

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-10011433076	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011433743	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Body temperature increased (0d - Recovered/Resolved -), Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011434034	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011434057	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011434535	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011434543	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Body temperature increased (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011435546	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Night sweats (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011435985	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	No adverse event (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011436366	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthritis (n/a - Not Recovered/Not Resolved -), Arthritis reactive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011425698	29/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Circumoral oedema (1d - Recovered/Resolved -), Periorbital swelling (1d - Recovered/Resolved -), Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .2mL - n/a])	Not reported	ICSR
EU-EC-10011425840	29/01/2022	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-10011425906	29/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011425986	29/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .1mL - Intramuscular])	Not reported	ICSR
EU-EC-10011426046	29/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pulse absent (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Respiratory arrest (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR

EU-EC-10011427220	29/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Oxygen saturation decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved -), Rhinovirus infection (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011427436	29/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011427952	29/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Irregular sleep wake rhythm disorder (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Supraventricular tachycardia (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	ICSR
EU-EC-10011429963	29/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011410311	28/01/2022	Spontaneous	Non 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 - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011410312	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE, FLUTICASONE, SALMETEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [LYOPHILIZED BACTERIAL LYSATES, LYOPHILIZED BACTERIAL LYSATES OF: HAEMOPHILUS INFLUENZAE STREPTOCOCCUS (DIPLOCOCCUS) PNEUMONIAE KLEBSIELLA PNEUMONIAE AND OZAENAE STAPHYLOCOCCUS AUREUS STREPTOCOCCUS PYOGENES AND VIRIDANS MORAXELLA (BRANHAMELLA / NEISSERIA) CATARRHALIS] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011410321	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Erythema (n/a - Recovered/Resolved -), Night sweats (n/a - Recovered/Resolved -), Rash macular (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011410491	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pruritus (16d - Recovered/Resolved -), Rash (16d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011410638	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Recovered/Resolved -), Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-	28/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Hypoaesthesia (21d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011410896			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Paraesthesia (21d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10011413703	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Constipation (n/a - Recovered/Resolved -), Decreased appetite (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011414286	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011414300	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Disturbance in attention (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Subcutaneous])	Not reported	ICSR
EU-EC-10011414303	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Arthralgia (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011414481	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pain in extremity (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011415824	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011415897	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011417357	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (2d - Recovered/Resolved - Other Medically Important Condition), Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - .2mL - n/a])	Not reported	ICSR
EU-EC-10011417651	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Muscular weakness (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011419735	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Malaise (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - n/a])	Not reported	ICSR
EU-EC-10011419923	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash pruritic (n/a - Not Recovered/Not Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR	Not reported	ICSR

											DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-10011421881	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cold sweat (10min - Recovered/Resolved -), Pallor (10min - Recovered/Resolved -), Syncope (10min - Recovered/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	ICSR
EU-EC-10011422069	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011422135	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (6d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011422378	28/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10011422379	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (6h - Recovered/Resolved -), Vomiting (6h - Recovered/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	ICSR
EU-EC-10011422489	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Mouth swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 10ug - n/a])	Not reported	ICSR
EU-EC-10011423019	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011423027	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011423042	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011423084	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chills (0d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Influenza (0d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Limb discomfort (0d - Recovered/Resolved -), Lymphadenopathy (2d - Recovered/Resolved -), Malaise (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011423086	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011423088	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011423095	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	COVID-19 (1d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-	28/01/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Female	No	Oedema peripheral	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011424684			Professional	Economic Area	available	Years				(2d - Recovered/Resolved -), Rash (n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])		
EU-EC-10011425284	28/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (16d - Not Recovered/Not Resolved -), Dyspnoea exertional (16d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011398607	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved -), Injection site pain (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011398713	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011398752	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (2d - Recovering/Resolving -), Limb discomfort (n/a - Recovering/Resolving -), Nausea (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011398897	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Fatigue (10min - Recovered/Resolved -), Palpitations (10min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011399018	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Oral herpes (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011399028	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -), Lymph node pain (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011399071	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vertigo (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011399198	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011399201	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	[CARVEDILOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISON] (C - n/a - n/a - [n/a - n/a - n/a]), [TACROLIMUS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011399206	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Nausea (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

											Vomiting (0d - Recovered/Resolved -)	n/a - [n/a - .2mL - Intramuscular]		
EU-EC-10011399209	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR	
EU-EC-10011399214	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR	
EU-EC-10011399299	27/01/2022	Spontaneous	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 - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011399505	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10011399573	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -), Vaccination site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011399635	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hyperaemia (n/a - Recovering/Resolving -), Injection site pustule (n/a - Recovering/Resolving -), Oedema peripheral (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Vaccination site injury (n/a - Recovering/Resolving -), Vaccination site vesicles (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR	
EU-EC-10011399636	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hyperaemia (n/a - Recovering/Resolving -), Injection site injury (n/a - Recovering/Resolving -), Injection site pustule (n/a - Recovering/Resolving -), Local reaction (n/a - Recovering/Resolving -), Oedema (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -), Vaccination site vesicles (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR	
EU-EC-10011401530	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10011401531	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10011401682	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (3d - Recovered/Resolved -), Confusional state (3d -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR	

