (n/a - Unknown - ), Pain in extremity (n/a - Recovering/Resolving - ), Paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - ), Respiratory disorder (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013179150	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013179284	05/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown - ), Product administered to patient of inappropriate age (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013179317	05/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - ), Pain (n/a - Unknown - ), Product administered to patient of inappropriate age (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013179319	05/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown - ), Product administered to patient of inappropriate age (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013179498	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Psychogenic seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-	05/08/2022	Spontaneous	Healthcare	Non	Not available	3-11	Not	Male	No	Psychogenic seizure	COMIRNATY	Not reported

10013179710			Professional	European Economic Area		Years	Specified			(n/a - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	
EU-EC-10013179853	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Psychogenic seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013179941	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown - ), Eye disorder (n/a - Unknown - ), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013179946	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not reported
EU-EC-10013180065	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cyanosis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013181070	05/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013181347	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Anaphylactic reaction (36d - Recovered/Resolved - Other Medically Important Condition), Pruritus (36d - Recovered/Resolved - Other Medically Important Condition), Rash (36d - Recovered/Resolved - Other Medically Important Condition), Vaccination site erythema (36d - Recovered/Resolved - ), Vaccination site pain (36d - Recovered/Resolved - ), Vaccination site swelling (36d - Recovered/Resolved - ), Varicella (36d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 2mL - Intramuscular use])	Not reported
EU-EC-10013182020	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013182023	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Psychogenic seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-	04/08/2022	Spontaneous	Healthcare	Non	Not available	3-11	Not	Female	No	COVID-19 (10d -	COMIRNATY	Not reported

10013163448			Professional	European Economic Area							Recovered/Resolved - Other Medically Important Condition), Fatigue (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperpyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tremor (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Trigeminal neuralgia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	
EU-EC-10013164169	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Sinus tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013166228	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ), Cough (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013167286	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013167329	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Heart rate increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013169350	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - ), Product administered to patient of inappropriate age (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013171420	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain lower (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Appendicitis (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported	

EU-EC-10013154514	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Medically Important Condition) Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013154878	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved - ), Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013155832	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013155849	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Seizure (0d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013156368	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013156504	03/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - ), COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not reported
EU-EC-10013157435	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Rash macular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013157820	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013157850	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013157878	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013158326	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013158331	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-	03/08/2022	Spontaneous	Healthcare	Non	Not available	3-11	Not	Male	No	Bell's palsy (n/a - )	COMIRNATY	Not reported

10013158412			Professional	European Economic Area		Years	Specified			Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	
EU-EC-10013158476	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013158601	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Alopecia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013158882	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Unknown - ), Neck pain (n/a - Unknown - ), Pain in extremity (4d - Recovered/Resolved - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013158935	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013158937	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Neurodermatitis (n/a - Recovered/Resolved - ), Rash (n/a - Recovered/Resolved - ), Vaccination site rash (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013159578	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013159710	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013159773	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eczema (n/a - Unknown - ), Rash (4d - Recovered/Resolved - ), Urticaria (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013159800	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013141595	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pruritus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013141716	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Deafness (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013141958	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

EU-EC-10013142232	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Other Medically Important Condition) Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Decreased appetite (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	n/a - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013142806	02/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Exercise tolerance decreased (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013143808	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported
EU-EC-10013143933	02/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Anaphylactic reaction (10min - Recovered/Resolved - Other Medically Important Condition), Confusional state (10min - Recovered/Resolved - Other Medically Important Condition), Hypotonia (10min - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (1.5min - Recovered/Resolved - Other Medically Important Condition), Pallor (10min - Recovered/Resolved - Other Medically Important Condition), Swollen tongue (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013144062	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Hypoesthesia (n/a - Recovered/Resolved With Sequelae -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported



										Caused/Prolonged Hospitalisation), Myelitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation)		
EU-EC-10013144528	02/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition), Head injury (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (2d - Recovered/Resolved - Other Medically Important Condition), Stress (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013144674	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Foreign body ingestion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013145070	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Periorbital oedema (6h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013145211	02/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013145221	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013145397	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Epididymitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013145721	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Palpitations (n/a - Recovering/Resolving - ), Poor quality sleep (n/a - Recovering/Resolving - ), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013145723	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013145841	02/08/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported

				Economic Area						- Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - Intramuscular use])	
EU-EC-10013145842	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Decreased appetite (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013146190	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not reported
EU-EC-10013147769	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pustule (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013149481	02/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Defaecation disorder (n/a - Unknown - Other Medically Important Condition), 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
EU-EC-10013150466	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Decreased appetite (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vertigo (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013150489	02/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

EU-EC-10013130757	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Flushing (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013130932	01/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Haemangioma (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013131300	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), COVID-19 (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cough (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013132155	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Gastroenteritis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013132904	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypersensitivity (32d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Miliaria (29d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Mycoplasma infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (36d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (36d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urticaria (34d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported
EU-EC-10013132953	01/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013133588	01/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (1wk - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported

EU-EC-10013133598	01/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Injection site swelling (n/a - Recovering/Resolving - ), Malaise (1d - Recovering/Resolving - ), Nausea (n/a - Not Recovered/Not Resolved - )	,3mL - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013133788	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013133790	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported
EU-EC-10013134070	01/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myalgia (2d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - n/a])	Not reported
EU-EC-10013134938	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Trismus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013134960	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Sinus tachycardia (27d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013135304	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013135663	01/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Generalised tonic-clonic seizure (2min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013135795	01/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013136418	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (23d - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (21d - Recovered/Resolved - Other Medically Important Condition), Nausea (23d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (23d - Recovered/Resolved - Other Medically Important Condition), Suspected COVID-19 (21d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

EU-EC-10013136487	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Other Medically Important Condition) Astigmatism (n/a - Recovering/Resolving - ), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electroencephalogram abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hallucinations, mixed (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Neuralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Neuritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovering/Resolving - ), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vision blurred (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vitreous degeneration (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013136516	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - ), Muscular weakness (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013136567	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - n/a])	Not reported

										Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Suspected COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013136587	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Immune thrombocytopenia (17d - Recovering/Resolving - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CLOTRIMAZOLE] (C - Discharge, Pruritus - n/a - [28d - n/a - n/a]), [DOCUSATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]) [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a])
EU-EC-10013136653	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013137759	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Alopecia (n/a - Unknown - ), COVID-19 (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013138988	01/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular use])	Not reported
EU-EC-10013140385	01/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013129913	31/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Headache (n/a - Unknown - ), Somnolence (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013128229	30/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Musculoskeletal pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013117217	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

EU-EC-10013117371	29/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Caused/Prolonged Hospitalisation) Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013117746	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (24d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported
EU-EC-10013118826	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013120544	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Overdose (n/a - Unknown - ), Product preparation issue (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported
EU-EC-10013121006	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (2d - Fatal - Results in Death), Abdominal pain upper (n/a - Unknown - ), Pyrexia (4d - Fatal - Results in Death), Rash (1d - Fatal - Results in Death), Seizure (30min - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013121290	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased activity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013122007	29/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

EU-EC-10013122468	29/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Injection site pain (2d - Recovered/Resolved - ), Malaise (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013123070	29/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013123109	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013123115	29/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013123475	29/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013125056	29/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013105609	28/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Liver disorder (n/a - Unknown - ), Rash follicular (n/a - Unknown - ), Smallpox (n/a - Unknown - Other Medically Important Condition), Spleen disorder (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular use])	Not reported
EU-EC-10013107219	28/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BACILLUS SUBTILIS, LACTOMIN, BIFIDOBACTERIUM] (C - 1 - n/a - [n/a - n/a - Oral use) [CARBOCISTEINE] (C - n/a - n/a - [n/a - n/a - Oral use) [DEXTRIN, FISH OIL, MINERALS NOS, VITAMIN NOS, AMINO ACIDS, MILK PROTEIN CONCENTRATE, RAPESEED OIL] (C - n/a - [n/a - n/a - Oral use]), [DEXTRIN, GLYCINE, SOD CITRATE, CALCIUM GLYCEROPHOSPHATE, L-ARGININE, L-HISTIDINE, LEUCINE, L-VALINE, L-CYSTEINE, L-GLUTAMIC ACID] (C - n/a - n/a - [n/a - n/a - Oral use])



													n/a - Oral use)), [GLYCEROL] (C - n/a - n/a [n/a - n/a - n/a])
EU-EC-10013110024	28/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Female	No	Off label use (1d - Recovered/Resolved - ), Vaccination site pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013110571	28/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013114217	28/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Product administered to patient of inappropriate age (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported	
EU-EC-10013114606	28/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	
EU-EC-10013114790	28/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10013114866	28/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013095911	27/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Subglottic laryngitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013096154	27/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Hypertensive crisis (n/a - Unknown - Other Medically Important Condition), Irritability (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Vaccination error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013098204	27/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition), Rash maculo-papular (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown - Other Medically Important Condition), Vaccination error (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013098873	27/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - ), Photopsia (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - )	Not reported	

