

Line Listing Report

Time run: 30/11/2022 03:07:41

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-10014103779	25/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Rash papular (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10014104013	25/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Ear haemorrhage (n/a - Fatal - Results in Death), Epistaxis (n/a - Fatal - Results in Death), Eye haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Mouth haemorrhage (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10014104935	25/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Asthenia (n/a - Unknown -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Gastrointestinal disorder (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous use])	Not reported	ICSR
EU-EC-10014097157	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Abdominal discomfort (n/a - Not Recovered/Not Resolved -), Constipation (n/a - Not Recovered/Not Resolved -), Crying (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10014088668	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Male	Yes	Bradycardia neonatal (45d - Recovering/Resolving - Life Threatening), Foetal growth restriction (n/a - Recovering/Resolving - Life Threatening), Maternal exposure during pregnancy (n/a - Recovered/Resolved -), Neonatal respiratory distress syndrome (n/a - Recovered/Resolved - Life Threatening), Premature baby (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10014091386	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hydranencephaly (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Necrotising enterocolitis neonatal (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Neonatal seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Perinatal stroke (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental]), [ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, ALGELDRADE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, ALUMINIUM, PERTUSSIS	Not reported	ICSR

											TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALUMINIUM PHOSPHATE, DIPHThERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHThERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHThERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, DIPHThERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, DIPHThERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS (INACTIVATED) ADSORBED] (S - Immunisation - Not applicable - [1d - 1{DF} - Transplacental])		
EU-EC-10014065254	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly), Pulmonary malformation (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10014067321	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Arthralgia (1wk - Recovering/Resolving -), Asthenia (1wk - Recovering/Resolving -), Body temperature increased (1wk - Recovering/Resolving -), Hyperhidrosis (1wk - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10014048984	18/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Febrile convulsion (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN (A/BRISBANE/59/2007 REASS, IVR-148), A/BRISBANE/10/2007 (H3N2)-LIKE STRAIN (A/URUGUAY/716/2007 REASS, NYMC X-175C), B/FLORIDA/4/2006-LIKE STRAIN (B/BRISBANE/3/2007), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/PHUKET/3073/2013-LIKE STRAIN, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009	ICSR

												REASS, NYMC X-187), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, A/TEXAS/50/2012 (H3N2) - DERIVED STRAIN USED (NYMC X-223A), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1) DERIVED STRAIN USED NYMC X-181, HAEMAGGLUTININ, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS, NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)-DERIVED STRAIN USED NYMC X-181, B/BRISBANE/60/2008, INFLUENZA VACCINE] (C - n/a - n/a - [1d - n/a - n/a])	
EU-EC-10014021274	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Epistaxis (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10014006851	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Congenital anomaly (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Deafness (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Foetal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transplacental]), [OMEPRAZOLE] (S - Product used for unknown indication - Not applicable - [n/a - 10mg - Transplacental])	Not reported	ICSR
EU-EC-10013997237	14/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Erythema (n/a - Recovering/Resolving -), Haematoma (n/a - Recovering/Resolving -), Joint swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013971287	10/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Blindness congenital (n/a - Unknown - Other Medically Important Condition), Congenital optic nerve anomaly (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10013947236	08/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (2d - Recovered/Resolved -)	COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10013936755	07/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3ug - n/a])	Not reported	ICSR
EU-EC-10013937458	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (3d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Poor feeding infant (3d - Recovered/Resolved -), Weight gain poor (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10013913739	03/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Restlessness (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013915670	03/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	CIMZIA 200 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE [CERTOLIZUMAB PEGOL] (C - Rheumatic disorder - n/a - [n/a - 1{DF} - n/a]), [SULFASALAZINE] (C - Rheumatic disorder - n/a - [n/a - 2{DF} - n/a]), [THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a -)	ICSR
EU-EC-10013889128	01/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013890678	01/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	No	Epidermolysis bullosa (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10013884304	31/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown -), Fatigue (n/a - Unknown -), Rhinoorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013840895	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	COVID-19 immunisation (n/a - Unknown -), Decreased appetite (n/a - Recovering/Resolving -), Discomfort (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -), Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[DOCONEXENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL ESTERS 90, OMEGA-3-ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C - n/a - n/a -), [VITAMIN D] (C - n/a - n/a -)	ICSR
EU-EC-10013842089	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Neonatal disorder (n/a - Unknown -), Restlessness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013843250	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abdominal pain (3d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Restlessness (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013833372	25/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Cellulitis (n/a - Recovered/Resolved - Other Medically Important Condition), Decreased appetite (22d - Recovered/Resolved - Other Medically Important Condition), Gingival disorder (n/a - Recovered/Resolved - Other Medically Important Condition), Gingival ulceration (23970min - Recovered/Resolved - Other Medically Important Condition), Inflammation (n/a - Recovered/Resolved - Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular use])	Not reported	ICSR

											Pyrexia (102h - Recovered/Resolved - Other Medically Important Condition), Rash (7d - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10013833440	25/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [DESOGESTREL] (C - n/a - n/a - [n/a - 75ug - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - 40mg - n/a])	ICSR
EU-EC-10013833441	25/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (n/a - Recovering/Resolving -), Exposure via breast milk (n/a - Unknown -), Infant irritability (n/a - Recovering/Resolving -), Poor quality sleep (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[DES Loratadine] (C - Hypersensitivity, Rhinitis allergic - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10013823427	24/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Congenital hydronephrosis (n/a - Unknown - Congenital Anomaly), Congenital ureteropelvic junction obstruction (n/a - Unknown - Congenital Anomaly), Foetal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]), [DOXYLAMINE HYDROGEN SUCCINATE, PYRIDOXINE HYDROCHLORIDE] (S - Morning sickness - n/a - [n/a - n/a - Transplacental])	TOZINAMERAN [TOZINAMERAN] (C - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - Chlamydial infection - n/a - [n/a - n/a - Transplacental]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - Transplacental]), [DIMENHYDRINATE] (C - Nausea - n/a - [n/a - n/a - Transplacental]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - Dyspepsia - n/a - [n/a - n/a - Transplacental])	ICSR
EU-EC-10013823987	24/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Cough (n/a - Unknown -), Decreased activity (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Hyperpyrexia (5d - Recovered/Resolved - Other Medically Important Condition), Rhinoorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10013825771	24/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Enterovirus infection (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperpyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Roseola (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10013826034	24/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Hydrocephalus (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10013800256	21/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Depressed mood (n/a - Not Recovered/Not Resolved -), Exposure via breast	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

											milk (n/a - Unknown -), Restlessness (n/a - Not Recovered/Not Resolved -)			
EU-EC-10013801798	21/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abnormal faeces (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Unknown -), Infantile vomiting (n/a - Recovering/Resolving -), Mucous stools (n/a - Unknown -), Retching (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10013801813	21/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal pain (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Unknown -), Hypersomnia (n/a - Recovering/Resolving -), Infrequent bowel movements (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10013805570	21/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	No	Acute respiratory distress syndrome (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Hepatic infarction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Hypertrophic cardiomyopathy (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Splenic infarction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intrauterine use])	Not reported	ICSR	
EU-EC-10013808359	21/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Apgar score low (n/a - Unknown - Caused/Prolonged Hospitalisation), Foetal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Neonatal respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation), Premature baby (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental])	[ANHYDROUS CHOLESTYRAMINE, COLESTYRAMINE, COLESTYRAMINE ANHYDROUS] (C - Diarrhoea - n/a - [n/a - n/a - Transplacental])	ICSR	
EU-EC-10013768782	18/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Asthenia (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Listless (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Transmammary])	Not reported	ICSR	