										Recovering/Resolving -), Diarrhoea (3d - Recovered/Resolved -), Dizziness (3d - Recovering/Resolving -), Headache (3d - Recovering/Resolving -)	Not applicable - [n/a - 10ug - n/a]		
EU-EC-10011403971	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Gait disturbance (3d - Recovered/Resolved - Disabling), Pain in extremity (3d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [0d - .2M[iU] - Intramuscular])	Not reported	ICSR
EU-EC-10011404312	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Asthenia (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diplopia (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscle twitching (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vertigo (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011404389	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	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-10011404475	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011405538	27/01/2022	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), Exposure to SARS-CoV-2 (n/a - Unknown -), Nasal congestion (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10011405901	27/01/2022	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), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dysmenorrhoea (n/a - Unknown -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Unknown -), Nodule (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Peripheral swelling (n/a - Recovered/Resolved -), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011406011	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	Yes	Deafness unilateral (1wk - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [0d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011406771	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hemihypoesthesia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Injected limb mobility decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011406925	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	Yes	Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011406951	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaginal haemorrhage (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011409403	27/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lacrimation increased (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011409441	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011409513	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011409955	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cholestasis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hepatitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Jaundice (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-10011411560	27/01/2022	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} - n/a])	AERIUS [DESLOTRADINE] (C - Urticaria - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011411711	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011411745	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthralgia (n/a - Unknown - 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 - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011411778	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011411977	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011411992	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arrhythmia (1d - Recovered/Resolved - Other Medically Important Condition), Chest pain (1d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition), Tachycardia (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	[OXCARBAZEPINE] (C - Epilepsy - Unknown - [n/a - n/a - n/a])	ICSR

										Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011412038	27/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011412584	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Male	No	Peripheral coldness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011412588	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arrhythmia (2d - Recovered/Resolved -), Influenza (5d - Recovered/Resolved -), Tachycardia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011412663	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (36d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011412670	27/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011386475	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Infusion site reaction (n/a - Recovering/Resolving -), Injection site erythema (n/a - Recovering/Resolving -), Injection site haematoma (n/a - Recovering/Resolving -), Injection site pruritus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011387266	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011387332	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eye pruritus (0d - Recovered/Resolved -), Eyelid oedema (0d - Recovered/Resolved -), Larynx irritation (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011388327	26/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Generalised tonic-clonic seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BROMPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE, BROMPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE, PHENYLPROPANOLAMINE HYDROCHLORIDE] (C - Cough, Nasopharyngitis - n/a - [4d - n/a - n/a])	ICSR
EU-EC-10011388637	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cough (n/a - Recovering/Resolving -), Dysphonia (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Rhinitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011388999	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypotonic-hyporesponsive episode (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										Visual impairment (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011389789	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011390063	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved -), Product administered to patient of inappropriate age (n/a - Recovered/Resolved -), Wrong product administered (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011390241	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011390757	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eye swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Periorbital swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011391851	26/01/2022	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), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011392679	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011393186	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash maculo-papular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011393215	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011394688	26/01/2022	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 - Intramuscular])	Not reported	ICSR
EU-EC-10011394767	26/01/2022	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 - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011395173	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011395178	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011395190	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (0d - Recovering/Resolving -), Pyrexia (0d - Recovering/Resolving -), Vomiting (7d -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011395365	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011395525	26/01/2022	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), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011395603	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Hand-foot-and-mouth disease (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011395627	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011395630	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Epistaxis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011395632	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (0d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Injection site swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011395636	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011395640	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovering/Resolving - Other Medically Important Condition), Syncope (0d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011395983	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Vaccination site pruritus (n/a - Recovering/Resolving -), Vaccination site swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011396008	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Recovering/Resolving -), Decreased appetite (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396158	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011396165	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Allergy to vaccine (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396175	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Presyncope (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396179	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site erythema (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

				Area						Unknown -), Vaccination site pain (n/a - Unknown -)	Not applicable - [1d - 1{DF} - n/a]		
EU-EC-10011396180	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396183	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (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-10011396189	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396191	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396193	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396197	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (16d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396202	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396261	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396280	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Atopy (n/a - Recovering/Resolving -), Dermatitis atopic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011396282	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[MICONAZOLE, MICONAZOLE NITRATE, MICONAZOLE NITRATE, HYDROCORTISONE] (C - n/a - n/a - [14d - n/a - Cutaneous])	ICSR
EU-EC-10011396290	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthritis reactive (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Joint effusion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Joint effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011396322	26/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Petechiae (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011396902	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	Myalgia (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