											<p>Syncopal (n/a - Recovered/Resolved - Other Medically Important Condition),</p> <p>Vaccination error (n/a - Unknown - Other Medically Important Condition)</p>	n/a - Intramuscular use]	
EU-EC-10013100272	27/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	<p>Arthralgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2mL - Intramuscular use])	[LORATADINE] (C - Rhinit allergic - n/a - [n/a - n/a - Oral use]), [MONTELUKAST, MONTELUKAST SODIUM] Asthma - n/a - [n/a - n/a Oral use])	
EU-EC-10013103221	27/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	<p>Gaze palsy (n/a - Unknown - Other Medically Important Condition),</p> <p>Partial seizures (n/a - Unknown - Other Medically Important Condition),</p> <p>Seizure (n/a - Unknown - Other Medically Important Condition),</p> <p>Vaccination error (n/a - Unknown - Other Medically Important Condition),</p> <p>Vomiting (n/a - Unknown - )</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use - More in ICSR])	Not reported	
EU-EC-10013103938	27/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	<p>Blood pressure abnormal (n/a - Unknown - Other Medically Important Condition),</p> <p>Dizziness (n/a - Unknown - ),</p> <p>Nausea (n/a - Unknown - ),</p> <p>Oxygen saturation decreased (n/a - Unknown - ),</p> <p>Pain (n/a - Unknown - ),</p> <p>Sensitive skin (n/a - Unknown - ),</p> <p>Vaccination error (n/a - Unknown - )</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	
EU-EC-10013104408	27/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10013084686	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013086290	26/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	<p>Fatigue (n/a - Unknown - ),</p> <p>Lymph node pain (n/a - Unknown - ),</p> <p>Lymphadenopathy (n/a - Unknown - )</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013086892	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013087429	26/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	<p>COVID-19 (n/a - Unknown - Other Medically Important Condition),</p> <p>Vaccination failure (n/a - Unknown - Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013087730	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	<p>Asthenia (n/a - Unknown - Other Medically Important Condition),</p> <p>Dizziness (n/a - Unknown - Other Medically Important Condition),</p> <p>Fatigue (n/a - Unknown - Other Medically Important Condition),</p> <p>Pallor (n/a - Unknown - )</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	

EU-EC-10013087913	26/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	- Other Medically Important Condition) Groin pain (n/a - Unknown - ), Peripheral swelling (26d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (26d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013088051	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Febrile convulsion (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Tonic convulsion (n/a - Unknown - Other Medically Important Condition), Vaccination error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013088052	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eyelid oedema (n/a - Unknown - Other Medically Important Condition), Inflammation (n/a - Unknown - ), Oedema (n/a - Unknown - ), Rash (n/a - Unknown - ), Skin lesion (n/a - Unknown - ), Vaccination error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013088132	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dengue fever (n/a - Unknown - Caused/Prolonged Hospitalisation), Dengue virus test positive (n/a - Unknown - ), Diarrhoea (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013088526	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013089516	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Bladder sphincter atony (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paresis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fall (n/a - Not Recovered/Not Resolved/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

										Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypokinesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination error (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10013089659	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown - ), Loss of consciousness (15s - Recovered/Resolved - Other Medically Important Condition), Vaccination error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013089942	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition), Vaccination error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013090099	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash (n/a - Unknown - Other Medically Important Condition), Vaccination error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013090920	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Ataxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Craniocerebral injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Eye movement disorder (n/a - Not Recovered/Not Resolved/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported

										Resolved - Caused/Prolonged Hospitalisation), Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypertonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10013090962	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - ), Hypotension (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013091075	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Eye pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination error (n/a - Unknown - Caused/Prolonged Hospitalisation), Vision blurred (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013091101	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Odynophagia (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition), Vaccination error (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013091337	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported

											Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	n/a - Intramuscular use]]	
EU-EC-10013093189	26/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Blood pressure abnormal (n/a - Unknown - Other Medically Important Condition), Eye injury (n/a - Unknown - ), Vaccination error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013093888	26/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10013076741	25/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013077054	25/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Presyncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 2mL - Intramuscular use])	Not reported	
EU-EC-10013077477	25/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Febrile convulsion (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination error (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013077707	25/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myalgia (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Vaccination site reaction (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013078459	25/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cough (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013080378	25/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013080644	25/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	
EU-EC-10013081013	25/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013085220	25/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Gait disturbance (n/a - Recovered/Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	

				Economic Area							Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Recovered/Resolved - )	immunisation - Not applicable - [n/a - n/a]	
EU-EC-10013067171	22/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cough (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Rhinorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013067827	22/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypersensitivity (n/a - Recovered/Resolved - ), Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular use])	Not reported	
EU-EC-10013069235	22/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown - ), Gastrointestinal disorder (n/a - Unknown - ), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013071562	22/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Activated partial thromboplastin time prolonged (n/a - Unknown - ), Adenotonsillectomy (n/a - Unknown - ), Amplified musculoskeletal pain syndrome (n/a - Unknown - ), Anxiety (n/a - Unknown - ), Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), COVID-19 (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Complex regional pain syndrome (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Eosinophilia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	

										Disabling, Other Medically Important Condition), Hyperaesthesia (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Left ventricular hypertrophy (n/a - Unknown - ), Lethargy (n/a - Unknown - ), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - ), Polyarthritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - ), Syncope (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10013052091	21/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Clostridium test (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular use])	[AMOXICILLIN TRIHYDRATE CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE POTASSIUM CLAVULANATE AMOXICILLIN, CLAVULANIC ACID] (C - n/a - n/a - [n/a - n/a])
EU-EC-1001305450	21/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013056827	21/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Condition aggravated (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	AERIUS [DESLORATADINE - n/a - n/a - [n/a - n/a - n/a]], [BUDESONIDE, FORMOTE



