

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 (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-10011261773	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	[MICONAZOLE, MICONAZOLE NITRATE, MICONAZOLE NITRATE, HYDROCORTISONE] (C - Oral candidiasis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011226545	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Urticaria (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011226569	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011226779	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hyperpyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011227122	12/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown -), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011229651	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011231604	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (2h - Recovered/Resolved -), Vomiting (3h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011239680	12/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown -), Nausea (n/a - Unknown -), Pallor (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

											Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011240888	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011241241	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011241367	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011241504	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011241533	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (2d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011241624	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011241745	12/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CEFALEXIN, CEFALOXIN MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10011241897	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011241955	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -), Lymphadenopathy (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011242073	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Anaphylactic reaction (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10011242085	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved - Other Medically Important Condition), Hyperglycaemia (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10011242262	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Multisystem inflammatory syndrome in children (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .1mL - Intramuscular])	Not reported	ICSR	
EU-EC-10011242290	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dysphagia (1d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition), Odynophagia (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10011242491	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011242799	12/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Haemorrhage (n/a - Unknown - Other Medically Important Condition), Premature menarche (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011242873	12/01/2022	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), Nasal congestion (n/a - Unknown -), Pyrexia (n/a - Unknown -), Suspected COVID-19	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	

										(n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10011242979	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011245094	12/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -), Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10011245536	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011245550	12/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213850	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Constipation (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213854	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213855	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -), Lymphadenopathy (1d - Unknown -), Pyrexia (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213858	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (4d - Not Recovered/Not Resolved -), Alopecia (3d - Recovering/Resolving -), Headache (7d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213862	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (5d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213873	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Peripheral swelling (2d - Recovering/Resolving -), Pruritus (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213889	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213891	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213893	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213897	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Enuresis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011213900	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (8d - Recovering/Resolving -), Influenza like illness (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011214488	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011214604	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

										Recovered/Not Resolved -)	Not applicable - [n/a - 10ug - Intramuscular])		
EU-EC-10011218942	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Anaphylactic reaction (1h - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011221329	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Off label use (n/a - Unknown -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Product administered to patient of inappropriate age (n/a - Unknown -), Pruritus (25min - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011223134	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Chills (1d - Recovering/Resolving -), Fatigue (0d - Not Recovered/Not Resolved -), Pyrexia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011223152	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011223214	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011223705	11/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [B/PHUKET/3073/2013-LIKE STRAIN, A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011224119	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Headache (n/a - Recovered/Resolved -), Hypotonia (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -), Pain in extremity (n/a - 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 - More in ICSR])	Not reported	ICSR
EU-EC-10011225018	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Altered state of consciousness (40s - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cold sweat (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Eye movement disorder (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tenderness (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10011225020	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cough (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011225062	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Eye pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lacrimation increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Ocular hyperaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011225072	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Henoch-Schonlein purpura (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

										Hospitalisation), Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10011225127	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011225145	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC-10011225220	11/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011225231	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vaccination site inflammation (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC-10011225364	11/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	[KETOPROFEN, METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011225461	11/01/2022	Spontaneous	Healthcare Professional	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 - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011225820	11/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Disorientation (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Hallucination (n/a - Unknown - Other Medically Important Condition), Pyrexia (56h - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011201437	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011202219	10/01/2022	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 - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011202819	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011205459	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011206430	10/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cough (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Increased upper airway secretion (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Pharyngeal erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011208173	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011208498	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arrhythmia (n/a - Unknown -), Chest pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011208587	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Pain in extremity (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011209800	10/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Haematoma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011210234	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011210687	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Varicella (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011212887	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (6d - Recovered/Resolved -), Arthralgia (5d - Recovered/Resolved -), Headache (7d - Recovered/Resolved -), Nausea (4d - Recovered/Resolved -), Pyrexia (6d - Recovered/Resolved -), Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011212917	10/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (1d - Recovered/Resolved - Other Medically Important Condition), Tachycardia (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011197462	08/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011198233	08/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Tremor (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011198760	08/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-	07/01/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Male	No	Headache (2d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