											Pain in extremity (4d - Recovered/Resolved -)		
EU-EC-10011397030	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Female	No	Asthenia (25d - Not Recovered/Not Resolved -), Erythema (25d - Not Recovered/Not Resolved -), Headache (25d - Not Recovered/Not Resolved -), Influenza (25d - Not Recovered/Not Resolved -), Palpitations (25d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397059	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Dizziness (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011397101	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (1d - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Pyrexia (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397159	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (1d - Recovered/Resolved -), Headache (3d - Recovering/Resolving -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397160	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Malaise (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397175	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovering/Resolving -), Injection site erythema (n/a - Unknown -), Injection site pain (n/a - Unknown -), Injection site swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397183	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Chills (0d - Not Recovered/Not Resolved -), Headache (0d - Not Recovered/Not Resolved -), Pyrexia (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397194	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Nausea (13d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397213	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397234	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397273	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397308	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (21d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397438	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Influenza (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397509	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397548	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (9d - Not Recovered/Not Resolved -), Headache (3d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved -), Lymphadenopathy (2d - Not Recovered/Not Resolved -)			
EU-EC-10011397555	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (1d - Recovering/Resolving -), Vomiting (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011397624	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397631	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovering/Resolving -), Fatigue (0d - Unknown -), Headache (0d - Recovering/Resolving -), Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397640	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Influenza (2d - Not Recovered/Not Resolved -), Myalgia (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397654	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (3d - Not Recovered/Not Resolved -), Pyrexia (3d - Not Recovered/Not Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397696	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (2d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site pain (2d - Unknown -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011372850	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hyperpyrexia (n/a - Recovering/Resolving -), Nightmare (n/a - Recovering/Resolving -), Somnambulism (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011372876	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Confusional state (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Hot flush (n/a - Recovered/Resolved -), Peripheral coldness (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011372909	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011373037	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

										Chest pain (n/a - Recovering/Resolving -), Heavy menstrual bleeding (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -)			
EU-EC-10011373121	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site erythema (n/a - Recovering/Resolving -), Injection site haematoma (n/a - Recovering/Resolving -), Injection site necrosis (n/a - Recovering/Resolving -), Injection site oedema (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Vaccination site reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - Intramuscular])	Not reported	ICSR
EU-EC-10011373146	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011373451	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011373752	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (3d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011373753	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[INSULIN, INSULIN HUMAN] (C - Type 1 diabetes mellitus - n/a - [n/a - 36[IU] - Subcutaneous])	ICSR
EU-EC-10011373754	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[INSULIN, INSULIN HUMAN] (C - Type 1 diabetes mellitus - n/a - [n/a - 36[IU] - Subcutaneous])	ICSR
EU-EC-10011373755	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (7d - Recovered/Resolved -), Pyrexia (7d - Recovered/Resolved -), Somnolence (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[AZITHROMYCIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DORNASE ALFA] (C - Cystic fibrosis - n/a - [n/a - 2.5mg - Respiratory (inhalation)]), [PANCREALIPASE] (C - Cystic fibrosis - n/a - [n/a - 12(DF) - Oral])	ICSR
EU-EC-10011373756	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (5d - Recovered/Resolved -), Fatigue (5d - Recovered/Resolved -), Irritability (5d - Recovered/Resolved -), Somnolence (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[DORNASE ALFA] (C - Cystic fibrosis - n/a - [n/a - 2.5mg - Respiratory (inhalation)]), [PANCREALIPASE] (C - Cystic fibrosis - n/a - [n/a - 12(DF) - n/a])	ICSR
EU-EC-10011373757	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (5d - Recovered/Resolved -), Nasopharyngitis (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[FOLIC ACID, ANHYDROUS] (C - n/a - n/a - [n/a - 5mg - Oral]), [METHOTREXATE] (C - Rheumatoid arthritis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011373758	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (4d - Recovered/Resolved -), Injection site pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[FOLIC ACID, ANHYDROUS] (C - n/a - n/a - [n/a - 5mg - Oral]), [METHOTREXATE] (C - Rheumatoid arthritis - n/a - [n/a - n/a - n/a])	ICSR

