

Line Listing Report

Time run: 30/11/2022 03:14:21

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-10011130058	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (23h - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011131838	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011132212	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011132246	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site oedema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011132247	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Peritonsillar abscess (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-10011132254	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Body temperature increased (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011134363	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Blood glucose increased (n/a - Not Recovered/Not Resolved -), Increased insulin requirement (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) NOVORAPID [INSULIN ASPART] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a])	LANTUS [INSULIN GLARGINE] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a]), NOVORAPID [INSULIN ASPART] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011135059	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fall (0d - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011135175	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyskinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye movement disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011135183	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[OXCARBAZEPINE] (C - Epilepsy - n/a - [n/a - n/a - Oral])	ICSR

										-), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011135824	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011121829	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolved -), Fatigue (n/a - Recovering/Resolved -), Pruritus (n/a - Recovered/Resolved -), Target skin lesion (1d - Recovered/Resolved - Other Medically Important Condition), Vaccination site erythema (n/a - Recovered/Resolved -), Vaccination site rash (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[INFLUENZA A VIRUS A/CALIFORNIA/7/2009 X-179A (H1N1) HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), INFLUENZA B VIRUS B/BRISBANE/60/2008 HEMAGGLUTININ ANTIGEN (FORMALDEHYDE INACTIVATED), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [n/a - n/a - Intramuscular])	ICSR
EU-EC-10011122004	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nephrotic syndrome (n/a - Unknown - Other Medically Important Condition), Overdose (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011126638	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	Influenza (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104589	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Accidental overdose (n/a - Unknown -), Incorrect dose administered (n/a - Unknown -), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011107598	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Stomatitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113383	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Hypomenorrhoea (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011093134	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Psychomotor hyperactivity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011093137	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011093643	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Exposure via breast milk (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011093969	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC-10011096440	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Autism spectrum disorder (n/a - Unknown - Other Medically Important Condition), Poor quality product administered (n/a - Unknown -), Product temperature excursion issue (n/a - Unknown -), Social anxiety disorder (n/a -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Unknown -), Therapeutic product effect variable (n/a - Unknown -)			
EU-EC-10011097297	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Influenza like illness (30h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011097575	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (12d - Recovered/Resolved - Other Medically Important Condition), Gait disturbance (12d - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (2d - Recovered/Resolved - Other Medically Important Condition), Synovitis (n/a - Unknown - Other Medically Important Condition), Taste disorder (n/a - Unknown -), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - 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 - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011097681	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Immunisation reaction (n/a - Recovering/Resolving -), Product preparation error (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097682	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Immunisation reaction (n/a - Recovered/Resolved -), Product preparation error (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097683	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Immunisation reaction (n/a - Recovering/Resolving -), Product preparation error (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097684	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Immunisation reaction (2d - Recovered/Resolved -), Product preparation error (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011099731	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011099748	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011099754	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (3d - Recovered/Resolved -), Injection site pain (4d - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -), Vomiting (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099762	28/12/2021	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 - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011099767	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (2d - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -), Vomiting (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Non	European	Not	3-11	Child	Female	No	Fatigue (2d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011099787			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10011099792	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100751	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011100764	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011100767	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Oropharyngeal pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100778	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Peripheral vascular disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100779	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthralgia (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011100782	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Erythema (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011100783	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (2d - Recovered/Resolved -), Influenza (2d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100788	28/12/2021	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-10011100790	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100795	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual disorder (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100810	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011100841	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Myalgia (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011100883	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pain in extremity (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011079869	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011080074	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Gastroenteritis viral (n/a - Recovering/Resolving -), Gastrointestinal disorder (n/a - Recovering/Resolving - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

											Condition), Pyrexia (n/a - Recovering/Resolving -)		
EU-EC-10011080779	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Axillary pain (n/a - Recovering/Resolving -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011081356	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011086260	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eye pain (n/a - Unknown - Other Medically Important Condition), Ocular hyperaemia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED), INFLUENZA A VIRUS A/TEXAS/50/2012 X-223A (H3N2) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED), INFLUENZA B VIRUS B/MASSACHUSETTS/2/2012 ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011086838	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Accidental overdose (n/a - Unknown -), Bronchial disorder (n/a - Unknown -), Cough (n/a - Recovering/Resolving - Other Medically Important Condition), Crying (n/a - Unknown -), Headache (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Wrong product administered (n/a - Unknown -)	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 (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (N - Immunisation - Not applicable - [1d - n/a - n/a])	ICSR
EU-EC-10011088673	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Administration site lymphadenopathy (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC-10011088682	27/12/2021	Spontaneous	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-10011088689	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC-10011088727	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011088733	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Eczema herpeticum (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