										Mast cell activation syndrome (n/a - Not Recovered/Not Resolved - ),  Urticaria (n/a - Recovered/Resolved - )	1{DF} - Intramuscular use]	FUMARATE DIHYDRATE, FORMOTEROL FUMARATE BUDESONIDE] (C - n/a - r [n/a - n/a - n/a]),  [MONTELUKAST, MONTELUKAST SODIUM] n/a - n/a - [n/a - n/a - n/a],  [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - n/a - n/a)
EU-EC-10013059301	21/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),  Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013061309	21/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (n/a - Recovering/Resolving - ),  Vaccination site pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013061342	21/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Unknown - ),  Pyrexia (n/a - Unknown - ),  Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013061396	21/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site inflammation (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013043931	20/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),  Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013044038	20/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (19min - Recovered/Resolved - Other Medically Important Condition),  Atrioventricular block (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Atrioventricular block second degree (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Bradycardia (n/a - Unknown - Other Medically Important Condition),  Cardiomegaly (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Cough (9min - Recovered/Resolved - Other Medically Important Condition),  Crying (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Flushing (n/a - Recovered/Resolved - Other Medically Important Condition),  Heart rate decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pruritus (n/a - Recovered/Resolved - ),  Scratch (1min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013044459	20/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (0d - Recovered/Resolved - ),  Headache (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

										Recovered/Resolved - ), Injection site pain (1d - Recovering/Resolving - )		
EU-EC-10013046667	20/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Breast enlargement (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013046672	20/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Breast enlargement (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013046819	20/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Female	No	Asthenia (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Vomiting (5h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013050727	20/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013050748	20/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013050749	20/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Face oedema (n/a - Unknown - ), Lip oedema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013031694	19/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013032025	19/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013032568	19/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (89h - Recovered/Resolved - ), Diarrhoea (89h - Recovered/Resolved - ), Rash (89h - Recovered/Resolved - ), Seizure (89h - Recovered/Resolved - Other Medically Important Condition), Vomiting (89h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013032636	19/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Angina pectoris (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

											Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10013034637	19/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Body temperature increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013034857	19/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ), Pyrexia (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013036299	19/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - I{DF} - Intramuscular use])	[FLUTICASONE PROPION/SALMETEROL] (C - n/a - r [n/a - n/a - Intramuscular use])	
EU-EC-10013037895	19/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nasopharyngitis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013038093	19/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dengue virus test positive (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013039710	19/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthritis (532h - Recovered/Resolved - Other Medically Important Condition), Joint effusion (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular use])	Not reported	
EU-EC-10013040594	19/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013019749	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Suspected COVID-19 (n/a - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013020325	18/07/2022	Spontaneous	Non Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	

				Economic Area						Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - Intramuscular use])	
EU-EC-10013021173	18/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013022514	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013025331	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Post vaccination syndrome (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013025812	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013025840	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Influenza like illness (1d - Recovered/Resolved - ), Vomiting (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013026309	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthritis (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013029555	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013029719	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypersensitivity (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013018075	16/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Body temperature increased (3d - Recovered/Resolved - ), Eczema (n/a - Not Recovered/Not Resolved - ), Malaise (1wk - Recovered/Resolved - ), Swelling face (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013005776	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Joint swelling (n/a - Unknown - ), Vaccination site erythema (n/a - Unknown - ), Vaccination site reaction (3d - Recovered/Resolved - ), Vaccination site swelling (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013008458	15/07/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Fall (n/a - Unknown - Other Medically	COMIRNATY 10 MICROGRAMS/DOSE	Not reported

			Professional	Area						Important Condition), Head injury (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	
EU-EC-10013010234	15/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013010246	15/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013015631	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Asthenia (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Temperature regulation disorder (2d - Recovered/Resolved - ), Vaccination site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012994708	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Ear discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ear pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012995410	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - ), Costochondritis (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Recovering/Resolving - ), Gastrooesophageal reflux disease (n/a - Unknown - ), Headache (n/a - Recovered/Resolved - ), Interchange of vaccine products (n/a - Recovering/Resolving - ), Lethargy (n/a - Unknown - ), Musculoskeletal pain (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition), Off label use (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular use])	Not reported

EU-EC-10012997559	14/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (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
EU-EC-10013001150	14/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myalgia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013001677	14/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Suspected COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013003302	14/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013003793	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013003797	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013004939	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012983720	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Hypersomnia (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012984631	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10012986000	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012986128	13/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[SODIUM VALPROATE] (C n/a - Dose not changed - )
EU-EC-10012988420	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Heavy menstrual bleeding (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10012988490	13/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Immunisation reaction (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10012988885	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anxiety (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .2mL - Intramuscular use])	Not reported

										Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Noninfective sialoadenitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Parotid gland enlargement (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Salivary gland pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Swelling face (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10012989446	13/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - ), Nasal congestion (n/a - Not Recovered/Not Resolved - ), Rhinorrhoea (n/a - Not Recovered/Not Resolved - ), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012992058	13/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10012992225	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012992264	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[A/HONG KONG/4801/201 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/201 X-263B), B/BRISBANE/60/2008-LIK STRAIN (B/BRISBANE/60/2008, W TYPE), A/CALIFORNIA/7/2 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-1: A/HONG KONG/4801/201 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/201 X-263B), B/BRISBANE/60/2008-LIK STRAIN (B/BRISBANE/60/2008, W TYPE), A/MICHIGAN/45/2 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2 IVR-180), INFLUENZA VACCINE] (C - Immunisation n/a - [n/a - n/a - n/a])
EU-EC-10012993679	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Moscara, L.. Immunogenicity and safety of BNT162b2 mRNA COVID-19 vaccine in a subject affected by Shapiro's syndrome: A case report. Human Vaccines and Immunotherapeutics. 2022;10.1080/21645515.2022.2094148. doi:10.1080/21645515.2022.2094148	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012971943	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported

EU-EC-10012972528	12/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Medically Important Condition) Urticaria (n/a - Unknown - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012972706	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Diarrhoea (n/a - Unknown - ), Pyrexia (72h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012972772	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotonic-hyporesponsive episode (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10012973090	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012973814	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	External ear disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin lesion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012974444	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012975148	12/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Acute lymphocytic leukaemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012978128	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - ), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012978663	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported



EU-EC-10012980060	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (3d - Recovered/Resolved - ), Malaise (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10012980789	12/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012981676	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Autonomic nervous system imbalance (7d - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (7d - Recovered/Resolved - Other Medically Important Condition), Musculoskeletal chest pain (7d - Recovered/Resolved - Other Medically Important Condition), Pallor (7d - Recovered/Resolved - Other Medically Important Condition), Respiratory distress (7d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012955607	11/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not reported
EU-EC-10012955846	11/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10012956334	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ear, nose and throat infection (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012956494	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (7d - Recovered/Resolved - ), Diarrhoea (7d - Recovered/Resolved - ), Headache (7d - Recovered/Resolved - ), Pain in extremity (7d - Recovered/Resolved - ), Product administered to patient of inappropriate age (7d - Recovered/Resolved - ), Pyrexia (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .1mL - Intramuscular use])	Not reported
EU-EC-10012957508	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ear, nose and throat infection (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012959333	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10012960471	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Lymphadenopathy (n/a - Unknown - ), Pyrexia (24h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012961678	11/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

											Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [n/a - n/a - n/a]	
EU-EC-10012961840	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypertonia (n/a - Unknown - ), Oxygen saturation abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - n/a])	Not reported	
EU-EC-10012963027	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown - ), Pneumonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10012965307	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (1d - Not Recovered/Not Resolved - ), Vomiting (1d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10012968939	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Off label use (n/a - Unknown - Other Medically Important Condition), Wrong technique in product usage process (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular use]), [HUMAN PAPILLOMAVIRUS VACCINE] (S - Immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	
EU-EC-10012969240	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal distension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Jaundice (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10012949773	08/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10012949812	08/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10012950719	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Balance disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported	

										Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tremor (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		
EU-EC-10012951409	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Olfactory dysfunction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012951821	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012953635	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Fatigue (n/a - Recovered/Resolved - ), Off label use (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported
EU-EC-10012953731	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Immune-mediated dermatitis (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012938487	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10012938560	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Contusion (n/a - Unknown - ), Rash (n/a - Unknown - ), Skin lesion (n/a - Unknown - ), Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10012938842	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Altered state of consciousness (1min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (1min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012939103	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

EU-EC-10012939476	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Hospitalisation, Other Medically Important Condition) Pyrexia (24h - Recovered/Resolved - ), Vaccination site reaction (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012939664	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Asthenia (n/a - Unknown - ), Erythema (n/a - Unknown - ), Paraesthesia (n/a - Unknown - ), Tachycardia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10012939763	07/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Leukaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	HUMIRA [ADALIMUMAB] (n/a - n/a - [n/a - n/a - n/a])
EU-EC-10012940092	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Back pain (n/a - Unknown - ), Erythema (n/a - Unknown - ), Headache (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (48h - Recovered/Resolved - ), Vaccination site reaction (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10012941787	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Face oedema (n/a - Unknown - ), Localised oedema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10012942195	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Idiopathic urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular use])	Not reported
EU-EC-10012942296	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Depressed level of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile convulsion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012942884	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Accidental overdose (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported

										Pain in extremity (n/a - Recovering/Resolved - ), Peripheral swelling (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown - )	30ug - Intramuscular use]]	
EU-EC-10012943394	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Recovering/Resolved - Other Medically Important Condition), Rash (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012944696	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved - ), Fall (n/a - Recovered/Resolved - ), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Tonic convulsion (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012944712	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012945210	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Gait disturbance (n/a - Unknown - ), Monoplegia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012946122	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Aspartate aminotransferase decreased (n/a - Unknown - ), Blood alkaline phosphatase increased (n/a - Unknown - ), Blood creatine phosphokinase decreased (n/a - Unknown - ), Eye pain (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Mean cell volume abnormal (n/a - Unknown - ), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Red blood cell count	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

										increased (n/a - Unknown - ), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10012946422	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10012946432	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Malaise (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10012927432	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012927532	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012928148	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site reaction (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012928618	06/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (3h - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012929213	06/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Hepatic enzyme increased (n/a - Not Recovered/Not Resolved - ), Hepatitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012929579	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypersensitivity (n/a - Recovering/Resolving - ), Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012929703	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular use])	[LEVOTHYROXINE] (C - n, n/a - [n/a - n/a - Oral use
EU-EC-10012930911	06/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012933953	06/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Adachi, K.. A Case of 10-Year-Old Male-Child Presenting With Generalised Erythema After Novel Coronavirus Vaccination. The 116th Meeting of the Japan Pediatric Society Yamagata Prefectural Regional. 2022;116th:8	3-11 Years	Not Specified	Male	No	Blister (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Erythema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Erythema multiforme (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012935376	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

EU-EC-10012915290	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (1h - Recovered/Resolved - ), Syncope (30min - Recovered/Resolved - n/a - Intramuscular use)	applicable - [1d - 1{DF}] - n/a)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012915366	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (26min - Recovered/Resolved - Other Medically Important Condition)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012915378	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012916331	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown - ), Cough (n/a - Unknown - ), Malaise (n/a - Unknown - ), Syncope (n/a - Other Medically Important Condition)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [INFLUENZA QUADRIVALENT VACCINE (RDNA)] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012916554	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012916781	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asymptomatic COVID-19 (3d - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012916834	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Skin lesion (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012918213	05/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	Yes	Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012919404	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - ), Rhinorrhoea (n/a - Not Recovered/Not Resolved - )		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012920856	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Incontinence (n/a - Not Recovered/Not Resolved - )		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF}] - Intramuscular use])	Not reported
EU-EC-10012921239	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Hypersensitivity (n/a - Recovered/Resolved - ), Urticaria (n/a - Recovered/Resolved - )		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF}] - Intramuscular use])	Not reported
EU-EC-	05/07/2022	Spontaneous	Non	European	Not available	3-11	Child	Male	No	Pyrexia (n/a -		COMIRNATY	Not reported

10012921247			Healthcare Professional	Economic Area		Years					Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	
EU-EC-10012921248	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash papular (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10012923045	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovered/Resolved - ), Cough (n/a - Recovered/Resolved - ), Decreased appetite (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ), Nasopharyngitis (n/a - Recovered/Resolved - ), Parasitic gastroenteritis (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10012923737	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Conjunctivitis (n/a - Unknown - ), Helminthic infection (n/a - Unknown - Other Medically Important Condition), Viral infection (n/a - Unknown - ), Viral rash (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10012906270	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Ageusia (n/a - Unknown - ), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10012906331	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Body temperature increased (3d - Recovered/Resolved - ), COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - ), Nasopharyngitis (n/a - Recovered/Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ), Productive cough (n/a - Recovering/Resolving - ), Rhinitis (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported	



										- ), Rhinorrhoea (n/a - Recovering/Resolving - ), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10012908149	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Feeling hot (89min - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012908156	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not reported
EU-EC-10012908217	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Pallor (n/a - Unknown - ), Presyncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular use])	Not reported
EU-EC-10012908572	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epilepsy (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10012909891	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012911494	04/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyspnoea (18h - Recovered/Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - ), Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012912221	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cardiac failure (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Supraventricular tachycardia (40min - Recovered/Resolved - Life Threatening, Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012910171	03/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Injection site inflammation (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Not Recovered/Not Resolved - ), Injection site swelling (n/a - Not Recovered/Not Resolved - ), Injection site warmth (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[BECLOMETASONE DIPROPIONATE] (C - n/a n/a - [n/a - n/a - n/a])
EU-EC-10012894411	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported

EU-EC-10012894415	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (5min - Recovered/Resolved - ), Syncope (4min - Recovered/Resolved - Other Medically Important Condition)	n/a - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012894418	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoacusis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vision blurred (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012894960	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10012895271	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - ), Contusion (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Hypotension (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012895272	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pruritus (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012895275	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Muscular weakness (26510min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (23h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012895276	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (3min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012895297	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012896690	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012904385	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported

										Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10012904752	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition aggravated (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition), Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012906618	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012907839	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - ), Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012883445	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Dyskinesia (n/a - Unknown - ), Tic (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012883763	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular use])	Not reported
EU-EC-10012886246	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012886274	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenitis bacterial (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Thrombocytopenic purpura (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10012886283	30/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012886669	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - ), Costochondritis (n/a - Recovering/Resolving - ), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										(n/a - Recovering/Resolving - ), Dyspnoea (n/a - Recovering/Resolving - ), Gastroesophageal reflux disease (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Recovering/Resolving - ), Musculoskeletal pain (n/a - Recovering/Resolving - ), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10012887767	30/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012890615	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10012869966	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Malaise (2496min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (2781min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012870953	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012871539	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10012872029	29/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	Yes	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012873827	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypotonic-hyporesponsive episode (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Syncope (n/a - Unknown - ), Vaccination site reaction (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10012874858	29/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [COVID-19 VACCINE] (S - COVID-19)	Not reported

EU-EC-10012875000	29/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - ), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Unknown - ), Vomiting (n/a - Unknown - )	immunisation - Not applicable - [n/a - n/a]	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10012875353	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral calcification (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BETAMETHASONE VALERATE, GENTAMICIN SULFATE] (C - Dermatitis atopic - n/a - [n/a - n/a - Transdermal]), [CHONDROITIN POLYSULFATE, CHONDROITIN SULFATE SODIUM, GLUCOSAMINOGLYCAN POLYSULFATE, HEPARINO MUCOPOLYSACCHARIDE POLYSULFURIC ACID EST MUCOPOLYSACCHARIDES - Dermatitis atopic - n/a - [n/a - n/a - Transdermal]), [FLUTICASON FUROATE] - n/a - n/a - [n/a - n/a - n/a]), [LEVOCETIRIZINE] (C - n, n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] n/a - n/a - [n/a - n/a - n/a], [PREDNISOLONE VALERATE ACETATE] (C - Dermatitis atopic - n/a - [n/a - n/a - Transdermal])	
EU-EC-10012877451	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (45min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Intramuscular])	Not reported	
EU-EC-10012877689	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - 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])	[BETAMETHASONE VALERATE, GENTAMICIN SULFATE] (C - Dermatitis atopic - n/a - [n/a - n/a - Transdermal]), [CHONDROITIN POLYSULFATE, CHONDROITIN SULFATE SODIUM, GLUCOSAMINOGLYCAN POLYSULFATE, HEPARINO MUCOPOLYSACCHARIDE POLYSULFURIC ACID EST MUCOPOLYSACCHARIDES - Dermatitis atopic - n/a - [n/a - n/a - Transdermal]), [FLUTICASON FUROATE] - n/a - n/a - [n/a - n/a - n/a]), [LEVOCETIRIZINE] (C - n, n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] n/a - n/a - [n/a - n/a - n/a], [PREDNISOLONE VALERATE ACETATE] (C - Dermatitis atopic - n/a - [n/a - n/a - Transdermal])	
EU-EC-10012879349	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - n/a])	Not reported	
EU-EC-10012879931	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10012858665	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Erythema (n/a - Recovered/Resolved - ), Peripheral swelling (n/a - Recovered/Resolved - ), Tenderness (n/a - Recovered/Resolved - ), Vaccination site reaction (n/a - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	

EU-EC-10012863231	28/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved - ) Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (20h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012863254	28/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Contusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012865359	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Anxiety (n/a - Unknown - ), Cerebral thrombosis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Headache (n/a - Recovered/Resolved - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Mental fatigue (n/a - Unknown - ), Muscle atrophy (n/a - Unknown - ), Muscle spasms (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Retinal injury (n/a - Unknown - Other Medically Important Condition), Tendon rupture (n/a - Unknown - ), Vision blurred (n/a - Not Recovered/Not Resolved - ), Visual impairment (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012865638	28/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - ), Hallucination (1d - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (1d - Recovered/Resolved - ), Nausea (1d - Recovered/Resolved - ), Nightmare (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	MELATONIN [MELATONIN - n/a - n/a - [n/a - n/a - n/a - n/a - n/a]
EU-EC-10012866326	28/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (20h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported

											Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10012867342	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Eye lid oedema (1d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10012848279	27/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Upper airway obstruction (8d - Unknown - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - n/a])	Not reported	
EU-EC-10012849174	27/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10012849860	27/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	
EU-EC-10012850049	27/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Cough (n/a - Unknown - ), Headache (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported	
EU-EC-10012855385	27/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	
EU-EC-10012846604	25/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Peripheral swelling (n/a - Unknown - ), Pyrexia (48h - Recovered/Resolved - ), Vaccination site reaction (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	
EU-EC-10012835341	24/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Stridor (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10012836384	24/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Incorrect dose administered (n/a - Unknown - ), Product administered to patient of inappropriate age (n/a - Unknown - ), Vaccination site oedema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10012836394	24/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	Yes	Product administered to patient of inappropriate age (n/a - Unknown - ), Vaccination site discomfort (n/a - Unknown - ), Vaccination site oedema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10012837037	24/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	
EU-EC-10012838409	24/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	