										Lymphadenopathy (4d - Recovered/Resolved -), Myalgia (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)			
EU-EC-10011373769	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011373770	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Nasopharyngitis (6d - Recovered/Resolved -), Rhinorrhoea (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10ug - Intramuscular])	[CARBAMAZEPINE] (C - Epilepsy - n/a - [n/a - 18mL - Oral])	ICSR
EU-EC-10011375634	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Asthenia (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011375940	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (1h - Recovered/Resolved -), Rash (1h - Recovered/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	ICSR
EU-EC-10011377158	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011377220	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011377374	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011378668	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (1h - Recovered/Resolved -), Vomiting (10h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - n/a])	Not reported	ICSR
EU-EC-10011379366	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (12h - Recovered/Resolved -), Loss of personal independence in daily activities (n/a - Recovered/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	ICSR
EU-EC-10011379806	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -), Hyporesponsive to stimuli (n/a - Recovering/Resolving -), Panic attack (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011380932	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011381284	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Epilepsy (0d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011382317	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Hallucination (1d - Recovered/Resolved -), Influenza like illness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011384779	25/01/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Female	No	Myositis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

				Economic Area						Caused/Prolonged Hospitalisation, Disabling), Off label use (n/a - Unknown -)	Not applicable - [n/a - n/a - n/a]		
EU-EC-10011385260	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011385289	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Erythema (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ANHYDROUS FUSIDIC ACID, FUSIDIC ACID, FUSIDIC ACID PH. EUR., SODIUM FUSIDATE, SODIUM FUSIDATE PH. EUR.] (C - Skin infection - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC-10011385304	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011385361	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011385365	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AERIUS [DESLORATADINE] (C - Urticaria - n/a - [n/a - n/a - Oral]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Urticaria - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011385447	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011385462	25/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Feeling jittery (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Muscle spasms (3d - Recovered/Resolved -), Tic (3d - Recovered/Resolved -), Vomiting (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011385730	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Herpes zoster (10d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011385960	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .1mL - Intramuscular])	Not reported	ICSR
EU-EC-10011361409	24/01/2022	Spontaneous	Non 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), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011363243	24/01/2022	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), 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	ICSR
EU-EC-10011363749	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011363838	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011363841	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011363874	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011364863	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										Important Condition), Arthritis (n/a - Recovered/Resolved - Other Medically Important Condition), C-reactive protein increased (n/a - Recovered/Resolved - Other Medically Important Condition), Joint effusion (n/a - Recovered/Resolved - Other Medically Important Condition), Petechiae (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011365329	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011365426	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (1d - Recovered/Resolved -), Injection site erythema (2d - Recovering/Resolving -), Injection site pain (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011365537	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Recovering/Resolving -), Neck pain (n/a - Recovering/Resolving -), Petechiae (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011365620	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Erythema (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011365676	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Gastroesophageal reflux disease (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Rhinitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011368548	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Not Recovered/Not Resolved -), Urticaria (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	ICSR
EU-EC-10011368979	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011371782	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011371995	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .1mL - Intramuscular])	Not reported	ICSR
EU-EC-10011371999	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011372018	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Recovering/Resolving -), Vulvitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[LEVOTHYROXINE SODIUM] (C - n/a - Dose not changed - [n/a - 50ug - Oral])	ICSR
EU-EC-10011372282	24/01/2022	Spontaneous	Non Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	ICSR

				Economic Area						Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Heart rate irregular (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (3d - Recovering/Resolving -)	19 immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10011354987	22/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -), Tachycardia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011355572	22/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011355575	22/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Decreased appetite (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011341878	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011342077	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Erythema (n/a - Recovering/Resolving -), Mechanical urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011342183	21/01/2022	Spontaneous	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-10011342189	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Gait disturbance (n/a - Not Recovered/Not Resolved -), Synovitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011342221	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chills (0d - Recovered/Resolved -), Diarrhoea (0d - Recovered/Resolved -), Tachycardia (0d - Recovered/Resolved -), Vertigo (0d - Recovered/Resolved -), Vomiting (0d -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10011342343	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Delusion (2d - Recovered/Resolved - Other Medically Important Condition), Dizziness (2d - Recovered/Resolved - Other Medically Important Condition), Hallucinations, mixed (2d - Recovered/Resolved - Other Medically Important Condition), Nausea (2d - Recovered/Resolved - Other Medically Important Condition), Nightmare (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Somnambulism (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011344831	21/01/2022	Spontaneous	Non 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 -), Syncope (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-10011345427	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Electroencephalogram abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Gaze palsy (n/a - Unknown - Caused/Prolonged Hospitalisation), Lividty (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Salivary hypersecretion (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Slow response to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation), Trismus (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011345630	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Oedema peripheral (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Peripheral swelling (n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION 10 MICROGRAMS/DOSE [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										-), Somnolence (n/a - Recovering/Resolving -)			
EU-EC-10011346478	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011347099	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011348972	21/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Depression (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eczema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011350170	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Hallucination, visual (1d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Urinary incontinence (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011350421	21/01/2022	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), 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	ICSR
EU-EC-10011350892	21/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Flushing (n/a - Recovering/Resolving - Other Medically Important Condition), Lip swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011350927	21/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011352185	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Dizziness (2d - Recovering/Resolving -), Ear pain (2d -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Recovering/Resolving -), Headache (3d - Recovered/Resolved -), Limb discomfort (3d - Recovering/Resolving -), Muscle spasms (2d - Recovering/Resolving -), Myalgia (2d - Recovering/Resolving -), Nausea (3d - Recovered/Resolved -), Pyrexia (2d - Recovering/Resolving -)			
EU-EC-10011352261	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Myopia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011352479	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Unknown -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011352570	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011352726	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011352747	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011352772	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011353495	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vasculitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011353499	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011353511	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011353514	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia intercostal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10011353515	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011353898	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urinary retention (60min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011353984	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011353992	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (1d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011354021	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Abdominal discomfort (1d - Recovered/Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Influenza (n/a - Not Recovered/Not Resolved -), Nausea (1d - Recovered/Resolved -), Skin swelling (7d - Recovered/Resolved -), Vaccination site reaction (7d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011354040	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011320571	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Hypokinesia (4h - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011320755	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Recovered/Resolved -), Agitation (n/a - Recovered/Resolved -), Irritability (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011320756	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Recovered/Resolved -), Agitation (n/a - Recovered/Resolved -), Irritability (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011320919	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011321012	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