EU-EC-10011088741	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Presyncope (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	Drug withdrawn - [1d - n/a - Intramuscular]) COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	[B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, NIB-104), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A)] (C - Influenza immunisation - Not applicable - [1d - 1{DF} - n/a])	ICSR
EU-EC-10011074960	25/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC-10011065871	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pain in extremity (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011070379	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Petechiae (n/a - Unknown -)	COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Parenteral])	Not reported	ICSR
EU-EC-10011074280	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Bronchospasm (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular])	ANTHIS - ANTIHISTAMINICOS [NOT AVAILABLE] (C - n/a - Unknown -), BRONCO - BRONCODILATADOR [NOT AVAILABLE] (C - n/a - Unknown -)	ICSR
EU-EC-10011051362	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (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-10011061048	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eye lid function disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Facial paresis (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011064073	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037096	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .2mL - n/a])	Not reported	ICSR
EU-EC-10011037953	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ataxia (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011040325	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Tachycardia (n/a -	COMIRNATY (TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Unknown - Other Medically Important Condition)				
EU-EC-10011046470	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Disabling), Influenza like illness (n/a - Unknown - Disabling), Musculoskeletal stiffness (n/a - Unknown - Disabling), Nausea (n/a - Recovered/Resolved - Disabling), Neck pain (n/a - Recovering/Resolving - Disabling), Pain (n/a - Unknown - Disabling), Vomiting (1d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011049547	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition), Menstrual disorder (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-10011049931	22/12/2021	Spontaneous	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 - Not applicable - [0d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011049993	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011050070	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (4d - Recovered/Resolved -), Vision blurred (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011050075	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (3d - Recovered/Resolved - Other Medically Important Condition), Dizziness (2d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011050088	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011050143	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Presyncope (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-10011050150	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011050190	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (0d - Recovered/Resolved - Life Threatening), Anaphylactic reaction (0d - Recovered/Resolved - Life Threatening), Anaphylactic shock (0d - Recovered/Resolved - Life Threatening), Dizziness (0d - Recovered/Resolved - Life Threatening), Rash (0d - Recovered/Resolved - Life Threatening), Vomiting (0d - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10011027125	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR	
EU-EC-10011027131	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	

EU-EC-10011027133	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Respiratory distress (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011035056	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC-10011035322	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (5d - Recovered/Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rash erythematous (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011035336	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011035337	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cough (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011035353	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011035355	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site 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-10011035433	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dermatitis atopic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [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]), [MOMETASONE FUROATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC-10011035458	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011035468	21/12/2021	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 - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011035471	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - Inflammation - n/a - [n/a - n/a - Oral]), [ANHYDROUS FUSIDIC ACID, FUSIDIC ACID, FUSIDIC ACID HEMIHYDRATE, FUSIDIC ACID PENTAHYDRATE] (C - Eye infection - n/a - [n/a - n/a - Ophthalmic]), [PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Inflammation - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011035476	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011035483	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (6h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011035509	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[HYDROCORTISONE BUTYRATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC-10011012309	20/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dysphagia (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Important Condition), Oropharyngeal discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011014929	20/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Malaise (0d - Recovered/Resolved -), Pallor (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011014995	20/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Feeling abnormal (0d - Recovered/Resolved -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Mydriasis (0d - Recovered/Resolved -), Posture abnormal (0d - Recovered/Resolved -), Respiratory rate increased (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [B/PHUKET/3073/2013-LIKE STRAIN, A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011002570	18/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Malaise (15min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010990214	17/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010999177	17/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 10ug - n/a])	Not reported	ICSR
EU-EC-10010984795	16/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 20ug - n/a])	Not reported	ICSR
EU-EC-10010986554	16/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010959396	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthritis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010959399	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chills (n/a - Unknown -), Dizziness (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10010963631	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Fatigue (n/a - Unknown -), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010970929	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dyskinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Unknown -), Headache (n/a - Unknown -), Muscle twitching (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Strabismus (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010945924	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myopericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Vomiting (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010946801	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Swelling face (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010946806	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved -), Pleuritic pain (n/a - Recovered/Resolved -), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010953001	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010955757	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cold sweat (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10010955764	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovering/Resolving -), 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-10010956059	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Recovering/Resolving -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956072	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ATOMOXETINE, ATOMOXETINE HYDROCHLORIDE] (C - Disturbance in attention - n/a - [n/a - n/a - Oral]), [BUDESONIDE] (C - Asthma prophylaxis - n/a - [n/a - n/a - Respiratory (inhalation)]), [KETOCONAZOLE, KETOCONAZOLE PH. EUR.] (C - n/a - n/a - [n/a - n/a - Cutaneous]), [MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10010956087	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956089	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	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 - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	AVAMYS [FLUTICASON FUROATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]), OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]), [LORATADINE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]), [PHLEUM PRATENSE, PHLEUM PRATENSE (225), PHLEUM PRATENSE POLLEN EXTRACT, TIMOTHY GRASS POLLEN EXTRACT] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10010956101	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956103	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diarrhoea (n/a - Recovering/Resolving -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956106	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[FLUOCINOLONE ACETONIDE, FLUOCINOLONE ACETONIDE PH. EUR, NEOMYCIN SULFATE, POLYMYXIN B SULFATE, FLUOCINOLONE ACETONIDE, NEOMYCIN, POLYMYXIN B, FLUOCINOLONE ACETONIDE] (C - Eczema - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC-10010956131	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Nausea (n/a - Recovering/Resolving -), Pyrexia (2d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956156	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956223	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain lower (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	AERIUS [DESLORATADINE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]), AVAMYS [FLUTICASON FUROATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]), OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]), PROTOPIC [TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]),	ICSR