EU-EC-10013771237	18/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Pruritus (14d - Recovered/Resolved -), Rash maculo-papular (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10013775124	18/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Ankyloglossia congenital (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Congenital musculoskeletal disorder of spine (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Congenital skin dimples (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Developmental delay (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysmorphism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Eye inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mandibulofacial dysostosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Neonatal deafness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Oculoauriculovertebral dysplasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Ophthalmia neonatorum (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal fusion anomaly (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Selective eating disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Transplacental]), [DOXYLAMINE HYDROGEN SUCCINATE, PYRIDOXINE HYDROCHLORIDE] (C - Nausea - n/a - [n/a - n/a - Transplacental]), [METOCLOPRAMIDE, METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE ANHYDROUS, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (C - Nausea - n/a - [n/a - 3{DF} - Transplacental]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - Hiatus hernia, Oesophagitis - n/a - [n/a - n/a - Transplacental]), [ZINGIBER OFFICINALE] (C - Nausea - n/a - [n/a - {DF} - Transplacental])	ICSR

EU-EC-10013765234	17/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown -), Underweight (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013743586	14/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10013730542	13/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Abdominal pain upper (n/a - Recovering/Resolving -), Crying (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -), Insomnia (n/a - Unknown -), Pain (n/a - Unknown -), Restlessness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013724629	12/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Cellulitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (0d - Unknown -), Product administration error (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED, ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS ANTIGEN (INACTIVATED), HEPATITIS A VIRUS ANTIGEN, STRAIN HM175, INACTIVATED, ADSORBED ON ALUMINIUM HYDROXIDE, ALUMINIUM HYDROXIDE, HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), ALUMINIUM HYDROXIDE] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [MEASLES, MUMPS AND RUBELLA VACCINE (LIVE)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [VARICELLA VIRUS OKA/MERCK STRAIN (LIVE, ATTENUATED), VARICELLA VIRUS OKA/MERCK STRAIN, (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use])	[COLECALCIFEROL] (C - n/a - Dose not changed - [n/a - n/a - n/a])	ICSR
EU-EC-10013725949	12/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Overdose (n/a - Unknown -), Product preparation error (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - n/a])	Not reported	ICSR
EU-EC-10013701219	10/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death), Exposure via breast milk (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013701751	10/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Foetal exposure during pregnancy (n/a - Unknown -), Foetal hypokinesia (2d - Recovered/Resolved - Other Medically Important Condition), Foetal hypokinesia (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10013692453	07/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Diarrhoea (6wk - Recovered/Resolved - Other Medically Important Condition), Haematochezia (6wk - Recovered/Resolved - Other Medically Important Condition), Neutropenia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10013666978	05/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site reaction (n/a - Recovering/Resolving -), Scar pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10013663037	04/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Cataract congenital (n/a - Not Recovered/Not Resolved - Disabling, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Disabling, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10013636400	30/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Foetal growth restriction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10013623159	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Exposure via breast milk (n/a - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013625277	29/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Appendicitis (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-10013625306	29/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Appendicitis (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-10013613662	28/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Cardiac failure (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10013608236	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Febrile convulsion (0d - Recovered/Resolved - Other Medically Important Condition), Product administration error (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED, ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS ANTIGEN (INACTIVATED), HEPATITIS A VIRUS ANTIGEN, STRAIN HM175, INACTIVATED, ADSORBED ON ALUMINIUM HYDROXIDE, ALUMINIUM	Not reported	ICSR

											HYDROXIDE, HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), ALGELDRADE, HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), ALUMINIUM HYDROXIDE] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use])		
EU-EC-10013597411	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013579083	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Overdose (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -), Vaccination site pain (6h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 5ug - Intramuscular use])	Not reported	ICSR
EU-EC-10013573162	22/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013574248	22/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Brief resolved unexplained event (n/a - Unknown - Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal pain (n/a - Unknown -), Infantile apnoea (n/a - Unknown - Other Medically Important Condition), Laryngospasm (n/a - Unknown - Caused/Prolonged Hospitalisation), Pharyngeal inflammation (n/a - Unknown -), Screaming (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013542287	19/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	Haemangioma congenital (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10013542475	19/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Anal atresia (n/a - Fatal - Results in Death, Congenital Anomaly), Atrial septal defect (n/a - Fatal - Results in Death, Congenital Anomaly), Foetal death (n/a - Fatal - Results in Death), Generalised oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10013520245	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Hypotonia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	ICSR

										Somnolence (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)			
EU-EC-10013503082	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Recovering/Resolving -), Exposure via breast milk (n/a - Unknown -), Frequent bowel movements (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[DESOGESTREL] (C - Contraception - n/a - [n/a - 75ug - n/a])	ICSR
EU-EC-10013504219	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Atrial septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [197d - 3{DF} - Intraamniotic use])	Not reported	ICSR
EU-EC-10013485105	12/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Infantile back arching (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sleep terror (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	LEVETIRACETAM [LEVETIRACETAM] (C - Tuberos sclerosis complex - n/a - [1y - 400mg - Oral use])	ICSR
EU-EC-10013458180	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013436371	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013414155	02/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Diarrhoea (39d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10013405304	01/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Haematochezia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lactose intolerance (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), ROTARIX [HUMAN ROTAVIRUS RIX4414 STRAIN (LIVE ATTENUATED), HUMAN ROTAVIRUS RIX4414 STRAIN (LIVE ATTENUATED) PRODUCED ON VERO CELLS] (S - n/a - 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] (S - n/a - Not applicable - [n/a - n/a - n/a]), [DIPHTheria TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, HEPATITIS B SURFACE ANTIGEN (RDNA), PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN)] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013381539	30/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm)	Male	Yes	Atrial septal defect (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVOTHYROXINE SODIUM] (C - Autoimmune thyroiditis - n/a - [n/a - 125ug - Transplacental])	ICSR

										and Term newborns)	Resolved - Congenital Anomaly), Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly), Hypospadias (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Mitral valve incompetence (n/a - Recovered/Resolved - Congenital Anomaly), Neonatal respiratory distress syndrome (n/a - Recovered/Resolved - Congenital Anomaly), Newborn persistent pulmonary hypertension (n/a - Recovered/Resolved - Congenital Anomaly), Patent ductus arteriosus (n/a - Recovered/Resolved - Congenital Anomaly), Premature baby (n/a - Recovered/Resolved - Congenital Anomaly), Small for dates baby (n/a - Recovered/Resolved - Congenital Anomaly)	n/a - [n/a - n/a - Transplacental])		
EU-EC-10013349847	26/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Foetal exposure during pregnancy (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Foetal growth restriction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Labial tie (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Low birth weight baby (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Microcephaly (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use]), [ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, ALUMINIUM, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN,	Not reported	ICSR	