										Headache (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	Not applicable - [n/a - 1{DF} - Intramuscular]		
EU-EC-10011321142	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011321193	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Catarrh (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011321661	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011321681	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vertigo (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[EPLERENONE] (C - Asthma - n/a - [n/a - n/a - n/a]), [MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011323382	20/01/2022	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), Exposure to SARS-CoV-2 (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	ICSR
EU-EC-10011324492	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovering/Resolving -), Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011324614	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cough (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325209	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325278	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325289	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -), Influenza (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325429	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325439	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325785	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325831	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chills (1d - Recovering/Resolving -), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Recovering/Resolving -), Injection site pain (1d - Recovering/Resolving -), Limb discomfort (1d - Recovering/Resolving -)			
EU-EC-10011325926	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cough (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325971	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (5min - Recovered/Resolved -), Tremor (5min - Recovered/Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326019	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326170	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cough (n/a - Not Recovered/Not Resolved -), Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326368	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (4d - Recovered/Resolved -), Headache (5d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Injection site pain (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326478	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326502	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326563	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (1d - Not Recovered/Not Resolved -), Headache (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326651	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (5d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326775	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (28d - Not Recovered/Not Resolved -), Fatigue (28d - Not Recovered/Not Resolved -), Nausea (28d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326791	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Unknown -), Headache (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Unknown -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011327182	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011327207	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011327222	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011327560	20/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011328068	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Fatigue (5d - Recovering/Resolved -), Headache (3d - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011328219	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011328483	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	Injection site pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011328528	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Fatigue (15d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011329723	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011329744	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011329820	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved -), Headache (1d - Not Recovered/Not Resolved -), Influenza (2d - Not Recovered/Not Resolved -), Injection site pain (1d - Recovered/Resolved -), Nausea (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011329913	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011330346	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011330385	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011330386	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011330515	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011330632	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011331007	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011331514	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Ecchymosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Henoch-Schonlein purpura (n/a - Unknown - Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011331719	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Rash (2d - Recovered/Resolved -), Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011332452	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (4d - Recovered/Resolved -), Pyrexia (1d -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