												[BUDESONIDE] (C - Asthma prophylaxis - n/a - [n/a - n/a - Respiratory (inhalation)]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)]), [VITAMIN D, CALCIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - Oral])	
EU-EC-10010956249	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956250	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dermatitis allergic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010956277	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Recovering/Resolved -), Headache (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010932580	13/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Rash (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010934576	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010938752	13/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010940393	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010940457	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10010940461	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cardiovascular disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10010940464	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010940467	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (1d - Recovered/Resolved -), Diarrhoea (0d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010940506	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Local reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010940521	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010940532	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010940534	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010940535	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010940560	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010913532	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[A/CHRISTCHURCH/16/2010 NIB-74XP (H1N1) (AN A/CALIFORNIA/7/2009-LIKE VIRUS), B/PHUKET/3073/2013-LIKE STRAIN, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013,	ICSR

										Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Lethargy (n/a - Recovered/Resolved - Other Medically Important Condition)		NIB-88), ANTIGENS OF THE INFLUENZA VIRUS B/BRISBANE/60/2008-LIKE VIRUS, B/PHUKET/3073/2013-LIKE STRAIN, A/VICTORIA/2570/2019 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/2570/2019, IVR-215), INFLUENZA VIRUS B/AUSTRIA/1359417/2021-LIKE STRAIN (B/AUSTRIA/1359417/2021, BVR-26), A/DARWIN/9/2021 (H3N2) - LIKE STRAIN (A/DARWIN/6/2021, IVR-227), INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (C - n/a - n/a - [1d - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10010921868	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eye irritation (n/a - Recovered/Resolved - Other Medically Important Condition), Eye swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010927964	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010912074	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Hyperventilation (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscle spasms (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Presyncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010893489	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Myopericarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010893528	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010896881	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymph node pain (n/a - Not Recovered/Not Resolved -), Product administered to patient of	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	

											inappropriate age (n/a - Unknown -), Product preparation issue (n/a - Unknown -)			
EU-EC-10010877107	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010880429	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pallor (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010884809	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010886153	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Contusion (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010886191	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010886309	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Face oedema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010862941	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010865212	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Monoplegia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved -), Product administered to patient of inappropriate age (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - n/a])	Not reported	ICSR	
EU-EC-10010868342	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Eczema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010871223	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Respiratory disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010850586	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fall (0d - Recovered/Resolved -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]), [B/PHUKET/3073/2013-LIKE STRAIN, A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, IVR-186)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010830018	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010831766	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Gynaecomastia (n/a - Unknown -), Overdose (n/a - Unknown -), Product preparation error (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	

										-), Product use issue (n/a - Unknown -), Wrong product administered (n/a - Unknown -)			
EU-EC-10010831909	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010834601	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Pruritus (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-10010818945	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dermatitis contact (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	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 (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])	ICSR
EU-EC-10010820053	01/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Product administered to patient of inappropriate age (n/a - Unknown -), Vaccination site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a])	Not reported	ICSR
EU-EC-10010795347	29/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Papule (n/a - Unknown -), Skin reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010785347	28/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (1d - Recovered/Resolved -), Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010772721	26/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Product administered to patient of inappropriate age (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010643145	15/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Skin discolouration (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-10010610715	10/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Child	Female	No	Product prescribing error (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