										(3d - Recovered/Resolved - ), Fatigue (n/a - Unknown - ), Pyrexia (4d - Recovered/Resolved - ), Somnolence (n/a - Unknown - ), Tachypnoea (n/a - Recovering/Resolving - )	n/a - Intramuscular)	
EU-EC-10012838761	24/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Malaise (n/a - Fatal Results in Death), Pyrexia (n/a - Fatal Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012839056	24/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Erythema multiforme (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - ), Pruritus (n/a - Unknown - ), Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10012844014	24/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Cognitive disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Food aversion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported



										Hospitalisation, Disabling), Memory impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Visual impairment (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling)		
EU-EC-10012844477	24/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported
EU-EC-10012825697	23/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported
EU-EC-10012826137	23/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypoglycaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	ABILIFY [ARIPIRAZOLE] Autism spectrum disorder n/a - [n/a - n/a - Oral]), [MAGNESIUM OXIDE] (C - Constipation - n/a - [n/a - Oral])
EU-EC-10012828467	23/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dehydration (38h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gastroenteritis (38h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (38h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (38h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported
EU-EC-10012829093	23/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown - ), Tachypnoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012829318	23/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Autoimmune thyroiditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypothyroidism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Thyroid disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10012831366	23/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Recovered/Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012832518	23/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported
EU-EC-	23/06/2022	Spontaneous	Healthcare	Non	Not available	3-11	Not	Female	No	COVID-19 (n/a -	COMIRNATY	Not reported

10012833008			Professional	European Economic Area		Years	Specified			Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	
EU-EC-10012815172	22/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeding disorder (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012816316	22/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported
EU-EC-10012817447	22/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - ), Dehydration (n/a - Recovering/Resolving - ), Feeling hot (n/a - Recovered/Resolved - ), Headache (n/a - Recovering/Resolving - ), Malaise (3d - Recovered/Resolved - ), Nausea (2490min - Recovered/Resolved - Other Medically Important Condition), Pyrexia (3030min - Recovered/Resolved - ), Vomiting (2490min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10012818202	22/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Strabismus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10012819036	22/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Partial seizures (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10012819400	22/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Face oedema (n/a - Recovering/Resolving - ), Immunisation reaction (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported
EU-EC-10012819474	22/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular])	Not reported
EU-EC-10012821302	22/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular])	[IBUPROFEN] (C - Antiinflammatory therapy Unknown - [n/a - 4mL - Oral]), [PARACETAMOL] (C - Analgesic therapy - Unknnc - [n/a - 4.2mL - Oral])
EU-EC-10012822667	22/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cellulitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - ), Epistaxis (n/a - Recovering/Resolving - ), Gingivitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Immune thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tenderness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Thrombocytopenic purpura (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		
EU-EC-10012802923	21/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012803331	21/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Croup infectious (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
EU-EC-10012803389	21/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Recovered/Resolved - ), Loss of consciousness (10min - Recovered/Resolved - Other Medically Important Condition), Pallor (10min - Recovered/Resolved - ), Rash (n/a - Recovered/Resolved - ), Skin abrasion (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10012803835	21/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Loss of consciousness (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012804106	21/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012805566	21/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Flushing (109h - Recovered/Resolved - ), Pyrexia (109h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012806376	21/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (30min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012809990	21/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscle twitching (n/a - Unknown - Caused/Prolonged Hospitalisation), Tinnitus (n/a - Unknown - Caused/Prolonged Hospitalisation)		
EU-EC-10012810568	21/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Gianotti-Crosti syndrome (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Increased viscosity of upper respiratory secretion (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012810976	21/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported
EU-EC-10012785760	20/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10012786011	20/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dengue virus test positive (n/a - Unknown - ), Platelet count decreased (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012788852	20/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (2d - Recovered/Resolved - Other Medically Important Condition), Chest pain (2d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10012789684	20/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Other Medically Important Condition), Disease recurrence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10012789839	20/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Delirium (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported
EU-EC-10012790941	20/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Axillary pain (n/a - Unknown - ), Breast pain (n/a - Unknown - ), Cold urticaria (n/a - Unknown - )	COMIRNATY 10 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10012792586	20/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Troponin I increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - [n/a - n/a - n/a]),

													[ZONISAMIDE] (C - n/a - - [n/a - n/a - n/a])
EU-EC-10012793841	20/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),  Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]),  [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10012793881	20/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site reaction (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	
EU-EC-10012794008	20/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (3d - Recovered/Resolved - ),  Immunisation reaction (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	
EU-EC-10012795138	20/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Nausea (n/a - Unknown - ),  Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Syncope (n/a - Unknown - Other Medically Important Condition),  Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	
EU-EC-10012795170	20/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Croup infectious (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Hypoaesthesia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Rash (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10012798442	20/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),  Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	

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