EU-EC-10011340709	20/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menarche (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011306441	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011306667	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eye irritation (3d - Recovered/Resolved -), Ocular hyperaemia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011306670	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011306680	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011306690	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vaccination site pain (0d - Recovered/Resolved -), Vertigo (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	[CEFIXIME] (C - n/a - n/a - [n/a - n/a - n/a]), [CICLOSPORIN] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MYCOPHENOLATE MOFETIL] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISON] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011306758	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011306932	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash morbilliform (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[OXATOMIDE, OXATOMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011307170	19/01/2022	Spontaneous	Non 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 - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011307173	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011310468	19/01/2022	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 - 10ug - n/a])	Not reported	ICSR
EU-EC-10011310475	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Hypotonia (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Pain in extremity (n/a - Unknown -), 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	ICSR
EU-EC-10011312034	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011312136	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchitis (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10011312466	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (2d - Recovered/Resolved -), Rash (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011312467	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011312578	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011312627	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011312629	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011312644	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011312660	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011314108	19/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eye pain (n/a - Unknown -), Uveitis (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-10011314314	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011314483	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (1d - Recovering/Resolving -), Rash (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011314549	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011316729	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (19h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (6h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Neck pain (7h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (24h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011318518	19/01/2022	Spontaneous	Non Healthcare Professional	Non 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 Medically Important Condition), 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	ICSR
EU-EC-10011318839	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Swelling (n/a - Recovering/Resolving -), Tenderness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	EMADINE [EMEDASTINE, EMEDASTINE DIFUMARATE] (C - Rhinitis allergic - n/a - [n/a - n/a - n/a - Ophthalmic]), OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]), [MICONAZOLE NITRATE, HYDROCORTISONE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]), [NAPROXEN] (C - Pain - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-	19/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Diarrhoea (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011318848			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-10011318849	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011318851	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AVAMYS [FLUTICASON FUROATE] (C - Rhinorrhoea - n/a - [n/a - n/a - Nasal]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [IBUPROFEN] (C - Pain - n/a - [n/a - n/a - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011318868	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (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-10011318935	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Male	No	Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[BECLOMETASONE DIPROPIONATE, BECLOMETASONE DIPROPIONATE ANHYDROUS] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011318983	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash papular (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[AZELASTINE, AZELASTINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]), [BETAMETHASONE, BETAMETHASONE DIPROPIONATE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]), [NAPROXEN] (C - Myalgia - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011318992	19/01/2022	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 - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011318998	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011319005	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Insomnia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011319006	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved -), Rash erythematous (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011319032	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011319033	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011319035	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Female	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AVAMYS [FLUTICASON FUROATE] (C - Rhinorrhoea - n/a - [n/a - n/a - Nasal])	ICSR
EU-EC-10011319167	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011319199	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	19/01/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Male	No	Injection site	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011319237			Professional	Economic Area	available	Years				erythema (n/a - Unknown -), Vaccination site warmth (n/a - Unknown -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10011320330	19/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011293263	18/01/2022	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 - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011293317	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011293525	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011293547	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Initial insomnia (n/a - Not Recovered/Not Resolved -), Middle insomnia (n/a - Not Recovered/Not Resolved -), Nightmare (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011293962	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Bone pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011294146	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Recovered/Resolved -), Agitation (n/a - Recovered/Resolved -), Irritability (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011294147	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Recovered/Resolved -), Agitation (n/a - Recovered/Resolved -), Irritability (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011296347	18/01/2022	Spontaneous	Non 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 - n/a])	Not reported	ICSR
EU-EC-10011300364	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011300558	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chillblains (2d - Recovered/Resolved - Other Medically Important Condition), Ill-defined disorder (2d - Recovered/Resolved - 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])	[LANSOPRAZOLE] (C - n/a - n/a -), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a -), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a -), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a -)	ICSR
EU-EC-10011301042	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	ICSR

			Professional	Economic Area						Bell's palsy (n/a - Unknown - Other Medically Important Condition), Hypoesthesia (n/a - Unknown -), Illness (n/a - Unknown -)	19 immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10011301564	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011301776	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Feeling hot (10min - Recovered/Resolved -), Hyperhidrosis (10min - Recovered/Resolved -), Pallor (10min - Recovered/Resolved -), Tinnitus (10min - Recovered/Resolved -), Vision blurred (10min - Recovered/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	ICSR
EU-EC-10011301926	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Hypokalaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericardial effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericarditis (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-10011302299	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Arthralgia (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Petechiae (n/a - Not Recovered/Not Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011302563	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Immunisation reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011302635	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Angioedema (n/a - Recovering/Resolving -), Decreased appetite (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011304041	18/01/2022	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 - More in ICSR])	Not reported	ICSR
EU-EC-10011304530	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Oropharyngeal pain (n/a - Recovering/Resolving -), Pyrexia (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10011304531	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	[AMOXICILLIN] (C - n/a - Unknown -), [IBUPROFEN] (C - n/a - Unknown -), [PARACETAMOL] (C - n/a - Unknown -)	ICSR
EU-EC-10011304537	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	[PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Streptococcal infection - Drug withdrawn - [11d - 250mg - Oral])	ICSR
EU-EC-10011304539	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Decreased appetite (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011304542	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	[ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3] (C - Immunisation - Drug withdrawn - [1d - n/a - n/a])	ICSR
EU-EC-10011304549	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site inflammation (n/a - Not Recovered/Not Resolved -), Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011304551	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pain (n/a - Recovering/Resolving -), Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011305350	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Condition aggravated (n/a - Not Recovered/Not Resolved -), Tic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011305402	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Dizziness (1d - Recovering/Resolving -), Injection site pain (0d - Recovering/Resolving -), Paraesthesia (0d - Recovered/Resolved -), Pruritus (0d - Recovered/Resolved -), Vaccination site pain (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011305441	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Granuloma annulare (13d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011305442	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition), Erythema (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011305475	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (0d - Recovered/Resolved -), Palpitations (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011306004	18/01/2022	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), Suspected COVID-19 (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-10011283005	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (n/a - Recovering/Resolving -), Tremor (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011283256	17/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchial wall thickening (n/a - Unknown -), Fatigue (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011283496	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011284557	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Not Specified	No	Injection site pain (1d - Not Recovered/Not Resolved -), Rash (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011284620	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (0d - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011284651	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (1d - Recovering/Resolving -), Malaise (3d - Recovering/Resolving -), Nausea (1d - Recovering/Resolving -), Nausea (2d - Recovering/Resolving -), Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011284675	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011286858	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cold sweat (n/a - Not Recovered/Not Resolved -), Confusional state (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Not Recovered/Not Resolved -), Feeling hot (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011288289	17/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (2d - Recovered/Resolving -), Headache (2d - Recovered/Resolving -), Pyrexia (n/a - Unknown -), Tardive dyskinesia (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a - .05mg - Oral]), [OXCARBAZEPINE] (C - Seizure - n/a - [n/a - 14mL - Oral])	ICSR