				Area						-)	n/a - [n/a - 1{DF} - Intramuscular]		
EU-EC-10010596208	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Malaise (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [PARACETAMOL] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010583876	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10010553382	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010558679	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Disabling), Fall (n/a - Not Recovered/Not Resolved - Disabling), Hypokinesia (n/a - Not Recovered/Not Resolved - Disabling), Joint range of motion decreased (n/a - Not Recovered/Not Resolved - Disabling), Off label use (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling), Paraesthesia (n/a - Not Recovered/Not Resolved - Disabling), Peroneal nerve palsy (n/a - Not Recovered/Not Resolved - Disabling), Product use issue (n/a - Not Recovered/Not Resolved -), Walking disability (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010509518	02/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Renal pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010502560	01/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Adverse event (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010477176	28/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Paraesthesia (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010455332	27/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Chest discomfort (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010419761	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Off label use (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010419762	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Off label use (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010419763	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Off label use (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010424761	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pain of skin (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -), Rash papular (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

										Urticaria (n/a - Recovering/Resolved -), Vaccination site pain (n/a - Recovering/Resolved -)			
EU-EC-10010424793	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pain of skin (n/a - Recovered/Resolved -), Pruritus (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Rash papular (n/a - Recovered/Resolved -), Urticaria (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010388997	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Crying (n/a - Recovering/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown -), Pain in extremity (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10010337858	15/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), 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-10010338998	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010316246	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthralgia (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010284263	11/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	Yes	Crying (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Eye pruritus (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition), Rash (1d - Recovering/Resolved - Other Medically Important Condition), Rash macular (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR

EU-EC-10010265940	08/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site reaction (7d - Recovered/Resolved -), Off label use (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010266180	08/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Medication error (1d - Recovered/Resolved -), Off label use (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular])	Not reported	ICSR
EU-EC-10010266181	08/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Medication error (1d - Recovered/Resolved -), Off label use (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular])	Not reported	ICSR
EU-EC-10010266182	08/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Medication error (1d - Recovered/Resolved -), Off label use (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular])	Not reported	ICSR
EU-EC-10010266183	08/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Medication error (1d - Recovered/Resolved -), Off label use (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular])	Not reported	ICSR
EU-EC-10010266184	08/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Medication error (1d - Recovered/Resolved -), Off label use (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular])	Not reported	ICSR
EU-EC-10010266187	08/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Medication error (1d - Recovered/Resolved -), Off label use (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular])	Not reported	ICSR
EU-EC-10010215704	05/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Arthralgia (n/a - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperpyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010225377	05/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Off label use (n/a - Unknown -), Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product use issue (n/a - Unknown -), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[KETOTIFEN, KETOTIFEN HYDROGEN FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010212028	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Female	No	Off label use (1d - Recovered/Resolved -), Wrong schedule (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - 1{DF}] - Intramuscular])	Not reported	ICSR
EU-EC-10010212030	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Male	No	Off label use (22d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 1{DF}] - Intramuscular])	Not reported	ICSR

										Wrong schedule (22d - Recovered/Resolved -)			
EU-EC-10010212031	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Male	No	Off label use (29d - Recovered/Resolved -), Wrong schedule (29d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [29d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010196643	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Male	No	Off label use (23d - Recovered/Resolved -), Wrong schedule (23d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [23d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010197221	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Malaise (0d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010171262	29/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Idiopathic intracranial hypertension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010172171	29/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010153425	28/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010158435	28/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Skin discolouration (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CELLCEPT 1 G/5 ML POWDER FOR ORAL SUSPENSION [MYCOPHENOLATE MOFETIL] (C - Autoimmune disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010141742	27/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010116633	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Erythema (2559d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010129071	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Epilepsy (1.5d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Dystonia - n/a - [n/a - n/a - n/a]), [MELATONIN] (C - Insomnia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010129474	24/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010083826	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Asthmatic crisis (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010057181	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Chills (0d - Recovered/Resolved -), Cough (5d - Recovering/Resolving -), Fatigue (0d - Recovered/Resolved -), Injection site movement impairment (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Nausea (0d - Recovered/Resolved -), Pain in extremity (4d - Recovered/Resolved -)			
EU-EC-10010028665	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (2d - 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-10010030619	17/09/2021	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-10010030626	17/09/2021	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-10010030635	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010030652	17/09/2021	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-10010030658	17/09/2021	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-10010030666	17/09/2021	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-10010030669	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Not Specified	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010030673	17/09/2021	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-10010037759	17/09/2021	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-10010041358	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Exposure via breast milk (n/a - Recovered/Resolved -), Pyrexia (15h - Recovered/Resolved -), Vomiting (15h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009982482	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Product administered to patient of inappropriate age (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009982483	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Product administered to patient of inappropriate age (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009982484	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Product administered to patient of inappropriate age (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009982487	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Product administered to patient of inappropriate age (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009969547	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009928378	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009860400	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cyanosis (24h - Recovered/Resolved -), Diarrhoea (24h - Recovered/Resolved -), Headache (24h - Recovered/Resolved -), Malaise (24h - Recovered/Resolved -), Product administered to patient of inappropriate age	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR


										(n/a - Recovered/Resolved -), Vomiting (24h - Recovered/Resolved -)			
EU-EC-10009819434	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Cardiac disorder (n/a - Not Recovered/Not Resolved -), Cardiac flutter (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Pain (n/a - Unknown -), Palpitations (n/a - Not Recovered/Not Resolved -), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009805350	26/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Aphthous ulcer (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Stomatitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009807865	26/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (1d - Recovered/Resolved -), Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10009792622	25/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (2d - Recovered/Resolved -), Oropharyngeal pain (2d - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Throat irritation (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009772861	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (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-10009760799	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Off label use (n/a - Unknown -), Pain in extremity (0d - Recovered/Resolved -), Product use issue (n/a - Unknown -), Underdose (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .1mL - n/a])	Not reported	ICSR
EU-EC-10009762088	23/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

			Professional	Area						Recovered/Not Resolved -)	Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10009764615	23/08/2021	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-10009766275	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	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-10009766339	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved -), Injection site pain (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009723457	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009726044	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10009698038	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	No adverse event (n/a - Unknown -), Off label use (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009603222	05/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[DIAZEPAM] (C - Anxiety - n/a - [n/a - n/a - Transmammary]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - Depression - n/a - [n/a - n/a - Transmammary])	ICSR
EU-EC-10009575105	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	No adverse event (n/a - Unknown -), Off label use (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009516752	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Female	No	Asthenia (4d - Recovering/Resolving -), Dizziness (4d - Recovering/Resolving -), Fatigue (4d - Recovering/Resolving -), Somnolence (4d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009517361	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Male	No	Pyrexia (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009520036	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Dizziness (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Limb discomfort (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (5d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009410132	19/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Ageusia (n/a - Not Recovered/Not Resolved -), Anosmia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved -), Chills (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Hyperhidrosis (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)			
EU-EC-10009302556	08/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10009310268	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	No adverse event (n/a - Unknown -), Off label use (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009255839	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myasthenia gravis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myasthenia gravis crisis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009226936	01/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Fatigue (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009122188	23/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009108853	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008985375	11/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Paraesthesia (11d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008824471	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008703925	19/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (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

											Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product use issue (n/a - Unknown -)			
EU-EC-10008038260	23/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Vomiting (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-10007850766	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR	
EU-EC-10007852067	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Decreased appetite (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Intestinal obstruction (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Neck pain (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Retching (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10007852666	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Chills (3d - Recovering/Resolving -), Diarrhoea (3d - Recovering/Resolving -), Dizziness (3d - Recovering/Resolving -), Fatigue (3d - Recovering/Resolving -), Pain in extremity (3d - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Pyrexia (3d - Recovering/Resolving -), Vomiting (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR	
EU-EC-10007694585	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Unknown - Other Medically Important Condition), Mastitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	

										Other Medically Important Condition), Swelling (n/a - Recovering/Resolved - Other Medically Important Condition)			
EU-EC-10007652467	18/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (3d - Recovered/Resolved - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007618207	15/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Eye irritation (n/a - Not Recovered/Not Resolved - Disabling), Neurogenic bladder (n/a - Not Recovered/Not Resolved - Disabling)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007561097	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved -), Polymerase chain reaction positive (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007532787	05/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Confusional state (n/a - Not Recovered/Not Resolved - Disabling), Decreased appetite (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Hypokalaemic syndrome (n/a - Not Recovered/Not Resolved - Disabling), Mobility decreased (n/a - Not Recovered/Not Resolved - Disabling)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	APIXABAN [APIXABAN] (C - Heart rate irregular - n/a - [n/a - n/a - n/a]), [BENDROFLUMETHIAZIDE] (C - Blood pressure measurement - n/a - [n/a - n/a - n/a]), [DONEPEZIL] (C - Dementia - n/a - [n/a - n/a - n/a]), [ESTRADIOL] (C - Urea urine increased - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Heart rate - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007329608	11/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Infant	Female	No	Respiratory distress (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007311877	07/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Psoriasis (n/a - Not Recovered/Not Resolved -), Rash pruritic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

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