											DIPHtheria TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS (INACTIVATED) ADSORBED] (S - Immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])		
EU-EC-10013331390	25/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Angioedema (92d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013322774	24/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Product administered at inappropriate site (n/a - Unknown -), Pyrexia (9d - 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-10013309252	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	No	Asthenia (259d - Not Recovered/Not Resolved -), Menstrual disorder (259d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous use])	Not reported	ICSR
EU-EC-10013310417	23/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Poor quality product administered (n/a - Unknown -), Product administration error (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	ICSR
EU-EC-10013298659	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Feeling cold (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013299054	22/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown -), Infantile vomiting (n/a - Unknown -), Multisystem inflammatory syndrome in children (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -), Rash (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013287682	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Bradycardia foetal (1d - Recovered/Resolved - Life Threatening), Haemorrhage intracranial (161d - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10013289403	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Depressed mood (1d - Recovered/Resolved -), Exposure via breast milk (n/a - Recovered/Resolved -), Irritability (1d - Recovered/Resolved -), Restlessness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013274796	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013276738	18/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013278264	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Amniotic cavity infection (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental])	Not reported	ICSR

										Important Condition), Foetal growth restriction (n/a - Recovering/Resolving - Other Medically Important Condition), Foetal vascular malperfusion (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10013250709	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Flatulence (n/a - Unknown -), Salivary hypersecretion (n/a - Unknown -), Sleep disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013256820	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (10d - Recovered/Resolved -), Headache (10d - Recovered/Resolved -), Hypotonia (10d - Recovered/Resolved -), Pyrexia (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013229743	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Eye movement disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myoclonus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10013211690	10/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Product administered at inappropriate site (n/a - Unknown -), Wheezing (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013201423	09/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Atrial septal defect (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10013168835	04/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Cough (n/a - Recovering/Resolving -), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Illness (n/a - Recovering/Resolving -), Pneumonia (n/a - Recovering/Resolving - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Recovering/Resolving -), Suspected COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Wheezing (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10013172435	04/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months	Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

EU-EC-10013154761	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	- 2 Years 0-1 Month	Not Specified	Not Specified	Yes	- Other Medically Important Condition) Exposure via breast milk (n/a - Unknown -), Restlessness (n/a - Unknown -)	Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013154856	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown -), Pyrexia (n/a - Unknown -), Restlessness (n/a - Unknown -), Tearfulness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013159004	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Rash (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013135803	01/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Abdominal pain (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -), Infantile vomiting (n/a - Recovered/Resolved -), Restlessness (n/a - Unknown -), Screaming (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[LECITHIN] (C - n/a - n/a -)	ICSR
EU-EC-10013120599	29/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Immunisation reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10013123571	29/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	COVID-19 (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -), Infection (n/a - Unknown -), Otitis media (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013102110	27/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Foetal exposure during pregnancy (n/a - Unknown -), Jaundice (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), [PERTUSSIS VACCINE] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10013091480	26/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Eye movement disorder (17d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product use issue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (17d - Recovered/Resolved - 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-10013080461	25/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Enanthema (n/a - Recovering/Resolving - Other Medically Important Condition), Foetal exposure during pregnancy (0d - Unknown - Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental])	Not reported	ICSR

										- Other Medically Important Condition), Petechiae (n/a - Recovering/Resolved - Other Medically Important Condition), Thrombocytopenia (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10013084727	25/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Dyskinesia (n/a - Recovered/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013072606	22/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered at inappropriate site (n/a - Unknown -), Pyrexia (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 - [1d - .2mL - n/a])	Not reported	ICSR
EU-EC-10013053463	21/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Not Specified	Yes	Adactyly (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly), Infantile haemangioma (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly), Maternal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10013007911	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Haematochezia (15d - Not Recovered/Not Resolved - Other Medically Important Condition), Mucous stools (15d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10013013722	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Hypotonia (13d - Recovering/Resolved -), Paraesthesia (13d - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous use])	Not reported	ICSR
EU-EC-10013013736	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Mobility decreased (1d - Recovering/Resolved -), Vaccination site joint pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	ICSR
EU-EC-10012986275	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Foetal exposure during pregnancy (n/a - Unknown -), Polydactyly (n/a - Unknown - Congenital Anomaly), Syndactyly (n/a - Unknown - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]), [BUDESONIDE, FORMOTEROL, BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, BUDESONIDE, FORMOTEROL FUMARATE HYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (S - Asthma - n/a - [n/a - n/a - Transplacental])	COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - n/a - [n/a - Transplacental]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (C - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]), [MISOPROSTOL] (C - Labour induction - n/a - [n/a - n/a - Transplacental])	ICSR
EU-EC-10012976419	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Limb reduction defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10012980010	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10012957476	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Ear, nose and throat infection (n/a - Unknown -), Off label use (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

											Product use issue (n/a - Unknown -)		
EU-EC-10012953750	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Blister (1d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Rash macular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012941942	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Myoclonus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Transplacental]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (S - Abdominal pain - Drug withdrawn - [n/a - n/a - Transmammary])	[IBUPROFEN] (C - Abdominal pain - Drug withdrawn - [n/a - n/a - Transmammary]), [PARACETAMOL] (C - Abdominal pain - Drug withdrawn - [n/a - n/a - Transmammary])	ICSR
EU-EC-10012929119	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Basedow's disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012933296	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Infantile spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Partial seizures (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10012909441	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Haematochezia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012909446	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Haematemesis (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012909822	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Maternal exposure during breast feeding (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012896742	01/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Exposure via breast milk (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012905097	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Rectal haemorrhage (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012905868	01/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Syndactyly (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [45d - 2{DF} - Intramuscular use])	Not reported	ICSR
EU-EC-10012906942	01/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Poor feeding infant (6d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012882595	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal discomfort (299d - Recovered/Resolved With Sequelae -), Bone pain (299d - Recovered/Resolved With Sequelae -), Diarrhoea (299d - Recovered/Resolved With Sequelae -), Dyspnoea (299d - Recovered/Resolved With Sequelae -), Feeling hot (299d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012883790	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes	Crying (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR

											Insomnia (n/a - Not Recovered/Not Resolved -)		
EU-EC-10012836291	24/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Unknown -), Mucous stools (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012827061	23/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	No	Exposure via breast milk (n/a - Unknown -), Eye pruritus (n/a - Not Recovered/Not Resolved -), Eye swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10012815735	22/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown -), Restlessness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012815751	22/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Lymphadenopathy (n/a - Unknown -), Tachycardia (206d - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012789410	20/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes	Maternal exposure during breast feeding (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012789700	20/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown -), Seizure (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-10012794575	20/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012766917	17/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Dermatitis atopic (n/a - Recovering/Resolving -), Exposure via breast milk (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012726288	15/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Unknown -), Maternal exposure during breast feeding (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Other])	Not reported	ICSR
EU-EC-10012729516	15/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Cardiomyopathy neonatal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])	ICSR
EU-EC-10012731442	15/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Developmental delay (n/a - Not Recovered/Not Resolved - Disabling), Hypotonia (n/a - Not Recovered/Not Resolved - Disabling), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10012712451	14/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm)	Female	Yes	Atrial septal defect (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	[(S)-LACTIC ACID, SODIUM LACTATE, (S)-LACTIC ACID,	ICSR

				Area				and Term newborns)					
													<p>Congenital Anomaly), - n/a - Transplacental])</p> <p>Foetal arrhythmia (n/a - Recovered/Resolved - Congenital Anomaly),</p> <p>Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly),</p> <p>Patent ductus arteriosus (n/a - Unknown - Congenital Anomaly)</p> <p>SODIUM S-LACTATE SOLUTION, LACTIC ACID, SODIUM LACTATE, LACTIC ACID, SODIUM S-LACTATE SOLUTION] (C - Product used for unknown indication - n/a - [n/a - n/a - Transplacental]),</p> <p>[ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FIMBRIAE TYPE 2 AND 3 ADSORBED ON ALUMINIUM PHOSPHATE, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, POLIOVIRUS TYPE 1 (INACTIVATED), POLIOVIRUS TYPE 2 (INACTIVATED), POLIOVIRUS TYPE 3 (INACTIVATED), PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 1 PRODUCED IN VERO CELLS, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 2 PRODUCED IN VERO CELLS, POLIOMYELITIS VIRUS (INACTIVATED) TYPE 3 PRODUCED IN VERO CELLS, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, PERTUSSIS FIMBRIAL AGGLUTINOGENS (FIM) 2 AND 3, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS, POLIOVIRUS TYPE 1, POLIOVIRUS TYPE 3] (C - Immunisation - n/a - [n/a - n/a - Transplacental]),</p> <p>[DEQUALINIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Transplacental]),</p> <p>[FOLIC ACID] (C - Prophylaxis of neural tube defect - n/a - [n/a - n/a - Transplacental])</p>
EU-EC-10012715062	14/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012716321	14/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012716322	14/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012704322	13/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Off label use (n/a - Unknown -),			

										Product use issue (n/a - Unknown -), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10012705367	13/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Maternal exposure during pregnancy (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), VACTERL syndrome (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[PROGESTERONE, PROGESTERONE, MICRONISED] (C - Prophyllaxis - n/a - [47d - 200mg - n/a])	ICSR
EU-EC-10012689161	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012693657	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	White blood cell count decreased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10012682435	09/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ANHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [BUPRENORPHINE, NALOXONE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10012667670	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012667684	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (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-10012667686	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Macular degeneration (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10012667687	08/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Herpes zoster (n/a - Recovered/Resolved -), Injection site reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [OLMESARTAN MEDOXOMIL] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10012667823	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Feeling of body temperature change (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Hyperhidrosis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Not Recovered/Not Resolved - Disabling), Myalgia (n/a - Not Recovered/Not Resolved - Disabling), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Sleep disorder (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC-10012667846	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Infertility female (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Injection site reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012669634	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Arthralgia (n/a - Not Recovered/Not Resolved -), Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Tremor (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-10012671748	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Dyspnoea exertional (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10012656636	07/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Loss of consciousness (4d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	ICSR
EU-EC-10012660840	07/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Vomiting projectile (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012647040	06/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Double outlet right ventricle (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly), Exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly), Fallot's tetralogy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	06/06/2022	Spontaneous	Healthcare	European	Not	0-1	Not	Not	No	Arthralgia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10012647207			Professional	Economic Area	available	Month	Specified	Specified		Unknown -), Asthenia (n/a - Unknown -), Chills (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Myalgia (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pyrexia (24h - Recovered/Resolved -), Vaccination site pain (n/a - Unknown -)	(S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC-10012643151	04/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012620339	02/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10012624822	02/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Dry skin (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exfoliative rash (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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10012600218	31/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (n/a - Recovered/Resolved -), Crying (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Restlessness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012592963	30/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Not Recovered/Not Resolved -), Poor feeding infant (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012571531	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Pyrexia (46d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012574541	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Fatigue (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012574544	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Pyrexia (1d - Recovered/Resolved -), Stomatitis (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012575247	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

										Eye infection (n/a - Recovered/Resolved -)			
EU-EC-10012576833	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012562832	26/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), C-reactive protein increased (n/a - Not Recovered/Not Resolved -), Lymphopenia (n/a - Not Recovered/Not Resolved -), Neutropenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Other])	Not reported	ICSR
EU-EC-10012551265	25/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (1d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Teething (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012551293	25/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Poor feeding infant (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012556144	25/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Decreased appetite (5d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Rash (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Oral])	Not reported	ICSR
EU-EC-10012532626	23/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012534952	23/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Diarrhoea (1d - Recovered/Resolved -), Exposure via breast milk (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012492606	18/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012484725	17/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Death neonatal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10012484730	17/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Death neonatal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC-10012485952	17/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Cough (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

), Infant irritability (n/a - Unknown -), Infection (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -)			
EU-EC-10012472163	16/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Exposure via breast milk (40h - Recovered/Resolved -), Pyrexia (2d - Not Recovered/Not Resolved -), Pyrexia (40h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Other])	Not reported	ICSR	
EU-EC-10012473725	16/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10012477353	16/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Dizziness (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10012459163	13/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR	
EU-EC-10012433972	11/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Anaphylactic shock (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10012437055	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Gastroesophageal reflux disease (n/a - Recovered/Resolved -), Hypokinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR	
EU-EC-10012424208	10/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Glassy eyes (n/a - Recovered/Resolved -), Maternal exposure during breast feeding (n/a - Unknown -), Muscle spasms (n/a - Recovered/Resolved -), Screaming (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10012424448	10/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Abdominal pain (3d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -), Vomiting (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR	
EU-EC-10012412074	09/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NAPROXEN, NAPROXEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	

Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Lethargy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Night sweats (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),
Off label use (n/a -