1001186378			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	(S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])		
EU-EC-1001186398	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Palpitations (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1001191663	07/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Disorientation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1001193489	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1001193650	07/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Wrong product administered (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [31d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1001195107	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -), Vaccination site movement impairment (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1001195110	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site inflammation (6d - Recovered/Resolved -), Vaccination site pain (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1001195135	07/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Somnolence (n/a - Recovering/Resolving -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011174888	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011174901	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nasopharyngitis (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011174902	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Myalgia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011174926	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Erythema (n/a - Recovering/Resolving -), Face oedema (n/a - Recovering/Resolving -), Feeling hot (n/a - Recovering/Resolving -), Localised oedema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011177507	06/01/2022	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR


EU-EC-10011179852	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011180190	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (15min - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011180243	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011180528	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011180529	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011182001	06/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Alice in wonderland syndrome (n/a - Recovering/Resolving -), Hallucination (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Moaning (n/a - Unknown -), Speech disorder (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 10ug - n/a])	Not reported	ICSR
EU-EC-10011182999	06/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011184227	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Female	No	Rash (76d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011184261	06/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Female	No	Rash (76d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011185483	06/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Contusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011162829	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011162833	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011166995	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dyspnoea (n/a - Recovered/Resolved -), Erythema (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011167854	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Application site pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011171546	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011173888	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011173910	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

				Area						Resolved -)	Dose not changed - [n/a - n/a - n/a]		
EU-EC-10011173975	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Petechiae (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011173977	05/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Epistaxis (0d - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011174051	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pallor (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Presyncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011174053	05/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Presyncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011150400	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Presyncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011150525	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Mesenteritis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011150605	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011150753	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011151172	04/01/2022	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), Cough (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Feeling abnormal (n/a - Unknown -), Hypersensitivity (n/a - Recovering/Resolving -), Lip swelling (n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011151229	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011154425	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011156637	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown -), Nightmare (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown -), Tonic clonic movements (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011158332	04/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Night sweats (0d - Recovered/Resolved -), Panic attack (n/a - Unknown -), Pyrexia (0d - Recovered/Resolved -), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition), Tremor (0d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011160276	04/01/2022	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011161230	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011161231	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site papule (n/a - Not Recovered/Not Resolved -), Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011161243	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash maculo-papular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011161255	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Feeling cold (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

EU-EC-10011161284	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Palpitations (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011161304	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash macular (n/a - Recovering/Resolving -), Wound (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011161570	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Lymphadenopathy (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011161710	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash erythematous (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011161830	04/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain upper (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	[BLOMIA TROPICALIS] (C - Food allergy - Dose not changed - [n/a - n/a - n/a]), [DERMATOPHAGOIDES FARINAE] (C - Food allergy - Dose not changed - [n/a - n/a - n/a]), [DERMATOPHAGOIDES PTERONYSSINUS] (C - Food allergy - Dose not changed - [n/a - n/a - n/a])	ICSR
EU-EC-10011161915	04/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011145067	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Appendicitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multisystem inflammatory syndrome in children (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011146889	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Myopericarditis (8d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011148422	03/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (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 - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011149706	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Depressed level of consciousness (30s - Recovered/Resolved - Other Medically Important Condition), Fatigue (0d - Recovered/Resolved - Other Medically Important Condition), Seizure (30s - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AERIUS [DESFLORATADINE] (C - Urticaria - n/a - [n/a - n/a - Oral]), [FLUTICASON PROPRIONATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [HYDROCORTISONE BUTYRATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011149759	03/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Incorrect dose administered (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10011140635	02/01/2022	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 - n/a])	Not reported	ICSR
EU-EC-10011137619	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Aphthous ulcer (n/a - Not Recovered/Not Resolved -), Herpes zoster (n/a - Not Recovered/Not Resolved -), Mouth swelling (n/a - Not Recovered/Not Resolved -), Oral herpes (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011137626	01/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved With Sequelae -), Dyspnoea (n/a - Recovered/Resolved With Sequelae -), Nausea (n/a - Recovered/Resolved With Sequelae -), Tachycardia (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

 Rows 4501 - 4637 (end)

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