EU-EC-10011288491	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Medically Important Condition) Anaphylactoid reaction (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011289539	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Intermenstrual bleeding (n/a - Recovering/Resolving -), Premenstrual syndrome (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011289567	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Erythema nodosum (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011290319	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Ageusia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Anosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Parosmia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[LEVOCETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 5mg - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Hypersensitivity - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-10011291879	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Eczema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011291902	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstruation irregular (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011291947	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (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-10011291967	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011292179	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Febrile convulsion (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011277832	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pruritus (0d - Recovered/Resolved -), Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011278106	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011278227	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Tachypnoea (1d - Recovered/Resolved -), Urticaria (1d - Recovered/Resolved -), Wheezing (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[FLUTICASON PROPIONATE] (C - Bronchospasm - n/a - [n/a - 1{DF} - 1{DF} - Respiratory (inhalation)])	ICSR
EU-EC-10011278231	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eczema nummular (n/a - Recovering/Resolving -), Oedema (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -), Skin reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011278278	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site oedema (n/a - Unknown -), Oedema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011279224	15/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (2d - Recovered/Resolved -), Pyrexia (2d -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

EU-EC-10011262515	14/01/2022	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 - Intramuscular])	Not reported	ICSR
EU-EC-10011262637	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Respiratory fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011262755	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011262766	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011262768	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nausea (n/a - Unknown -), Retching (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011262992	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vaccination site vesicles (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011263785	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011264475	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Asthenia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011264714	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (2d - Recovered/Resolved -), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Headache (2d - Recovered/Resolved -), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	LEVETIRACETAM [LEVETIRACETAM] (C - Seizure - n/a - [n/a - 500mg - Oral])	ICSR
EU-EC-10011266685	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011266853	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011267825	14/01/2022	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	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10011267865	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Medically Important Condition) Abdominal pain upper (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Tardive dyskinesia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a - .05mg - Oral]), [OXCARBAZEPINE] (C - Seizure - n/a - [n/a - 14mL - Oral])	ICSR
EU-EC-10011268165	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Autoimmune disorder (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011268983	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypotonia (n/a - Recovered/Resolved - Other Medically Important Condition), Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (725min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011273061	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Migraine (5d - Recovered/Resolved - Disabling, Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	[FLUTICASON PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011273477	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011274479	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ataxia (n/a - Not Recovered/Not Resolved -), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011275254	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Disorientation (n/a - Recovered/Resolved -), Feeling hot (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Unknown -), Visual impairment (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BACILLUS COAGULANS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Other Medically Important Condition)			
EU-EC-10011275825	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Angioedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011275841	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011275861	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site bruising (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011275865	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011275877	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011275902	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition), Tremor (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011275905	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Lethargy (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 - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011276000	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011276002	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011276010	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011276034	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	NIMENRIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE [N. MENINGITIDIS GROUP C (STRAIN C11) POLYSACCHARIDE (DE-O-ACETYLATED) CONJUGATED TO TETANUS TOXOID, NEISSERIA MENINGITIDIS GROUP A POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP W-135 POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP Y POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN] (C - n/a - Drug withdrawn - [1d - n/a - n/a]), PANDEMIC INFLUENZA VACCINE H5N1 BAXTER [A/VIETNAM/1203/2004 (H5N1)] (C - Influenza immunisation - Drug withdrawn - [1d - n/a - n/a])	ICSR
EU-EC-10011276305	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Headache (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 - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011276317	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (n/a - Recovering/Resolving -), Nausea (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)			
EU-EC-10011276358	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Anaphylactic reaction (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	[BUDESONIDE] (C - Asthma - Dose not changed - [n/a - 200ug - Respiratory (inhalation)])	ICSR
EU-EC-10011277027	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011277468	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Chest discomfort (37d - Recovering/Resolving -), Influenza like illness (37d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011247330	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011247570	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011247513	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011247580	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (15d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	METHOTREXATE [METHOTREXATE] (C - n/a - n/a - [n/a - 10ug - n/a])	ICSR
EU-EC-10011247674	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011249129	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (42d - Not Recovered/Not Resolved -), Headache (68d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011249335	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011250238	13/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011250240	13/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN	ICSR