										Unknown -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Pruritus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vaccination site hypoaesthesia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC-10012413216	09/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arrhythmia (17d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (17d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Heart rate increased (17d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012405009	06/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Dry skin (12d - Recovered/Resolved -), Eczema (12d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Skin exfoliation (12d - Recovered/Resolved -), Swelling (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012389432	05/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Nipple exudate bloody (4d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10012364431	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Erythema (1d - Recovered/Resolved -), Papule (1d - Recovered/Resolved -), Product administered to patient of inappropriate age	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										(n/a - Unknown -), Pruritus (1d - Recovered/Resolved -)			
EU-EC-10012366853	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012367159	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Epilepsy (26d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Maternal exposure during breast feeding (26d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - .3mL - Oral])	Not reported	ICSR
EU-EC-10012368673	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Crying (8h - Recovered/Resolved -), Maternal exposure during breast feeding (n/a - Unknown -), Pyrexia (8h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012356835	02/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Fever neonatal (2d - Recovered/Resolved - Other Medically Important Condition), Influenza like illness (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012350389	30/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Arthralgia (n/a - Unknown -), Chills (n/a - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012350395	30/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012346114	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (7d - Recovering/Resolving -), Rash maculo-papular (7d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012346605	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Eczema (74d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (74d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012324593	28/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Irritability (n/a - Recovering/Resolving -), Listless (n/a - Recovering/Resolving -), Maternal exposure during breast feeding (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012326056	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal pain (2d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Flatulence (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

EU-EC-10012321084	27/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012302309	26/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012308766	26/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	Vaccination site lymphadenopathy (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (C - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	ICSR
EU-EC-10012291882	25/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	Yes	Exposure via breast milk (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Somnolence (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	[LEVOTHYROXINE] (C - Hypothyroidism - n/a - [n/a - n/a - Transmammary])	ICSR
EU-EC-10012297028	25/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Weight bearing difficulty (28d - Unknown - Other Medically Important Condition)	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-10012277531	22/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012264174	21/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Tachycardia (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-10012266109	21/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Foetus	Not Specified	Yes	Exomphalos (n/a - Unknown - Congenital Anomaly), Tricuspid valve incompetence (n/a - Unknown - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10012269208	21/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain lower (n/a - Not Recovered/Not Resolved -), Asthenia (n/a - Not Recovered/Not Resolved -), Back pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypotonia (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012257528	20/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Lip swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Urticaria (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-10012260185	20/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Headache (n/a - Recovering/Resolving -), Pain in jaw (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012201990	13/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Bronchitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Cardiac discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved -)			
EU-EC-10012185154	12/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infantile vomiting (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012188041	12/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Abdominal distension (n/a - Recovering/Resolving -), Abdominal pain (n/a - Recovering/Resolving -), Regurgitation (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012160873	08/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Crying (n/a - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Frequent bowel movements (n/a - Recovering/Resolving - Other Medically Important Condition), Irritability (n/a - Recovering/Resolving - Other Medically Important Condition), Poor feeding infant (n/a - Recovered/Resolved - Other Medically Important Condition), Somnolence (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012147946	07/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10012128125	06/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown -), Urinary tract infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012130423	06/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Resolved -), Induration (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Skin disorder (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)			
EU-EC-10012123456	05/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10012124994	05/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Crying (n/a - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infant irritability (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012097525	04/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Febrile convulsion (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10012106204	04/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012082143	01/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Exomphalos (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown -), Small for dates baby (n/a - Recovered/Resolved - Congenital Anomaly, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]), [PROGESTERONE, MICRONISED] (S - Prophylaxis of abortion - n/a - [n/a - 400mg - Transplacental])	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Immunisation - n/a - [n/a - n/a - Transplacental]), [ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, ALUMINIUM, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALGELDRATE, ALUMINIUM PHOSPHATE,	ICSR

												DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS (INACTIVATED) ADSORBED] (C - Immunisation - n/a - [n/a - n/a - Transplacental]), [CYANOCOBALAMIN, VITAMIN B12] (C - Self-medication - n/a - [n/a - n/a - Transplacental]), [FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - Transplacental]), [FOLIC ACID] (C - Prophylaxis of neural tube defect - n/a - [n/a - 5mg - Transplacental]), [LEVOTHYROXINE SODIUM] (C - Autoimmune thyroiditis - n/a - [n/a - n/a - Transplacental]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Transplacental]), [VITAMIN D] (C - Self-medication - n/a - [n/a - 1000[iU] - Transplacental])	
EU-EC-10012091136	01/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	No	Cerebral infarction (1d - Recovering/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Foetal exposure during pregnancy (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10012070413	31/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10012071906	31/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	No	Exposure via breast milk (n/a - Unknown -), Poor feeding infant (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Unknown])	Not reported	ICSR
EU-EC-10012078554	31/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Not Specified	Yes	Congenital musculoskeletal disorder of limbs (n/a - Fatal - Results in Death, Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - n/a])	Not reported	ICSR

										Anomaly, Other Medically Important Condition)			
EU-EC-10012062929	30/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exanthema subitum (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012045044	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012045181	29/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Confusional state (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Dizziness (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Facial paralysis (3d - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Heart rate increased (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Motor dysfunction (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Pain (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Palpitations (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Product administered at inappropriate site (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling), Urticaria (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10012045698	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Cardiac disorder (n/a - Not Recovered/Not Resolved -), Chest discomfort (n/a - Unknown -), Joint swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012051276	29/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Chills (n/a - Unknown -), Headache (n/a - Unknown -), Palpitations (n/a - Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012030633	28/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Cerebral disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Convulsion in childhood (n/a - Unknown - Caused/Prolonged Hospitalisation, Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR

										Medically Important Condition), Maternal exposure timing unspecified (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neonatal seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10012031054	28/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Abnormal faeces (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10012035984	28/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Poor feeding infant (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10012036717	28/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10012040461	28/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Cerebral infarction (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Porencephaly (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10012012814	25/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Exposure via breast milk (n/a - Recovered/Resolved -), Infantile vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011994747	24/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Asthenia (n/a - Unknown -), Injection site pain (n/a - Unknown -), Mixed anxiety and depressive disorder (n/a - Unknown -), Palpitations (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011984160	23/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Chills (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011987763	23/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Asthenia (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Fatigue (n/a - Recovered/Resolved -), Infant irritability (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011987774	23/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Moaning (n/a - Not Recovered/Not Resolved -), Neonatal disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011987779	23/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Infant irritability (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

										Somnolence (n/a - Recovered/Resolved -)			
EU-EC-10011987809	23/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Infant irritability (n/a - Not Recovered/Not Resolved -), Infantile vomiting (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011945992	21/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Infantile vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011946068	21/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Anxiety (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Infantile vomiting (n/a - Recovered/Resolved -), Poor feeding infant (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011960245	21/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Congenital anomaly (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Congenital foot malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Congenital musculoskeletal disorder of limbs (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])	ICSR
EU-EC-10011929122	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Rash macular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011929132	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011929519	18/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011929547	18/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011931189	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Crying (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Infant irritability (n/a - Recovered/Resolved -), Sleep disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011931292	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Agitation (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

), Increased appetite (n/a - Recovered/Resolved -), Irritability (n/a - Recovered/Resolved -)			
EU-EC-10011933762	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Abdominal pain upper (n/a - Recovered/Resolved -), Crying (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Insomnia (n/a - Unknown -), Restlessness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011933845	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011933847	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Somnolence (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011934764	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abnormal faeces (1d - Recovered/Resolved -), Crying (1d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Flatulence (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011935133	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Faeces discoloured (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011935140	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abdominal pain upper (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Infant irritability (n/a - Recovered/Resolved -), Tearfulness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011935977	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Abnormal faeces (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011935984	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal pain (n/a - Recovered/Resolved -), Crying (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Discomfort (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011922250	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abnormal faeces (2d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

										Frequent bowel movements (2d - Recovered/Resolved -)			
EU-EC-10011922459	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Cerebral haemorrhage neonatal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Foetal exposure timing unspecified (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Inappropriate antidiuretic hormone secretion (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Posthaemorrhagic hydrocephalus (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10011922814	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Irritability (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011922818	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011922832	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Infantile vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011922837	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Anxiety (n/a - Recovered/Resolved -), Body temperature increased (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Somnolence (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011923172	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Poor feeding infant (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011924087	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Apathy (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Somnolence (n/a - Recovered/Resolved -), Tearfulness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011924092	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

										Poor feeding infant (n/a - Recovered/Resolved -), Restlessness (n/a - Recovered/Resolved -), Tension (n/a - Recovered/Resolved -)			
EU-EC-10011924095	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011924445	17/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Laryngitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - {DF} - Oral])	Not reported	ICSR
EU-EC-10011925721	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abdominal pain (1d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011925759	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011926070	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Frequent bowel movements (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011905489	16/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Vaccination site reaction (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011905511	16/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011905513	16/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011905518	16/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011907019	16/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[IBUPROFEN, IBUPROFEN LYSINE, IBUPROFEN PH, EUR., IBUPROFEN SODIUM, IBUPROFEN SODIUM DIHYDRATE] (C - Pyrexia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011911712	16/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes	Perinatal stroke (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pulmonary arterial hypertension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]), [PAROXETINE MESILATE] (S - COVID-19 immunisation - n/a - [n/a - 10mg - Transplacental])	Not reported	ICSR
EU-EC-10011912731	16/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011890850	15/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011894769	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown -), Pyrexia (72h - Unknown -), Rash (72h - Unknown -), Roseola (72h - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011895085	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Pyrexia (2d - Recovered/Resolved -), Viral infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011895086	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Ocular hyperaemia	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

										(n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rhinorrhoea (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011895396	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Cough (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Rhinorrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011895402	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Rash (n/a - Not Recovered/Not Resolved -), Skin disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011897860	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Asthenia (n/a - Recovered/Resolved -), Cough (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Rhinorrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011875242	14/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Infection (n/a - Unknown -), Product administered at inappropriate site (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -), Product use issue (n/a - Unknown -), Pyrexia (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011876250	14/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011877343	14/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Haematochezia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011878086	14/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011884018	14/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011884142	14/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Exposure via breast milk (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011874430	13/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Cold sweat (2d - Recovered/Resolved -), Exposure via breast milk (n/a - Recovered/Resolved -), Insomnia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR

EU-EC-10011779584	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011780389	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011782596	03/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Congenital hand malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Kidney malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Small for dates baby (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transplacental])	Not reported	ICSR
EU-EC-10011784354	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arthralgia (n/a - Recovering/Resolving -), Limb discomfort (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011784363	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Epistaxis (9d - Not Recovered/Not Resolved -), Influenza like illness (9d - Not Recovered/Not Resolved -), Lymphadenopathy (9d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10011784368	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza like illness (30d - Not Recovered/Not Resolved -), Injection site pain (30d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011784415	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Sensory disturbance (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011784512	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Injection site pain (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011784517	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Neuralgia (2d - Recovered/Resolved With Sequelae -), Paraesthesia (2d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10011784630	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Influenza like illness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Local reaction (n/a - Unknown -), Vaccination site reaction (n/a - Unknown -)			
EU-EC-10011784643	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (2d - Recovered/Resolved -), Headache (5d - Recovering/Resolving -), Movement disorder (2d - Recovered/Resolved -), Pyrexia (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011784691	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site joint pain (n/a - Recovering/Resolving -), Limb discomfort (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011784709	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arthralgia (208d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (208d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011774085	02/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (89d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011743341	01/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011749012	01/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure to SARS-CoV-2 (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011749179	01/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Abnormal faeces (n/a - Recovering/Resolving -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011751399	01/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Oral])	Not reported	ICSR
EU-EC-10011752975	01/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	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-10011753206	01/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011729965	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Drug interaction (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -), Immune-mediated adverse reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (1 - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011734014	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Dyspnoea (n/a - Recovering/Resolving -), Respiratory distress (n/a - Recovering/Resolving -), Sleep disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011734015	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Asthenia (3d - Recovered/Resolved -), Breast pain (3d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10011738130	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10011742390	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Pityriasis rosea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011705318	24/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Crying (n/a - Recovered/Resolved -), Decreased appetite (n/a - Recovered/Resolved -), Diarrhoea (1d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transmammary])	Not reported	ICSR
EU-EC-10011692653	23/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Dyspnoea (n/a - Unknown -), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	CANNABIDIOL [CANNABIDIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ACICLOVIR, ACICLOVIR SODIUM] (C - n/a - n/a - [n/a - 400mg - Transplacental]), [ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 2{DF} - Transplacental]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - 400mg - Transplacental]), [BIOTIN] (C - n/a - n/a - [n/a - 500ug - Transplacental]), [BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [n/a - 300mg - n/a]), [CAFFEINE] (C - n/a - n/a - [n/a - 600mg - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Transplacental]), [CHLORPHENAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, IBUPROFEN, IBUPROFEN] (C - n/a - n/a - [n/a - 600mg - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 2{DF} - Transplacental]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Transplacental]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1000ug - Transplacental]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - Transplacental]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Transplacental]), [PYRIDOXINE HYDROCHLORIDE, VITAMIN B6] (C - n/a - n/a - [n/a - 2mg - Transplacental]), [RIZATRIPTAN, RIZATRIPTAN BENZOATE] (C - n/a - n/a - [n/a - 10mg - Transplacental]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - n/a]), [SUMATRIPTAN, SUMATRIPTAN SUCCINATE] (C - n/a - n/a - [n/a - 100mg - Transplacental]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - Transplacental])	ICSR
EU-EC-10011698108	23/02/2022	Spontaneous	Healthcare Professional	Non European	Not available	0-1 Month	Not Specified	Female	Yes	Epileptic encephalopathy (n/a - Unknown - Disabling,	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR

				Economic Area						Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Neonatal epileptic seizure (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Neonatal seizure (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition)	applicable - [1d - n/a - Transplacental])		
EU-EC-10011685747	22/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Musculoskeletal pain (2d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011685770	22/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Asthenia (3d - Not Recovered/Not Resolved -), Chills (3d - Not Recovered/Not Resolved -), Headache (3d - Not Recovered/Not Resolved -), Limb discomfort (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011664970	21/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Congenital Anomaly), Hemiplegia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10011667174	21/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Aneurysm (n/a - Recovered/Resolved - Congenital Anomaly), Thrombosis (n/a - Recovered/Resolved - Congenital Anomaly), Vena cava thrombosis (n/a - Recovered/Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011667588	21/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain (11d - Recovered/Resolved -), Dizziness (11d - Recovered/Resolved -), Fatigue (11d - Recovered/Resolved -), Headache (11d - Recovered/Resolved -), Muscular weakness (11d - Recovered/Resolved -), Pain in extremity (11d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011651825	18/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Nasopharyngitis (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011635425	17/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	Yes	Exposure via breast milk (n/a - Unknown -), Fatigue (3d - Recovered/Resolved -), Somnolence (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	ICSR

										Tearfulness (3d - Recovered/Resolved - Other Medically Important Condition), Vomiting (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011635645	17/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Influenza (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011635782	17/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Arrhythmia (6d - Recovering/Resolving -), Back pain (6d - Recovering/Resolving -), Burning sensation (6d - Recovering/Resolving -), Diarrhoea (6d - Recovering/Resolving -), Gastrointestinal pain (6d - Recovering/Resolving -), Myalgia (6d - Recovering/Resolving -), Nausea (6d - Recovering/Resolving -), Peripheral vascular disorder (6d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011635999	17/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Erectile dysfunction (n/a - Recovering/Resolving - Other Medically Important Condition), Eye pain (2880min - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011641330	17/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Overdose (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Product administered at inappropriate site (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011643768	17/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Overdose (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Product administered at inappropriate site (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Threatening, Caused/Prolonged Hospitalisation)				
EU-EC-10011621560	16/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011621665	16/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011621708	16/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Dizziness (1d - 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-10011622383	16/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site erythema (2d - Recovered/Resolved -), Injection site swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011629246	16/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Cellulitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Impaired healing (n/a - Recovering/Resolving - Other Medically Important Condition), Tenosynovitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR	
EU-EC-10011595836	14/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Aplasia cutis congenita (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - n/a - Transplacental]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Transplacental]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - Transplacental])	ICSR	
EU-EC-10011600779	14/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Decreased appetite (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -), Food refusal (n/a - Unknown -), Infant irritability (n/a - Unknown -), Restlessness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Transmammary])	Not reported	ICSR	
EU-EC-10011600821	14/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Transmammary])	Not reported	ICSR	
EU-EC-10011602708	14/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Cough (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Exposure via breast milk (n/a - Unknown -), Fatigue (n/a - Unknown -), Infant irritability (n/a - Unknown -), Mucosal discolouration (n/a - Unknown -), Ocular hyperaemia (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transmammary])	Not reported	ICSR	
EU-EC-10011604695	14/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Maternal exposure during breast feeding (n/a - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Transmammary])	Not reported	ICSR	
EU-EC-10011592251	13/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011592268	13/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months	Child	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	

						- 2 Years									
EU-EC-10011558333	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Rash vesicular (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved -), Influenza (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011558338	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011558474	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011558528	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Myalgia (22d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011558959	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011559102	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Body temperature increased (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Faeces discoloured (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011559519	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Atrial septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR		
EU-EC-10011559858	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Cough (15d - Recovered/Resolved -), Fatigue (15d - Recovered/Resolved -), Influenza like illness (15d - Recovered/Resolved -), Pyrexia (15d - Recovered/Resolved -), Rash (15d - Recovered/Resolved -), Subglottic laryngitis (15d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011563786	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Vaccination site reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR		
EU-EC-10011564378	10/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Crying (20min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSR		
EU-EC-10011546906	09/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Diet refusal (n/a - Fatal - Results in Death, Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR		

										Hospitalisation), Emotional distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Failure to thrive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Insomnia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	applicable - [1d - n/a - Transmammary])		
EU-EC-10011548862	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011549998	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Blister (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Unknown -), Listless (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-10011551210	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown -), Faeces discoloured (2wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011551861	09/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure via breast milk (n/a - Unknown -), Infant irritability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Livedo reticularis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR

										Condition), Rash macular (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Viral infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting projectile (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011554231	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Malaise (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - n/a])	Not reported	ICSR
EU-EC-10011556868	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Disturbance in attention (n/a - Unknown -), Fatigue (n/a - Unknown -), Tinnitus (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	ICSR
EU-EC-10011556916	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Swollen tongue (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Urticaria (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011557702	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Abnormal faeces (2d - Recovering/Resolving -), Faeces discoloured (2d - Recovering/Resolving -), Pyrexia (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011557752	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528160	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Fatigue (1d - Recovering/Resolving -), Rash (4d - Unknown -), Rash pruritic (1d - Recovering/Resolving -), Tremor (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528251	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Dizziness (0d - Recovering/Resolving -), Syncope (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528284	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (1d - Not Recovered/Not Resolved -), Chills (1d - Not Recovered/Not Resolved -), Headache (1d - Not Recovered/Not Resolved -), Nausea (1d - Not Recovered/Not Resolved -), Pain in extremity (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011528291	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Not Recovered/Not Resolved -), Chills (2d - Recovered/Resolved -), Diarrhoea (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528313	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Diarrhoea (1d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528452	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site pain (5d - Recovered/Resolved -), Swelling of eyelid (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528491	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528845	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Dizziness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011528926	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Eye infection (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011529079	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Limb discomfort (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011529089	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Ear pain (6d - Not Recovered/Not Resolved -), Malaise (6d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011535483	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011536674	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Abdominal pain (n/a - Unknown -), Crying (n/a - Unknown -), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Gastrointestinal motility disorder (n/a - Unknown -), Headache (n/a - Unknown -), Pallor (n/a - Unknown -), Pyrexia (n/a - Unknown -), Sleep disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011537568	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Pruritus (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011539085	08/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (C - n/a - n/a - [28d - n/a - n/a])	ICSR
EU-EC-10011514670	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011515982	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Milk allergy (n/a - Unknown -), Urticaria (2wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011516105	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Injection site swelling (1d -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