										Yellow skin (n/a - Recovered/Resolved -)		(B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Immunisation - n/a - [1d - n/a - n/a])	
EU-EC-10011250290	13/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blindness (5min - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Mydriasis (5min - Recovered/Resolved -), Pallor (n/a - Unknown -), Presyncope (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011251733	13/01/2022	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 - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011253410	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011253685	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011253841	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011255650	13/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (8h - Recovered/Resolved -), Hyperpyrexia (8h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011255683	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011256993	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Administration site pain (4d - Recovering/Resolving - Other Medically Important Condition), Constipation (4d - Recovering/Resolving - Other Medically Important Condition), Decreased appetite (4d - Recovering/Resolving - Other Medically Important Condition), Haematochezia (n/a - Recovering/Resolving - Other Medically Important Condition), Mucous stools (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (4d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - n/a]), [METHOTREXATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [METHOTREXATE] (C - n/a - n/a - [n/a - 2.5mg - n/a])	ICSR
EU-EC-10011257103	13/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Alopecia areata (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Inflammation (n/a - Unknown - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011260307	13/01/2022	Spontaneous	Non Healthcare	Non European	Not available	3-11 Years	Not Specified	Female	No	Disability (n/a - Unknown - Disabling,	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	ICSR

			Professional	Economic Area						Other Medically Important Condition)	19 immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10011260844	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (5h - Recovered/Resolved -), Vomiting (5h - Recovered/Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011261143	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261144	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011261150	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261166	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site hypersensitivity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011261173	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261177	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dyskinesia (n/a - Recovering/Resolving -), Tic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011261192	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Epistaxis (0d - Recovered/Resolved -), Ocular hyperaemia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[BETAMETHASONE VALERATE, FUSIDIC ACID, BETAMETHASONE VALERATE, FUSIDIC ACID HEMIHYDRATE, BETAMETHASONE, ANHYDROUS FUSIDIC ACID, BETAMETHASONE, FUSIDIC ACID HEMIHYDRATE, BETAMETHASONE, FUSIDIC ACID PH. EUR., FUSIDIC ACID HEMIHYDRATE, BETAMETHASONE VALERATE (PH. EUR.), FUSIDIC ACID, BETAMETHASONE] (C - Eczema infected - n/a - [n/a - n/a - Cutaneous]), [HYDROCORTISONE BUTYRATE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC-10011261198	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pruritus (4d - Recovered/Resolved -), Urticaria (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	[FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [HYDROCORTISONE BUTYRATE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]), [NAPROXEN] (C - Pain - n/a - [n/a - n/a - Oral]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011261200	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -), Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261209	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261215	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Decreased appetite (n/a - Unknown -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011261222	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261224	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Eczema (n/a - Recovering/Resolving -), Fungal infection (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a - Oral])	ICSR

EU-EC-10011261256	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Recovering/Resolving -) Discomfort (n/a - Recovering/Resolving -), General physical condition abnormal (n/a - Unknown -), Malaise (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Restlessness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261261	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Malaise (15min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]), [EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - Intramuscular]), [HYDROCORTISONE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]), [PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Pharyngitis - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011261566	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Feeling abnormal (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261567	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261576	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lip erythema (n/a - Recovering/Resolving -), Rash erythematous (1d - Recovered/Resolved -), Swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10011261579	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pruritus (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Restlessness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Urticaria (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	13/01/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Female	No	Contusion (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011261595			Professional	Economic Area	available	Years				Unknown - Caused/Prolonged Hospitalisation), Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		
EU-EC-10011261598	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Tremor (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261671	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011261672	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[DESMOPRESSIN, DESMOPRESSIN ACETATE, DESMOPRESSIN ACETATE TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - Oral]), [SOLIFENACIN, SOLIFENACIN SUCCINATE] (C - Incontinence - n/a - [n/a - n/a - Oral]), [TERBUTALINE SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011261676	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011261677	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthralgia (n/a - Recovering/Resolving -), Axillary pain (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Sensory disturbance (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261688	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Headache (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 - Dose not changed - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261691	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1.5d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1.5d - Recovered/Resolved -), Vomiting (1.5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	13/01/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Female	No	Chills (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011261695			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-10011261697	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Aphonia (n/a - Recovering/Resolving -), Chills (1d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261702	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261732	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261735	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261737	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261739	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dyspnoea (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261746	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lip swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261759	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261762	13/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (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])	AVAMYS [FLUTICASON FUROATE] (C - Allergy prophylaxis - n/a - [n/a - n/a - Nasal]), [FLUTICASON PROPIONATE] (C - Asthma prophylaxis - n/a - [n/a - n/a - Respiratory (inhalation)]), [MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10011261763	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site granuloma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261764	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011261770	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

 Rows 4001 - 4500

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