			Professional	Area		- 2 Years				Recovered/Resolved - n/a - n/a]			
EU-EC-10011516166	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011526970	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza (2d - Recovering/Resolving -), Swelling face (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011526978	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Eye pain (2d - Recovering/Resolving -), Influenza (2d - Recovering/Resolving -), Swelling face (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011527037	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (2d - Recovering/Resolving -), Headache (2d - Recovering/Resolving -), Menstrual disorder (n/a - Recovering/Resolving -), Nausea (2d - Recovering/Resolving -), Vertigo (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011527100	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arrhythmia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Tinnitus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011527125	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Appetite disorder (2d - Recovering/Resolving -), Chills (2d - Recovering/Resolving -), Dizziness (2d - Recovering/Resolving -), Feeling hot (n/a - Recovering/Resolving -), Malaise (2d - Recovering/Resolving -), Tachycardia (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011527143	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Dizziness (1d - Recovering/Resolving -), Hypoaesthesia (1d - Recovering/Resolving -), Myalgia (2d - Recovering/Resolving -), Paraesthesia (1d - Recovering/Resolving -), Tachycardia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011527328	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Chills (0d - Recovered/Resolved -), Dizziness (0d - Recovered/Resolved -), Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

											Muscle twitching (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011502286	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Exposure via breast milk (1d - Recovering/Resolving -), Faeces discoloured (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011502311	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Herpes virus infection (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011502818	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Weight decreased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011503219	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Diarrhoea (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011506105	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011506191	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (2d - Unknown -), Headache (2d - Unknown -), Limb discomfort (2d - Unknown -), Myalgia (2d - Unknown -), Rash (n/a - Unknown -), Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011506193	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (3d - Recovering/Resolving -), Headache (3d - Recovering/Resolving -), Limb discomfort (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011506335	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain (1d - Recovering/Resolving -), Back pain (1d - Recovering/Resolving -), Injection site pain (1d - Recovering/Resolving -), Nausea (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011506462	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Rash (30d - Not Recovered/Not Resolved -), Urticaria (30d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011496286	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011496311	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011496334	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011496336	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011496345	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10011496367	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-	04/02/2022	Spontaneous	Non	European	Not	2	Not	Female	No	Injection site pain (2d	COMIRNATY [TOZINAMERAN]	Not reported	ICSR	

10011496370			Healthcare Professional	Economic Area	available	Months - 2 Years	Specified			- Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10011496381	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011496513	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011497818	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -), Injection site swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011486056	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Exposure via breast milk (n/a - Unknown -), Staphylococcal scalded skin syndrome (8d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011472480	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arrhythmia (7d - Not Recovered/Not Resolved -), Bradycardia (7d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011472486	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Depressed mood (1d - 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-10011472510	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Feeling hot (37d - Recovering/Resolving -), Injection site pain (1d - Unknown -), Sleep disorder (37d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011473781	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain lower (n/a - Recovering/Resolving -), Arthropathy (n/a - Recovering/Resolving -), Cystitis (n/a - Recovering/Resolving -), Streptococcal urinary tract infection (n/a - Recovering/Resolving - Other Medically Important Condition), Yersinia infection (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011475739	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Dry skin (n/a - Not Recovered/Not Resolved -), Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved -), Skin exfoliation (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10011475946	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (6d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011450229	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Crying (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011462468	01/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Cough (n/a - Recovering/Resolving -), Nasopharyngitis (n/a - Recovering/Resolving -), Off label use (n/a - Unknown -), Product administered to patient of	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										inappropriate age (n/a - Unknown -), Pyrexia (34h - Recovered/Resolved -), Vaccination site swelling (n/a - Recovering/Resolving -)			
EU-EC-10011462475	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Diarrhoea (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011462534	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	No adverse event (21d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011462556	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011462560	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Diarrhoea (35d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011437329	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Injection site erythema (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011438287	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Depressed mood (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Recovered/Resolved -), Insomnia (n/a - Recovered/Resolved -), Irritability (n/a - Recovered/Resolved -), Limb mass (n/a - Recovered/Resolved -), Middle insomnia (n/a - Recovered/Resolved -), Oedema peripheral (n/a - Recovered/Resolved -), Peripheral swelling (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Skin discolouration (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011441723	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011441756	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011431669	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011431680	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	No adverse event (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011432311	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011433127	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011434980	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Dizziness (1d - Not Recovered/Not Resolved -), Somnolence (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011435638	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	No adverse event (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011435718	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011421879	28/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	2 Months	Infant	Not Specified	Yes	Exposure via breast milk (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

			Professional	Area		- 2 Years				Recovered/Resolved -) Pyrexia (2d - Recovered/Resolved -)	Not applicable - [1d - .3mL - Transmammary])		
EU-EC-10011399167	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Faeces discoloured (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC-10011405958	27/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown -), Pyrexia (72h - Recovered/Resolved -), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Viral infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011410054	27/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Limb discomfort (n/a - Recovering/Resolving -), Nasopharyngitis (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011389318	26/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary - More in ICSR])	Not reported	ICSR
EU-EC-10011389738	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Menstrual disorder (10d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011389743	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Cardiovascular disorder (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011389903	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Diarrhoea (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011396915	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Paraesthesia (14d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011396954	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Back pain (2d - Recovered/Resolved -), Chills (2d - Recovered/Resolved -), Cough (2d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Oropharyngeal pain (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011397089	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Arthralgia (4d - Recovered/Resolved -), Breast pain (4d - Recovered/Resolved -), Dyspnoea (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Oropharyngeal pain (4d - Recovered/Resolved -), Pain in jaw (4d - Recovered/Resolved -)			
EU-EC-10011397103	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Fatigue (1d - 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-10011397562	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 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-10011384729	25/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Poor feeding infant (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011361411	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Agitation (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Recovered/Resolved -), Infant irritability (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011366137	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (n/a - Recovering/Resolving -), Exposure via breast milk (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011367767	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011368227	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Foetal malnutrition (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [21d - 2(DF) - Transplacental])	Not reported	ICSR
EU-EC-10011368751	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Crying (n/a - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infant sedation (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011368760	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Recovered/Resolved - Other Medically Important Condition), Haematochezia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011370111	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Disease recurrence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

										Rhinorrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011370278	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011370684	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Angioedema (1d - Recovered/Resolved -), Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011371027	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Irritability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-10011341906	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Transmammary])	LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011345616	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown -), Fatigue (n/a - Not Recovered/Not Resolved -), Poor feeding infant (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[DESGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011351475	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown -), Faeces discoloured (3wk - Recovered/Resolved -), Infant irritability (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

											Tearfulness (n/a - Recovered/Resolved -)		
EU-EC-10011353915	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Herpes zoster (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011324519	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (21d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325412	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Chills (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325448	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011325602	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Application site pain (n/a - Recovered/Resolved -), Off label use (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011326989	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011328003	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (0d - Not Recovered/Not Resolved -), Injection site pain (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011328034	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Dizziness (0d - Recovered/Resolved -), Fatigue (4d - Recovering/Resolving -), Headache (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011328095	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011328576	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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